HELMHOLTZ MUNICH

Institute of Health Economics and Healthcare Management (IGM) until 2022

Publications: IGM from 2001 onwards, precursor 1987-2000 (Socioeconomics and Health System Analysis, Institute for Medical Informatics and Health Systems Research, Gesellschaft für Strahlen- und Umweltforschung)

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Ammended for later publications (links underlined)

2024

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Marijic P, Schwarzkopf L, Maier W, Trudzinski F, Kreuter M, Schwettmann L. Comparing outcomes of ILD patients managed in specialised versus non-specialised centres. Respir Res. 2022 Aug 27;23(1):220.

Pedron S, Hanselmann M, Burns J, Rich A, Peters A, Heier M, Schwettmann L, Bor JH, Bärnighausen T, Laxy M. The effect of population-based blood pressure screening on long-term cardiometabolic morbidity and mortality in Germany: A regression discontinuity analysis. PLoS Med. 2022 Dec 27;19(12):e1004151.

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Hellbach, F.; Baumeister, S.; Wilson, R.; Wawro, N.; Dahal, C.; Freuer, D.; Hauner, H.; Peters, A.; Winkelmann, J.; Schwettmann, L.; Rathmann, W.; Kronenberg, F.; Koenig, W.; Meisinger, C.; Waldenberger, M.; Linseisen, J.
Association between usual dietary intake of food groups and DNA methylation and effect modification by metabotype in the KORA FF4 cohort.
Life 12:1064 (2022)
Associations between diet and DNA methylation may vary among subjects with different metabolic states, which can be captured by clustering populations in metabolically homogenous subgroups, called metabotypes. Our aim was to examine the relationship between habitual consumption of various food groups and DNA methylation as well as to test for effect modification by metabotype. A cross-sectional analysis of participants (median age 58 years) of the population-based prospective KORA FF4 study, habitual dietary intake was modeled based on repeated 24-h diet recalls and a food frequency questionnaire. DNA methylation was measured using the Infinium MethylationEPIC BeadChip providing data on >850,000 sites in this epigenome-wide association study (EWAS). Three metabotype clusters were identified using four standard clinical parameters and BMI. Regression models were used to associate diet and DNA methylation, and to test for effect modification. Few significant signals were identified in the basic analysis while many significant signals were observed in models including food group-metabotype interaction terms. Most findings refer to interactions of food intake with metabotype 3, which is the metabotype with the most unfavorable metabolic profile. This research highlights the importance of the metabolic characteristics of subjects when identifying associations between diet and white blood cell DNA methylation in EWAS.
Life

Steinbeisser, K.; Schwarzkopf, L.; Schwettmann, L.; Laxy, M.; Grill, E.; Rester, C.; Peters, A.; Seidl, H.
Association of physical activity with utilization of long-term care in community-dwelling older adults in Germany: Results from the population-based KORA-Age observational study.
Int. J. Behav. Nutr. Phys. Act. 19:102 (2022)
BACKGROUND: Physical activity (PA) is a proven strategy to prevent chronic diseases and reduce falls. Furthermore, it improves or at least maintains performance of activities of daily living, and thus fosters an independent lifestyle in older adults. However, evidence on the association of PA with relevant subgroups, such as older adults with utilization of long-term care (LTC), is sparse. This knowledge would be essential for establishing effective, need-based strategies to minimize the burden on healthcare systems due to the increasing need for LTC in old age. METHODS: Data originate from the 2011/12 (t1) baseline assessment and 2016 (t2) follow-up of the population-based Cooperative Health Research in the Region of Augsburg (KORA-)Age study in southern Germany. In 4812 observations of individuals ≥65 years, the association between various types of PA (walking, exercise (i. e., subcategory of PA with the objective to improve or maintain one or more components of physical fitness), walking+exercise) and utilization of LTC (yes/no) was analyzed using generalized estimating equation logistic models. Corresponding models stratified by sex (females: 2499 observations; males: 2313 observations) examined sex-specific associations. Descriptive analyses assessed the proportion of individuals meeting the suggested minimum values in the German National Physical Activity Recommendations for older adults (GNPAR). RESULTS: All types of PA showed a statistically significant association with non-utilization of LTC in the entire cohort. "Walking+exercise" had the strongest association with non-utilization of LTC in the entire cohort (odds ratio (OR): 0.52, 95% confidence interval (CI): 0.39-0.70) and in males (OR: 0.41, CI: 0.26-0.65), whereas in females it was "exercise" (OR: 0.58; CI: 0.35-0.94). The proportion of

individuals meeting the GNPAR was higher among those without utilization of LTC (32.7%) than among those with LTC (11.7%) and group differences were statistically significant ($p \leq 0.05$). CONCLUSIONS: The GNPAR are rarely met by older adults. However, doing any type of PA is associated with non-utilization of LTC in community-dwelling older adults. Therefore, older adults should be encouraged to walk or exercise regularly. Furthermore, future PA programs should consider target-groups' particularities to reach individuals with the highest needs for support.
International Journal of Behavioral Nutrition and Physical Activity

Park, J.; Zhang, P.; Shao, H.; Laxy, M.; Imperatore, G.
Selecting a target population for type 2 diabetes lifestyle prevention programs: A cost-effectiveness perspective.
Diabetic Med. 39:e14847 (2022)
AIMS: Cost-effectiveness (CE) of lifestyle change programs (LCP) for type 2 diabetes (T2D) prevention is influenced by a participant's risk. We identified the risk threshold of developing T2D in the intervention population that was cost-effective for three formats of the LCP: delivered in-person individually or in groups, or delivered virtually. We compared the cost-effectiveness across program formats when there were more than one cost-effective formats. METHODS: Using the CDC-RTI T2D diabetes CE simulation model, we estimated CEs associated with three program formats in 8 population groups with an annual T2D incidence of 1% to 8%. We generated a nationally representative simulation population for each risk level using the 2011-2016 National Health and Nutrition Examination Survey data. We used an incremental cost-effectiveness ratio (ICER), cost per quality-adjusted life year (QALY) gained in 25-years, to measure the CEs of the programs. We took a health care system perspective RESULTS: To achieve an ICER of $50,000/QALY or lower, the annual T2D incidence of the program participant needed to be ≥5% for the in-person individual program, ≥4% for the digital individual program, and ≥3% for the in-person group program. For those with T2D risk of ≥4%, the in-person group program always dominated the digital individual program. The in-person individual program was cost-effective compared with the in-person group program only among persons with T2D risk of ≥8%. CONCLUSIONS: Our findings could assist decision-makers in selecting the most appropriate target population for different formats of lifestyle intervention programs to prevent T2D.
Diabetic Medicine

Elsbernd, K.; Emmert-Fees, K.; Erbe, A.; Ottobrino, V.; Kroidl, A.; Barnighausen, T.; Geisler, B.P.; Kohler, S.
Costs and cost-effectiveness of HIV early infant diagnosis in low- and middle-income countries: A scoping review.
Infect. Dis. Ther. 11:82 (2022)
Background: Continuing progress in the global pediatric human immunodeficiency virus (HIV) response depends on timely identification and care of infants with HIV. As countries scale-out improvements to HIV early infant diagnosis (EID), economic evaluations are needed to inform program design and implementation. This scoping review aimed to summarize the available evidence and discuss practical implications of cost and cost-effectiveness analyses of HIV EID. Methods: We systematically searched bibliographic databases (Embase, MEDLINE and EconLit) and grey literature for economic analyses of HIV EID in low- and middle-income countries published between January 2008 and June 2021. We extracted data on unit costs, cost savings, and incremental cost-effectiveness ratios as well as outcomes related to health and the HIV EID care process and summarized results in narrative and tabular formats. We converted unit costs to 2021 USD for easier comparison of costs across studies. Results: After title and abstract screening of 1278 records and full-text review of 99 records, we included 29 studies: 17 cost analyses and 12 model-based cost-effectiveness analyses. Unit costs were 21.46–51.80 USD for point-of-care EID tests and 16.21–42.73 USD for laboratory-based EID tests. All cost-effectiveness analyses stated at least one of the interventions evaluated to be cost-effective. Most studies reported costs of EID testing strategies; however, few studies assessed the same intervention or reported costs in the same way, making comparison of costs across studies challenging. Limited data availability of context-appropriate costs and outcomes of children with HIV as well as structural heterogeneity of cost-effectiveness modelling studies limits generalizability of economic analyses of HIV EID. Conclusions: The available cost and cost-effectiveness evidence for EID of HIV, while not directly comparable across studies, covers a broad range of interventions and suggests most interventions designed to improve EID are cost-effective or cost-saving. Further studies capturing costs and benefits of EID services as they are delivered in real-world settings are needed. Graphical Abstract: [Figure not available: see fulltext.]
Infectious diseases and therapy

Dandolo, L.; Hartig, C.; Telkmann, K.; Horstmann, S.; Schwettmann, L.; Selsam, P.; Schneider, A.E.; Bolte, G.
Decision tree analyses to explore the relevance of multiple sex/gender dimensions for the exposure to green spaces: Results from the KORA INGER study.
Int. J. Environ. Res. Public Health 19:7476 (2022)
Recently, attention has been drawn to the need to integrate sex/gender more comprehensively into environmental health research. Considering theoretical approaches, we define sex/gender as a multidimensional concept based on intersectionality. However, operationalizing sex/gender through multiple covariates requires the usage of statistical methods that are suitable for handling such complex data. We therefore applied two different decision tree approaches: classification and regression trees (CART) and conditional inference trees (CIT). We explored the relevance of multiple sex/gender covariates for the exposure to green spaces, measured both subjectively and objectively. Data from 3742 participants from the Cooperative Health Research in the Region of Augsburg (KORA) study were analyzed within the INGER (Integrating gender into environmental health research) project. We observed that the participants' financial situation and discrimination experience was relevant for their access to high quality public green spaces, while the urban/rural context was most relevant for the general greenness in the residential environment. None of the covariates operationalizing the individual sex/gender self-concept were relevant for differences in exposure to green spaces. Results were largely consistent for both CART and CIT. Most importantly we showed that decision tree analyses are useful for exploring the relevance of multiple sex/gender dimensions and their interactions for environmental exposures. Further investigations in larger urban areas with less access to public green spaces and with a study population more heterogeneous with respect to age and social disparities may add more information about the

relevance of multiple sex/gender dimensions for the exposure to green spaces.
International Journal of Environmental Research and Public Health

Marijic, P.; Schwarzkopf, L.; Maier, W.; Trudzinski, F.; Schwettmann, L.; Kreuter, M.
Effects of influenza vaccination in patients with interstitial lung diseases: An epidemiological claims data analysis.
Ann. Am. Thorac. Soc., DOI: 10.1513/AnnalsATS.202112-1359OC (2022)
Rationale Vaccination is the most effective protection against influenza. Patients with interstitial lung diseases (ILD) represent a high-risk group for influenza complications. Thus, yearly influenza vaccination is recommended, but evidence on its effects is sparse. Objective This study aimed to compare all-cause mortality and all-cause and respiratory-related hospitalization between vaccinated and unvaccinated patients with ILD. Methods Using data from the largest German statutory health insurance fund (about 27 million insurees in 2020), we analyzed four influenza seasons from 2014/15 to 2017/18 and compared vaccinated to unvaccinated ILD patients. Starting from September 1 of each year we matched vaccinated to unvaccinated patients in a 1:1 ratio using a rolling cohort design. Mortality and hospitalization were compared with Kaplan-Meier plots and effects were calculated during the influenza season (in-season) with risk ratios (RR). Results Both, the vaccinated and the unvaccinated cohort included 7,503 patients in 2014/15, 10,318 in 2015/16, 12,723 in 2016/17, and 13,927 in 2017/18. Vaccination rates were low with 43.2% in season 2014/15 and decreased over time to 39.9% in season 2017/18. The RR for all-cause mortality were 0.79 (95%CI: 0.65, 0.97; p = 0.02) in season 2014/15, 0.66 (95%CI: 0.54, 0.80; p < 0.001) in 2015/16, 0.89 (95%CI: 0.76, 1.04; p = 0.15) in 2016/17, and 0.95 (95%CI: 0.81, 1.12; p = 0.57) in 2017/18. The effects on all-cause hospitalization and respiratory-related hospitalization were similar in all seasons. Conclusions Although an unequivocally beneficial impact of influenza vaccination in patients with ILD could not be demonstrated, we observed promising results regarding avoidance of all-cause mortality in half of the seasons observed. Given the low vaccination rates, further efforts are necessary to improve rates in ILD patients.
Annals of the American Thoracic Society

Kreuter, M.; Picker, N.; Schwarzkopf, L.; Baumann, S.; Cerani, A.; Postema, R.; Maywald, U.; Dittmar, A.; Langley, J.; Patel, H.R.
Epidemiology, healthcare utilization, and related costs among patients with IPF: Results from a German claims database analysis.
Respir. Res. 23:62 (2022)
BACKGROUND: Idiopathic pulmonary fibrosis (IPF) is a progressive form of fibrosing interstitial pneumonia with poor survival. This study provides insight into the epidemiology, cost, and disease course of IPF in Germany. METHODS: A cohort of incident patients with IPF (n = 1737) was identified from German claims data (2014-2019). Incidence and prevalence rates were calculated and adjusted for age differences compared with the overall German population. All-cause and IPF-related healthcare resource utilization as well as associated costs were evaluated per observed person-year (PY) following the initial IPF diagnosis. Finally, Kaplan-Meier analyses were performed to assess time from initial diagnosis to disease deterioration (using three proxy measures: non-elective hospitalization, IPF-related hospitalization, long-term oxygen therapy [LTOT]); antifibrotic therapy initiation; and all-cause death. RESULTS: The cumulative incidence of IPF was estimated at 10.7 per 100,000 individuals in 2016, 10.9 in 2017, 10.5 in 2018, and 9.6 in 2019. The point prevalence rates per 100,000 individuals for the respective years were 21.7, 23.5, 24.1, and 24.1. On average, ≥ 14 physician visits and nearly two hospitalizations per PY were observed after the initial IPF diagnosis. Of total all-cause direct costs (€15,721/PY), 55.7% (€8754/PY) were due to hospitalizations and 29.1% (€4572/PY) were due to medication. Medication accounted for 49.4% (€1470/PY) and hospitalizations for 34.8% (€1034/PY) of total IPF-related direct costs (€2973/PY). Within 2 years of the initial IPF diagnosis (23.6 months), 25% of patients died. Within 5 years of diagnosis, 53.1% of patients had initiated LTOT; only 11.6% were treated with antifibrotic agents. The median time from the initial diagnosis to the first non-elective hospitalization was 5.5 months. CONCLUSION: The incidence and prevalence of IPF in Germany are at the higher end of the range reported in the literature. The main driver for all-cause cost was hospitalization. IPF-related costs were mainly driven by medication, with antifibrotic agents accounting for around one-third of the total medication costs even if not frequently prescribed. Most patients with IPF do not receive pharmacological treatment, highlighting the existing unmet medical need for effective and well-tolerated therapies.
Respiratory Research

Auzanneau, M.; Rosenbauer, J.; Warncke, K.; Maier, W.; Kamrath, C.; Hofmann, T.; Wurm, M.; Hammersen, J.; Schröder, C.; Hake, K.; Holl, R.W.
Frequency of ketoacidosis at diagnosis of pediatric type 1 diabetes associated with socioeconomic deprivation and Uubanization: Results from the German Multicenter DPV Registry.
Diabetes Care 45, 1807-1813 (2022)
OBJECTIVE: To investigate whether socioeconomic deprivation and urbanization are associated with the frequency of diabetic ketoacidosis (DKA) at diagnosis of pediatric type 1 diabetes. RESEARCH DESIGN AND METHODS: Children and adolescents aged ≤18 years, living in Germany, with newly diagnosed type 1 diabetes documented between 2016 and 2019 in the Diabetes Prospective Follow-up Registry (DPV; Diabetes-Patienten-Verlaufsdokumentation), were assigned to a quintile of regional socioeconomic deprivation (German Index of Socioeconomic Deprivation) and to a degree of urbanization (Eurostat) by using their residence postal code. With multiple logistic regression models, we investigated whether the frequency of DKA at diagnosis was associated with socioeconomic deprivation or urbanization and whether associations differed by age-group, sex, or migration status. RESULTS: In 10,598 children and adolescents with newly diagnosed type 1 diabetes, the frequency of DKA was lowest in the least deprived regions (Q1: 20.6% [95% CI 19.0-22.4], and increased with growing socioeconomic deprivation to 26.9% [25.0-28.8] in the most deprived regions [Q5]; P for trend <0.001). In rural areas, the frequency of DKA at diagnosis was significantly higher than in towns and suburbs (intermediate areas) or in cities (27.6% [95% CI 26.0-29.3] vs. 22.7% [21.4-24.0], P < 0.001, or vs. 24.3% [22.9-25.7], P = 0.007,

respectively). The results did not significantly differ by age-group, sex, or migration background or after additional adjustment for socioeconomic deprivation or urbanization. CONCLUSIONS: This study provides evidence that prevention of DKA at diagnosis by means of awareness campaigns and screening for presymptomatic type 1 diabetes should particularly target socioeconomically disadvantaged regions and rural areas.
Diabetes Care

Barc, J.°; Tadros, R.; Glinge, C.; Chiang, D.Y.; Jouni, M.; Simonet, F.; Jurgens, S.J.; Baudic, M.; Nicastro, M.; Potet, F.; Offerhaus, J.A.; Walsh, R.; Choi, S.H.; Verkerk, A.O.; Mizusawa, Y.; Anys, S.; Minois, D.; Arnaud, M.; Duchateau, J.; Wijeyeratne, Y.D.; Muir, A.; Papadakis, M.; Castelletti, S.; Torchio, M.; Ortuño, C.G.; Lacunza, J.; Giachino, D.F.; Cerrato, N.; Martins, R.P.; Campuzano, Ó.; Van Dooren, S.; Thollet, A.; Kyndt, F.; Mazzanti, A.; Clémenty, N.; Bisson, A.; Corveleyn, A.; Stallmeyer, B.; Dittmann, S.; Saenen, J.; Noël, A.; Honarbakhsh, S.; Rudic, B.; Marzak, H.; Rowe, M.K.; Federspiel, C.; Le Page, S.; Placide, L.; Milhem, A.; Barajas-Martínez, H.; Beckmann, B.M.; Krapels, I.P.; Steinfurt, J.; Winkel, B.G.; Jabbari, R.; Shoemaker, M.B.; Boukens, B.J.; Skoric-Milosavljevic, D.; Bikker, H.; Manevy, F.C.; Lichtner, P.; Ribasés, M.; Meitinger, T.; Müller-Nurasyid, M.; Veldink, J.H.; van den Berg, L.H.; van Damme, P.; Cusi, D.; Lanzani, C.; Rigade, S.; Charpentier, E.; Baron, E.; Bonnaud, S.; Lecointe, S.; Donnart, A.; Le Marec, H.; Chatel, S.; Karakachoff, M.; Bézieau, S.; London, B.; Tfelt-Hansen, J.; Roden, D.; Odening, K.E.; Cerrone, M.; Chinitz, L.A.; Volders, P.G.; van de Berg, M.P.; Laurent, G.; Faivre, L.; Antzelevitch, C.; Kääb, S.; Arnaout, A.A.; Dupuis, J.M.; Pasquie, J.L.; Billon, O.; Roberts, J.D.; Jesel, L.; Borggrefe, M.; Lambiase, P.D.; Mansourati, J.; Loeys, B.; Leenhardt, A.; Guicheney, P.; Maury, P.; Schulze-Bahr, E.; Robyns, T.; Breckpot, J.; Babuty, D.; Priori, S.G.; Napolitano, C.; de Asmundis, C.; Brugada, P.; Brugada, R.; Arbelo, E.; Brugada, J.; Mabo, P.; Behar, N.; Giustetto, C.; Molina, M.S.; Gimeno, J.R.; Hasdemir, C.; Schwartz, P.J.; McKeown, P.P.; Sharma, S.; Behr, E.R.; Haissaguerre, M.; Sacher, F.; Rooryck, C.; Tan, H.L.; Remme, C.A.; Postema, P.G.; Delmar, M.; Ellinor, P.T.; Lubitz, S.A.; Gourraud, J.B.; Tanck, M.W.; George, A.L.; MacRae, C.A.; Burridge, P.W.; Dina, C.; Probst, V.; Wilde, A.A.; Schott, J.J.; Redon, R.; KORA Study Group (Strauch, K.°; Peters, A.; Schulz, H.; Schwettmann, L.; Leidl, R.; Heier, M.)
Author Correction: Genome-wide association analyses identify new Brugada syndrome risk loci and highlight a new mechanism of sodium channel regulation in disease susceptibility.
Nat. Genet. 54:735 (2022)
In the version of this article initially published, Federico Manevy's name appeared with a middle initial in error. The name has been corrected in the HTML and PDF versions of the article.
Nature Genetics

Schatz, C.; Leidl, R.; Plötz, W.; Bredow, K.; Buschner, P.
Preoperative patients' health decrease moderately, while hospital costs increase for hip and knee replacement due to the first COVID-19 lockdown in Germany.
Knee Surg. Sports Traumatol. Arthrosc., DOI: 10.1007/s00167-022-06904-9 (2022)
PURPOSE: The purpose of this study was a comparison between osteoarthritis patients with primary hip and knee replacements before, during and after the first COVID-19 lockdown in Germany. Patients' preoperative health status is assumed to decrease, owing to delayed surgeries. Costs for patients with osteoarthritis were assumed to increase, for example, due to higher prices for protective equipment. Hence, a comparison of patients treated before, during and after the first lockdown is conducted. METHODS: In total, 852 patients with primary hip or knee replacement were included from one hospital in Germany. Preoperative health status was measured with the WOMAC Score and the EQ-5D-5L. Hospital unit costs were calculated using a standardised cost calculation. Kruskal-Wallis tests and Chi-squared tests were applied for the statistical analyses. RESULTS: The mean of the preoperative WOMAC Score was slightly higher ($p < 0.01$) for patients before the first lockdown, compared with patients afterwards. Means of the EQ-5D-5L were not significantly different regarding the lockdown status (NS). Length of stay was significantly reduced by approximately 1 day ($p < 0.001$). Total inpatient hospital unit costs per patient and per day were significantly higher for patients during and after the first lockdown ($p < 0.001$). CONCLUSION: Preoperative health, measured with the WOMAC Score, worsened slightly for patients after the first lockdown compared with patients undergoing surgery before COVID-19. Preoperative health, measured using the EQ-5D-5L, was unaffected. Inpatient hospital unit costs increased significantly with the COVID-19 pandemic. LEVEL OF EVIDENCE: Retrospective cohort study, III.
Knee Surgery, Sports Traumatology, Arthroscopy

Fiorito, G.#; Pedron, S.#; Ochoa-Rosales, C.#; McCrory, C.; Polidoro, S.; Zhang, Y.; Dugué, P.A.; Ratliff, S.; Zhao, W.N.; Mckay, G.J.; Costa, G.; Solinas, M.G.; Mullan Harris, K.; Tumino, R.; Grioni, S.; Ricceri, F.; Panico, S.; Brenner, H.; Schwettmann, L.; Waldenberger, M.; Matias-Garcia, P.R.; Peters, A.; Hodge, A.; Giles, G.G.; Schmitz, L.L.; Levine, M.; Smith, J.A.; Liu, Y.; Kee, F.; Young, I.S.; McGuinness, B.; McKnight, A.J.; van Meurs, J.; Voortman, T.; Kenny, R.A.; Vineis, P.; Carmeli, C.
The role of epigenetic clocks in explaining educational inequalities in mortality: A multi-cohort study and meta-analysis.
J. Gerontol. A Biol. Sci. Med. Sci., DOI: 10.1093/gerona/glac041 (2022)
Educational inequalities in all-cause mortality have been observed for decades. However, the underlying biological mechanisms are not well known. We aimed to assess the role of DNA methylation changes in blood captured by epigenetic clocks in explaining these inequalities. Data were from eight prospective population-based cohort studies, representing 13,021 participants. First, educational inequalities and their portion explained by Horvath DNAmAge, Hannum DNAmAge, DNAmPhenoAge, and DNAmGrimAge epigenetic clocks were assessed in each cohort via counterfactual-based mediation models, on both absolute (hazard difference) and relative (hazard ratio) scales, and by sex. Second, estimates from each cohort were pooled through a random effect meta-analysis model. Men with low education had an excess mortality from all causes of 57 deaths per 10,000 person-years (95% confidence interval (CI): 38, 76) compared to their more advantaged counterparts. For women, the excess mortality was 4 deaths per 10,000 person-years (95% CI: -11, 19). On the relative scale, educational inequalities corresponded to hazard ratios of 1.33 (95% CI: 1.12, 1.57) for men and 1.15 (95% CI: 0.96, 1.37) for women. DNAmGrimAge accounted for the largest proportion, approximately 50%, of the educational inequalities for men, while the proportion was negligible for women. Most of this mediation

was explained by differential effects of unhealthy lifestyles and morbidities of the WHO risk factors for premature mortality. These results support DNA methylation-based epigenetic aging as a signature of educational inequalities in life expectancy emphasizing the need for policies to address the unequal social distribution of these WHO risk factors.
Journals of Gerontology Series A: Biological Sciences and Medical Sciences

Hodiamont, F.; Schatz, C.; Gesell, D.; Leidl, R.; Boulesteix, A.L.; Nauck, F.; Wikert, J.; Jansky, M.; Kranz, S.; Bausewein, C.
COMPANION: Development of a patient-centred complexity and casemix classification for adult palliative care patients based on needs and resource use - a protocol for a cross-sectional multi-centre study.
BMC Palliat. Care 21:18 (2022)
BACKGROUND: A casemix classification based on patients' needs can serve to better describe the patient group in palliative care and thus help to develop adequate future care structures and enable national benchmarking and quality control. However, in Germany, there is no such an evidence-based system to differentiate the complexity of patients' needs in palliative care. Therefore, the study aims to develop a patient-oriented, nationally applicable complexity and casemix classification for adult palliative care patients in Germany. METHODS: COMPANION is a mixed-methods study with data derived from three subprojects. Subproject 1: Prospective, cross-sectional multi-centre study collecting data on patients' needs which reflect the complexity of the respective patient situation, as well as data on resources that are required to meet these needs in specialist palliative care units, palliative care advisory teams, and specialist palliative home care. Subproject 2: Qualitative study including the development of a literature-based preliminary list of characteristics, expert interviews, and a focus group to develop a taxonomy for specialist palliative care models. Subproject 3: Multi-centre costing study based on resource data from subproject 1 and data of study centres. Data and results from the three subprojects will inform each other and form the basis for the development of the casemix classification. Ultimately, the casemix classification will be developed by applying Classification and Regression Tree (CART) analyses using patient and complexity data from subproject 1 and patient-related cost data from subproject 3. DISCUSSION: This is the first multi-centre costing study that integrates the structure and process characteristics of different palliative care settings in Germany with individual patient care. The mixed methods design and variety of included data allow for the development of a casemix classification that reflect on the complexity of the research subject. The consecutive inclusion of all patients cared for in participating study centres within the time of data collection allows for a comprehensive description of palliative care patients and their needs. A limiting factor is that data will be collected at least partly during the COVID-19 pandemic and potential impact of the pandemic on health care and the research topic cannot be excluded. TRIAL REGISTRATION: German Register for Clinical Studies trial registration number: DRKS00020517 .
BMC palliative care

Jin, H.; Liu, Y.; Schweikert, B.; Hahman, H.; Wang, L.; Imhof, A.; Muche, R.; König, W.; Steinacker, J.M.
Serial changes in exercise capacity, NT-proBNP, and adiponectin in patients with acute coronary syndrome before and after phase II rehabilitation as well as at the 12-month follow-up.
Cardiol. Res. Pract. 2022:6538296 (2022)
Background: Acute coronary syndrome (ACS) causes pathophysiological changes in exercise capacity, N-terminal part of pro-brain natriuretic peptide (NT-proBNP), and adiponectin that impact the course of coronary artery disease and clinical outcomes after cardiac rehabilitation (CR). However, the serial changes and the relationship between the changes in these parameters for a prolonged term remain uninvestigated. Methods: Eighty-one patients with ACS underwent a three- or four-week CR program after acute care and were followed up for 12 months. Exercise capacity on a cycle ergometer and blood levels of NT-proBNP and adiponectin were determined before and after CR as well as at the 12-month follow-up. Results: Exercise capacity increased from 100 watts (in median) before CR to 138 watts after CR and 150 watts at 12 months. The NT-proBNP level (526 pg/ml before CR) remained almost unchanged after CR (557 pg/ml) and then decreased at 12 months (173 pg/ml). The adiponectin level (14.5 μg/ml before CR) increased after CR (16.0 μg/ml) and at 12 months (17.2 μg/ml). There was no significant correlation among the changes in these parameters at each observation time point. Conclusion: During the observation period from before CR to the 12-month follow-up, exercise capacity, NT-proBNP, and adiponectin underwent significant changes; however, these changes were independent from each other and not correlated linearly, and they provide complementary information in clinical practice. Thus, all these parameters should be included and determined at different time points for a prolonged period of time.
Cardiology Research and Practice

Kahnert, K.; Andreas, S.; Kellerer, C.; Lutter, J.; Lucke, T.; Yildirim, A.O.E.; Lehmann, M.; Seissler, J.; Behr, J.; Frankenberger, M.; Bals, R.; Watz, H.; Welte, T.; Trudzinski, F.C.; Vogelmeier, C.F.; Alter, P.; Jörres, R.A.
Reduced decline of lung diffusing capacity in COPD patients with diabetes and metformin treatment.
Sci. Rep. 12:1435 (2022)
We studied whether in patients with COPD the use of metformin for diabetes treatment was linked to a pattern of lung function decline consistent with the hypothesis of anti-aging effects of metformin. Patients of GOLD grades 1–4 of the COSYCONET cohort with follow-up data of up to 4.5 y were included. The annual decline in lung function (FEV1, FVC) and CO diffusing capacity (KCO, TLCO) in %predicted at baseline was evaluated for associations with age, sex, BMI, pack-years, smoking status, baseline lung function, exacerbation risk, respiratory symptoms, cardiac disease, as well as metformin-containing therapy compared to patients without diabetes and metformin. Among 2741 patients, 1541 (mean age 64.4 y, 601 female) fulfilled the inclusion criteria. In the group with metformin treatment vs. non-diabetes the mean annual decline in KCO and TLCO was significantly lower (0.2 vs 2.3, 0.8 vs. 2.8%predicted, respectively; $p < 0.05$ each), but not the decline of FEV1 and FVC. These results were confirmed using multiple regression and propensity score analyses. Our findings demonstrate an association between the annual decline of lung diffusing capacity and the intake of metformin in patients with COPD consistent with the hypothesis of anti-aging effects of metformin as reflected in a surrogate marker of emphysema.

Scientific Reports

Schatz, C.; Klein, N.; Marx, A.; Buschner, P.
Preoperative predictors of health-related quality of life changes (EQ-5D and EQ VAS) after total hip and knee replacement: A systematic review.
BMC Musculoskelet. Disord. 23:58 (2022)
BACKGROUND: Patient-reported outcomes are of ever-increasing importance in medical decision-making. The EQ-5D is one of the generic instruments measuring health-related quality of life (HRQoL) in arthroplasty. This review aimed to identify possible predictors of HRQoL changes for patients undergoing total knee replacements (TKR) or total hip replacements (THR). METHODS: A systematic literature review according to the PRISMA guidelines was conducted, searching several databases. Preoperative to postoperative HRQoL changes were evaluated in patients undergoing THR or TKR, using the EQ-5D visual analog scale (VAS) or the preference-based EQ-5D Index were evaluated. Articles were considered with prospectively or retrospectively collected data, as well as registry data, each with statistical analyses of patient-related factors. RESULTS: Eight hundred eighty-two articles were found, of which 21 studies met the inclusion criteria. Predictors were distinguished in alterable and non-alterable ones. The EQ-5D Index indicated a tendency towards beneficial improvements for patients with a high body mass index (BMI) (> 40) and no significant results for the VAS. Additionally, one study found that patient education and preoperative physiotherapy appeared to enhance HRQoL. Some evidence indicated that male gender was negatively associated with changes in the VAS and the EQ-5D Index, but one study reported the opposite. Changes in VAS and EQ-5D Index were lower for older patients, whereas a higher educational level seemed to be advantageous. A high Charnley class led to deteriorating changes in VAS, although a high Kellgren Lawrence classification was positively associated with the EQ-5D Index, in a limited number of studies. For all results, clinical relevance was calculated differently and mainly reported as uncertain or small. CONCLUSIONS: The literature on this topic was weak and offers only limited guidance. Results for alterable predictors, such as the BMI, indicated valuable improvements for highly obese patients. Further, high-quality research is required to support medical decision-making. LEVEL OF EVIDENCE: Level IV, according to the OCEBM Levels of Evidence Working Group.
BMC Musculoskeletal Disorders

Kurz, C.F.; König, A.°
Predicting time preference from social media behavior.
Futur. Gener. Comp. Syst. 130, 155-163 (2022)
Time preference, or delay discounting, plays an important role in how we make health- and life-related choices. The varying tendency to prefer smaller, immediate rewards to larger, delayed rewards has been found to be strongly associated with addictive, economic, and criminal behavior. We use general digital footprints from social media (i.e., Facebook Likes) to predict individual hyperbolic discount rates, using a sample of 2,378 participants who shared their Likes and completed questionnaires on a monetary discounting task. We employ an automated machine learning approach for the prediction task. We identified a variety of easily interpretable topics that have strong correlations with both high and low time preferences. Using only Likes, we were able to predict individual discount rates with much higher-than-random accuracy (up to r=0.30). We could distinguish a future-oriented person from a more present-biased person with fair accuracy (up to 65%). Using Facebook Likes as predictors was much more accurate than using information on an individual's substance use behavior, but combining both predictors slightly increased predictive accuracy. Predicting discount rates from social media behavior presents important opportunities for improving individual decision-making, but also comes with potential manipulation and privacy-related pitfalls.
Future Generation Computer Systems

Seidl, E.; Schwerk, N.; Carlens, J.; Wetzke, M.; Cunningham, S.; Emiralioğlu, N.; Kiper, N.; Lange, J.; Krenke, K.; Ullmann, N.; Krikovszky, D.; Maqhuzu, P.N.; Griese, C.A.; Schwarzkopf, L.; Griese, M.
Healthcare resource utilisation and medical costs for children with interstitial lung diseases (chILD) in Europe.
Thorax 77, 781–789 (2022)
BACKGROUND: No data on healthcare utilisation and associated costs for the many rare entities of children's interstitial lung diseases (chILD) exist. This paper portrays healthcare utilisation structures among individuals with chILD, provides a pan-European estimate of a 3-month interval per-capita costs and delineates crucial cost drivers. METHODS: Based on longitudinal healthcare resource utilisation pattern of 445 children included in the Kids Lung Register diagnosed with chILD across 10 European countries, we delineated direct medical and non-medical costs of care per 3-month interval. Country-specific utilisation patterns were assessed with a children-tailored modification of the validated FIMA questionnaire and valued by German unit costs. Costs of care and their drivers were subsequently identified via gamma-distributed generalised linear regression models. RESULTS: During the 3 months prior to inclusion into the registry (baseline), the rate of hospital admissions and inpatient days was high. Unadjusted direct medical per capita costs (€19 818) exceeded indirect (€1 907) and direct non-medical costs (€1 125) by far. Country-specific total costs ranged from €8 713 in Italy to €28 788 in Poland. Highest expenses were caused by the disease categories 'diffuse parenchymal lung disease (DPLD)-diffuse developmental disorders' (€45 536) and 'DPLD-unclear in the non-neonate' (€47 011). During a follow-up time of up to 5 years, direct medical costs dropped, whereas indirect costs and non-medical costs remained stable. CONCLUSIONS: This is the first prospective, longitudinal study analysing healthcare resource utilisation and costs for chILD across different European countries. Our results indicate that chILD is associated with high utilisation of healthcare services, placing a substantial economic burden on health systems.
Thorax

Karl, F.; Winkler, C.; Ziegler, A.-G.; Laxy, M.; Achenbach, P.
Costs of public health screening of children for presymptomatic type 1 diabetes in Bavaria, Germany.
Diabetes Care 45, 837-844 (2022)
OBJECTIVE: We sought to evaluate costs associated with public health screening for presymptomatic type 1 diabetes in 90,632 children as part of the Fr1da study in Bavaria and in forecasts for standard care. RESEARCH DESIGN AND METHODS: We report on resource use and direct costs for screening-related procedures in the Fr1da study coordination center and laboratory

and in participating pediatric practices and local diabetes clinics. Data were obtained from Fr1da study documents, an online survey among pediatricians, and interviews and records of Fr1da staff members. Data were analyzed with tree models that mimic procedures during the screening process. Cost estimates are presented as they were observed in the Fr1da study and as they can be expected in standard care for various scenarios. RESULTS: The costs per child screened in the Fr1da study were €28.17 (95% CI 19.96; 39.63) and the costs per child diagnosed with presymptomatic type 1 diabetes were €9,117 (6,460; 12,827). Assuming a prevalence of presymptomatic type 1 diabetes of 0.31%, as in the Fr1da study, the estimated costs in standard care in Germany would be €21.73 (16.76; 28.19) per screened child and €7,035 (5,426; 9,124) per diagnosed child. Of the projected screening costs, €12.25 would be the costs in the medical practice, €9.34 for coordination and laboratory, and €0.14 for local diabetes clinics. CONCLUSIONS: This study provides information for the planning and implementation of screening tests for presymptomatic type 1 diabetes in the general public and for the analysis of the cost-effectiveness of targeted prevention strategies.
Diabetes Care

Barc, J.; Tadros, R.; Glinge, C.; Chiang, D.Y.; Jouni, M.; Simonet, F.; Jurgens, S.J.; Baudic, M.; Nicastro, M.; Potet, F.; Offerhaus, J.A.; Walsh, R.; Choi, S.H.; Verkerk, A.O.; Mizusawa, Y.; Anys, S.; Minois, D.; Arnaud, M.; Duchateau, J.; Wijeyeratne, Y.D.; Muir, A.M.; Papadakis, M.; Castelletti, S.; Torchio, M.; Ortuño, C.G.; Lacunza, J.; Giachino, D.F.; Cerrato, N.; Martins, R.P.; Campuzano, Ó.; Van Dooren, S.; Thollet, A.; Kyndt, F.; Mazzanti, A.; Clémenty, N.; Bisson, A.; Corveleyn, A.; Stallmeyer, B.; Dittmann, S.; Saenen, J.; Noël, A.; Honarbakhsh, S.; Rudic, B.; Marzak, H.; Rowe, M.K.; Federspiel, C.; Le Page, S.; Placide, L.; Milhem, A.; Barajas-Martínez, H.; Beckmann, B.M.; Krapels, I.P.; Steinfurt, J.; Winkel, B.G.; Jabbari, R.; Shoemaker, M.B.; Boukens, B.J.; Skoric-Milosavljevic, D.; Bikker, H.; Manevy, F.C.; Lichtner, P.; Ribasés, M.; Meitinger, T.; Müller-Nurasyid, M.; Veldink, J.H.; van den Berg, L.H.; van Damme, P.; Cusi, D.; Lanzani, C.; Rigade, S.; Charpentier, E.; Baron, E.; Bonnaud, S.; Lecointe, S.; Donnart, A.; Le Marec, H.; Chatel, S.; Karakachoff, M.; Bézieau, S.; London, B.; Tfelt-Hansen, J.; Roden, D.; Odening, K.E.; Cerrone, M.; Chinitz, L.A.; Volders, P.G.; van de Berg, M.P.; Laurent, G.; Faivre, L.; Antzelevitch, C.; Kääb, S.; Arnaout, A.A.; Dupuis, J.M.; Pasquie, J.L.; Billon, O.; Roberts, J.D.; Jesel, L.; Borggrefe, M.; Lambiase, P.D.; Mansourati, J.; Loeys, B.; Leenhardt, A.; Guicheney, P.; Maury, P.; Schulze-Bahr, E.; Robyns, T.; Breckpot, J.; Babuty, D.; Priori, S.G.; Napolitano, C.; de Asmundis, C.; Brugada, P.; Brugada, R.; Brugada, J.; Mabo, P.; Behar, N.; Giustetto, C.; Molina, M.S.; Gimeno, J.R.; Hasdemir, C.; Schwartz, P.J.; McKeown, P.P.; Sharma, S.; Behr, E.R.; Haissaguerre, M.; Sacher, F.; Rooryck, C.; Tan, H.L.; Remme, C.A.; Postema, P.G.; Delmar, M.; Ellinor, P.T.; Lubitz, S.A.; Gourraud, J.B.; Tanck, M.W.; George, A.L.; MacRae, C.A.; Burridge, P.W.; Dina, C.; Probst, V.; Wilde, A.A.; Schott, J.J.; Redon, R.; Bezzina, C.R.°; KORA Study Group (Strauch, K.°; Peters, A.; Schulz, H.; Schwettmann, L.; Leidl, R.; Heier, M.)
Genome-wide association analyses identify new Brugada syndrome risk loci and highlight a new mechanism of sodium channel regulation in disease susceptibility.
Nat. Genet. 54, 232-239 (2022)
Brugada syndrome (BrS) is a cardiac arrhythmia disorder associated with sudden death in young adults. With the exception of SCN5A, encoding the cardiac sodium channel NaV1.5, susceptibility genes remain largely unknown. Here we performed a genome-wide association meta-analysis comprising 2,820 unrelated cases with BrS and 10,001 controls, and identified 21 association signals at 12 loci (10 new). Single nucleotide polymorphism (SNP)-heritability estimates indicate a strong polygenic influence. Polygenic risk score analyses based on the 21 susceptibility variants demonstrate varying cumulative contribution of common risk alleles among different patient subgroups, as well as genetic associations with cardiac electrical traits and disorders in the general population. The predominance of cardiac transcription factor loci indicates that transcriptional regulation is a key feature of BrS pathogenesis. Furthermore, functional studies conducted on MAPRE2, encoding the microtubule plus-end binding protein EB2, point to microtubule-related trafficking effects on NaV1.5 expression as a new underlying molecular mechanism. Taken together, these findings broaden our understanding of the genetic architecture of BrS and provide new insights into its molecular underpinnings.
Nature Genetics

Kemp, C.G.; Johnson, L.C.M.; Sagar, R.; Poongothai, S.; Tandon, N.; Anjana, R.M.; Aravind, S.; Sridhar, G.R.; Patel, S.A.; Emmert-Fees, K.; Rao, D.; Narayan, K.M.V.; Mohan, V.; Ali, M.K.; Chwastiak, L.A.
Effect of a collaborative care model on anxiety symptoms among patients with depression and diabetes in India: The INDEPENDENT randomized clinical trial.
Gen. Hosp. Psychiatry 74, 39-45 (2022)
Objective: We assessed the impact of a collaborative care intervention on anxiety symptoms among participants in India with comorbid depression, poorly controlled diabetes, and moderate to severe anxiety symptoms. Method: We analyzed data from a randomized controlled trial conducted at four diabetes clinics in India. Participants received either collaborative care or usual care. We included only participants who scored ⩾10 on the Generalized Anxiety Disorder-7 (GAD-7) at baseline. We estimated the effect of the intervention on clinically significant reduction in anxiety symptoms; we considered several potential baseline moderators and mediation by anti-depressant use. Results: One hundred and seventy-two participants scored 10 or above on the GAD-7 at baseline. Collaborative care participants were more likely than control participants to achieve a clinically significant reduction in anxiety symptoms at 6 and 12 months (65.7% vs. 41.4% at 12 months, $p = 0.002$); these differences were not sustained at 18 or 24 months. There was little evidence of moderation by participant characteristics at baseline, and effects were not mediated by anti-depressant use. Conclusions: Collaborative care for the treatment of depression and type 2 diabetes can lead to clinically significant reductions in anxiety symptoms among patients with anxiety. Effects were notable during the active intervention period but not over the year post-intervention.
General hospital psychiatry

2021

Olm, M.; Donnachie, E.; Tauscher, M.; Gerlach, R.; Linde, K.; Maier, W.; Schwettmann, L.; Schneider, A.

Hausärztliche Versorgungssteuerung vor und nach Abschaffung der Praxisgebühr. Ergebnisse einer Routinedatenanalyse aus Bayern.
Z. Allg. Med. 97, 444-450 (2021)
HintergrundUm die hausärztliche Koordination zu stärken, wurde 2004 die Praxisgebühr eingeführt. Diese wurde, begründet mit einer mangelnden Wirksamkeit gegenüber einem zu hohen bürokratischen Aufwand, 2012 abgeschafft. Die vorliegende Arbeit ist eine Zusammenfassung der relevantesten Ergebnisse zweier international publizierter Artikel, die die Änderung der hausärztlichen Steuerung nach Abschaffung der Praxisgebühr analysierten.MethodenEs erfolgte eine retrospektive Analyse anonymisierter Abrechnungsdaten der Kassenärztlichen Vereinigung Bayerns im Zeitraum von 2011–2016 (2011/2012 mit, 2013–2016 ohne Praxisgebühr). Eingeschlossen wurden alle gesetzlich Versicherten mit Mindestalter 18 Jahren und Hauptwohnsitz in Bayern. Patient*innen galten als „hausärztlich gesteuert", wenn sämtliche Facharztkontakte innerhalb eines Quartals auf einer hausärztlichen Überweisung basierten.ErgebnisseNach Abschaffung zeigte sich ein deutlicher Rückgang der hausärztlich gesteuerten Versorgung von 49,6 % (2011) auf 15,5 % (2016). Städtisch geprägte Regionen verzeichneten höhere Rückgänge als ländlicher geprägte Gebiete. Hinsicht-lich Morbidität nahmen die Anteile an chronischen und psy-chischen Erkrankungen bei ungesteuerten Patient*innen zu.SchlussfolgerungenDie Ergebnisse legen nahe, dass die Praxisgebühr in Teilen ein wirksames Instrument zur Unterstützung der koordinierten Primärversorgung war. Nach ihrer Abschaffung sind alternative Ansätze nötig, um die hausärztliche Versorgungssteuerung zu unterstützen.
Zeitschrift für Allgemeinmedizin

Marijic, P.; Murawski, M.; Maier, W.; Hamacher, K.; Laub, O.; Lang, M.; Grill, E.; Schwettmann, L.
Cost effects of a health coaching in children and adolescents with mental health and developmental disorders.
Acad. Pediatr., DOI: 10.1016/j.acap.2021.12.026 (2021)
OBJECTIVE: Health coaching (HC) aims to strengthen the role of primary care pediatricians in the treatment of children and adolescents with mental health and developmental disorders by extending consultation time and using disease-specific manuals. We evaluated the effect of HC on costs of specialized, pediatrician, and overall care. METHODS: In a retrospective cohort study based on German health insurance claims data, we identified children aged up to 17 years with a newly diagnosed mental health and/or developmental disorder between 2013 and 2015. Patients getting HC were matched to patients receiving usual care. Costs were calculated for one year following the start of the treatment and compared by Two-Part and Gamma Models. Absolute costs and cost differences were calculated with bootstrapped 95% confidence intervals. RESULTS: We compared 5,597 patients receiving HC with 5,597 control patients. The probability of incurring specialized care costs was similar between the groups (0.96, CI95%: 0.88; 1.05). However, for those who did incur costs, specialized care costs were significantly lower for HC-treated patients (0.77, CI95%: 0.63; 0.93). Accordingly, specialized care costs were lower by €-94 (CI95%: €-175; €-18), while pediatrician care costs were higher for HC-treated patients by €57 (CI95%: €49; €64). Hence, overall costs did not differ between the groups (€-59, CI95%: €-191; €71). CONCLUSION: Provision of HC has the potential to lower the costs of specialized care, while increasing the costs of pediatrician care. Overall costs did not differ, suggesting that the additional costs incurred by the HC were offset.
Academic Pediatrics

Katzenberger, B.; Schwettmann, L.; Weigl, M.; Paulus, A.; Pedron, S.; Fuchs, S.; Koller, D.; Grill, E.
Behavioural and patient-individual determinants of quality of life, functioning and physical activity in older adults (MobilE-TRA 2): Study protocol of an observational cohort study in a tertiary care setting.
BMJ Open 11:e051915 (2021)
INTRODUCTION: Vertigo, dizziness and balance problems (VDB) as well as osteoarthritis (OA) are among the health conditions with the greatest impact on mobility and social participation in older adults. Patients with VDB and OA were shown to benefit from specialised care such as vestibular rehabilitation therapy or joint replacement. However, these effects are not permanent and seem to disappear over time. One important reason might be a decreasing adherence to therapy recommendations. Findings from behavioural economics (BE) can help to shed light on individual effects on adherence behaviour and long-term outcomes of VDB and OA. OBJECTIVE: Based on insights from BE concepts (ie, self-efficacy, intention, and time and risk preferences), MobilE-TRA 2 investigates the determinants of functioning and health-related quality of life (HRQoL) 3 and 12 months after discharge from total hip replacement (THR)/total knee replacement (TKR) in patients with OA and after interdisciplinary evaluation for VDB. METHODS AND ANALYSIS: MobilE-TRA 2 is a longitudinal observational study with data collection in two specialised tertiary care centres at the university hospital in Munich, Germany between 2020 and 2023. Patients aged 60 and older presenting for their first THR/TKR or interdisciplinary evaluation of VDB at Ludwig Maximilians University (LMU) hospital will be recruited for study participation. Three and twelve months after baseline assessment, all patients will receive a follow-up questionnaire. Mixed-effect regression models will be used to examine BE concepts as determinants of adherence, HRQoL and functioning. ETHICS AND DISSEMINATION: The study was approved by the ethics committee at the medical faculty of the LMU Munich under the number 20-727. Results will be published in scientific, peer-reviewed journals and at national and international conferences. Findings will also be disseminated via newsletters, the project website and a regional conference for representatives of local and national authorities.
BMJ Open

Obermeier, V.; Murawski, M.; Heinen, F.; Landgraf, M.N.; Straube, A.; von Kries, R.; Ruscheweyh, R.
Total health insurance costs in children with a migraine diagnosis compared to a control group.
J. Headache Pain 22:140 (2021)
Background: Health care costs of migraine constitute a major issue in health economics. Several publications analyzed health care costs for adult migraine patients, based on questionnaires or secondary (health insurance) data. Although migraine often starts already in primary school age, data on migraine related costs in children is scarce. In this paper we aimed to assess the migraine-related health care costs in 6 to 11 year old children in Germany. Methods: Using claims data of a large German health insurer (BARMER), overall annual health care costs of 6 to 11 year old children with a diagnosis of migraine in 2017 (n = 2597)

were compared to a control group of 6 to 11 year old children without a headache diagnosis between 2013 and 2017 (n = 306,926). The association of migraine and costs was modeled by generalized linear regression (Gamma regression) with adjustment for sex, age and comorbidities. Results: Children with migraine caused considerably higher annual per capita health care costs than children without a headache diagnosis (migraine group: € 1018, control group: € 618). Excess costs directly related to migraine amounted to € 115. The remaining excess costs were related to comorbidities, which were more frequent in the migraine group. Mental and behavioural disorders constituted the most expensive comorbidity, accounting for € 105 of the € 400 annual excess costs in the migraine group. Conclusion: 6 to 11 year old children with a migraine diagnosis cause significant direct and comorbidity related excess costs in the German health care system.
Journal of Headache and Pain, The

Schaller, A.; Klas, T.; Gernert, M.; Steinbeisser, K.
Health problems and violence experiences of nurses working in acute care hospitals, longterm care facilities, and home-based longterm care in Germany: A systematic review.
PLoS ONE 16:e0260050 (2021)
Background Working in the nursing sector is accompanied by great physical and mental health burdens. Consequently, it is necessary to develop target-oriented, sustainable profession-specific support and health promotion measures for nurses. Objectives The present review aims to give an overview of existing major health problems and violence experiences of nurses in different settings (acute care hospitals, long-term care facilities, and home-based long-term care) in Germany. Methods A systematic literature search was conducted in PubMed and PubPsych and completed by a manual search upon included studies' references and health insurance reports. Articles were included if they had been published after 2010 and provided data on health problems or violence experiences of nurses in at least one care setting. Results A total of 29 studies providing data on nurses health problems and/or violence experience were included. Of these, five studies allowed for direct comparison of nurses in the settings. In addition, 14 studies provided data on nursing working in acute care hospitals, ten on nurses working in long-term care facilities, and four studies on home-based long-term care. The studies either conducted a setting-specific approach or provided subgroup data from setting-unspecific studies. The remaining studies did not allow setting-related differentiation of the results. The available results indicate that mental health problems are the highest for nurses in acute care hospitals. Regarding violence experience, nurses working in long-term care facilities appear to be most frequently affected. Conclusion The state of research on setting-specific differences of nurses' health problems and violence experiences is insufficient. Setting-specific data are necessary to develop target-group specific and feasible interventions to support the nurses' health and prevention of violence, as well as dealing with violence experiences of nurses.
PLoS ONE

Schutzmeier, P.#; Kutzora, S.#; Mittermeier, I.; Becker, J.; Bergmann, K.C.; Bose-O'Reilly, S.; Buters, J.T.M.; Damialis, A.; Heinrich, J.; Kabesch, M.; Mertes, H.; Nowak, D.; Korbely, C.; Walser-Reichenbach, S.M.; Weinberger, A.; Heinze, S.; Steckling-Muschack, N.; Herr, C.
Non-pharmacological interventions for pollen-induced allergic symptoms: Systematic literature review.
Pediatr. Allergy Immunol., DOI: 10.1111/pai.13690 (2021)
BACKGROUND: Allergic diseases pose a health problem worldwide. Pollen are widespread aeroallergens which can cause symptoms like shortness of breath, cough, itchy eyes or rhinitis. Apart from preventive measures and pharmacological treatment, also non-pharmacological interventions have been suggested to reduce symptoms. The objective of this work was to review studies investigating the effectiveness of non-pharmacologic interventions to reduce allergic symptoms. METHODS: PubMed, EMBASE and CENTRAL were systematically reviewed in July 2018 and April 2020. Several authors worked on the screening of titles, abstracts and full texts. One author for each literature search performed the data extraction and the Risk of Bias assessment. Studies were included if they met the inclusion criteria defined by the PECOs. Studies which investigating the effect of non-pharmacologic interventions on patients with allergic rhinitis were included. RESULTS: 29 studies investigating eleven types of non-pharmacologic interventions to avoid and reduce allergic symptoms due to pollen exposure were included in this review. Out of all studies, seven studies addressed nasal rinsing and 22 included acupuncture, air filtering, artisanal tears, individual allergen avoidance advice, various nasal applications, self-hypnosis, rhinophototherapy and wraparound sunglasses. CONCLUSION: Most studies had a high Risk of Bias and small sample sizes. There were only a few high-quality studies that give hints about the effectiveness of non-pharmacological interventions. For future research, more high-quality studies are required to confirm the effectiveness of simple, safe and cost-effective interventions.
Pediatric Allergy and Immunology

Schunk, M.; Berger, U.; Le, L.; Rehfuess, E.; Schwarzkopf, L.; Streitwieser, S.; Müller, T.; Hofmann, M.; Holle, R.; Huber, R.M.; Mansmann, U.; Bausewein, C.
BreathEase: Rationale, design and recruitment of a randomised trial and embedded mixed-methods study of a multiprofessional breathlessness service in early palliative care.
ERJ Open Res. 7:00228-2020 (2021)
Background: The Munich Breathlessness Service has adapted novel support services to the German context, to reduce burden in patients and carers from breathlessness in advanced disease. It has been evaluated in a pragmatic fast-track randomised controlled trial (BreathEase; NCT02622412) with embedded qualitative interviews and postal survey. The aim of this article is to describe the intervention model and study design, analyse recruitment to the trial and compare sample characteristics with other studies in the field. Methods: Analysis of recruitment pathways and enrolment, sociodemographic and clinical characteristics of participants and carers. Results: Out of 439 people screened, 253 (58%) were offered enrolment and 183 (42%) participated. n=97 (70%) carers participated. 186 (42%) people did not qualify for inclusion, mostly because breathlessness could not be attributed to an underlying disease. All participants were self-referring; 60% through media sources. Eligibility and willingness to participate were associated to social networks and illness-related activities as recruitment routes. Mean age of participants was 71 years (51% women), with COPD (63%), chronic heart failure (8%), interstitial lung disease (9%), pulmonary hypertension (6%) and cancer (7%) as

underlying conditions. Postal survey response rate was 89%. Qualitative interviews were conducted with 16 patients and nine carers. Conclusion: The BreathEase study has a larger and more heterogeneous sample compared to other trials. The self-referral-based and prolonged recruitment drawing on media sources approximates real-world conditions of early palliative care. Integrating qualitative and quantitative components will allow a better understanding and interpretation of the results of the main effectiveness study.
ERJ Open Research

Schwarzkopf, L.; Dorscht, L.; Kraus, L.; Luttenberger, K.
Is bouldering-psychotherapy a cost-effective way to treat depression when compared to group cognitive behavioral therapy – results from a randomized controlled trial.
BMC Health Serv. Res. 21:1162 (2021)
Background: Bouldering-Psychotherapy (BPT) has proven to effectively reduce depressive symptoms, but evidence on its cost-effectiveness is lacking. Corresponding information is paramount to support health policy decision making on a potential implementation of BPT in routine care. Methods: Using data from the German KuS trial BPT was compared with group Cognitive Behavioral Therapy (CBT). Severity of depression symptoms at end of the intervention was operationalized via Montgomery-Asberg Depression Rating Scale (MADRS) and Patient Health Questionnaire (PHQ-9). Adopting a societal perspective, direct medical costs and productivity loss were calculated based on standardized unit costs. To determine incremental cost-effectiveness ratios (ICER) and cost-effectiveness-acceptance curves (CEAC), adjusted mean differences (AMD) in costs (gamma-distributed model) and both effect parameters (Gaussian-distributed model) were obtained from 1000 simultaneous bootstrap replications. Results: BPT was related to improved effects (AMDs: MADRS -2.58; PHQ-9: − 1.35) at higher costs (AMD: +€ 754). No AMD was significant. ICERs amounted to €288 per MADRS-point and €550 per PHQ-9-point. For both effect parameters about 20% of bootstrap replications indicated dominance of BPT, and about 75% larger effects at higher costs. At hypothetical willingness to pay (WTP) thresholds of €241 (MADRS) and €615 (PHQ-9) per unit of change BPT had a 50% probability of being cost-effective. Conclusion: BPT is a promising alternate treatment strategy which – in absence of established WTP thresholds for improving symptoms of depression – cannot unambiguously be claimed cost-effective. Further studies defining subgroups that particularly benefit from BPT appear paramount to delineate recommendations for an efficient prospective roll-out to routine care.
BMC Health Services Research

Burns, J.; Kurz, C.F.; Laxy, M.
Effectiveness of the German disease management programs: Quasi-experimental analyses assessing the population-level health impact.
BMC Public Health 21:2092 (2021)
Background: In 2002–2003 disease management programs (DMPs) for type 2 diabetes and coronary heart disease were introduced in Germany to improve the management of these conditions. Today around 6 million Germans aged 56 and older are enrolled in one of the DMPs; however, their effect on health remains unclear. Methods: We estimated the impact of German DMPs on circulatory and all-cause mortality using a synthetic control study. Specifically, using routinely available data, we compared pre and post-intervention trends in mortality of individuals aged 56 and older for 1998–2014 in Germany to trends in other European countries. Results: Average circulatory and all-cause mortality in Germany and the synthetic control was 1.63 and 3.24 deaths per 100 persons. Independent of model choice, circulatory and all-cause mortality decreased non-significantly less in Germany than in the synthetic control; for the model with a 3 year time lag, for example, by 0.12 (95%-CI: − 0.20; 0.44) and 0.22 (95%-CI: − 0.40; 0.66) deaths per 100 persons, respectively. Further main analyses, as well as sensitivity and subgroup analyses supported these results. Conclusions: We observed no effect on circulatory or all-cause mortality at the population-level. However, confidence intervals were wide, meaning we could not reject the possibility of a positive effect. Given the substantial costs for administration and operation of the programs, further comparative effectiveness research is needed to clarify the value of German DMPs for type 2 diabetes and CHD.
BMC Public Health

Burns, J.; Kurz, C.F.; Laxy, M.
Correction to: Effectiveness of the German disease management programs: Quasi-experimental analyses assessing the population-level health impact.
BMC Public Health 21:2223 (2021)
After publication of the original article [1] the authors noticed that several affiliations were incorrect. The original affiliations were published as: • 1 Institute for Medical Information Processing, Biometry and Epidemiology, TU München, Marchioninistrasse 17, 80336 Munich, Germany. • 2 Institute for Medical Information Processing, Biometry and Epidemiology, LMU Munich Marchioninistrasse 17, 80336 Munich, Germany. • 3 Munich School of Management and Munich Center of Health Sciences, LMU Munich, Munich, Germany. • 4 Pettenkofer School of Public Health, Munich, Germany. • 5 Institute of Health Economics and Health Care Management, Helmholtz Zentrum München, German Research Center for Environmental Health (GmbH), Ingolstädter Landstraße 1, 85764 Neuherberg, Germany. The correction affiliations are: • 1 Department of Sport and Health Sciences, Technical University of Munich Georg-Brauchle-Ring 60/62 80992 Munich, Germany • 2 Institute for Medical Information Processing, Biometry and Epidemiology, LMU Munich Marchioninistrasse 17 80336 Munich, Germany • 3 Pettenkofer School of Public Health Munich, Germany • 4 Munich School of Management and Munich Center of Health Sciences, LMU Munich, Munich, Germany • 5 Institute of Health Economics and Health Care Management, Helmholtz Zentrum München • Research Center for Environmental Health (GmbH) Ingolstädter Landstraße 1 85764 Neuherberg, Germany The original article has been updated.
BMC Public Health
Marijic, P.; Schwarzkopf, L.; Schwettmann, L.; Ruhnke, T.; Trudzinski, F.; Kreuter, M.
Pirfenidone vs. nintedanib in patients with idiopathic pulmonary fibrosis: A retrospective cohort study.
Respir. Res. 22:268 (2021)
Background: Two antifibrotic drugs, pirfenidone and nintedanib, are licensed for the treatment of patients with idiopathic pulmonary fibrosis (IPF). However, there is neither evidence from prospective data nor a guideline recommendation, which drug should be preferred over the other. This study aimed to

compare pirfenidone and nintedanib-treated patients regarding all-cause mortality, all-cause and respiratory-related hospitalizations, and overall as well as respiratory-related health care costs borne by the Statutory Health Insurance (SHI). Methods: A retrospective cohort study with SHI data was performed, including IPF patients treated either with pirfenidone or nintedanib. Stabilized inverse probability of treatment weighting (IPTW) based on propensity scores was applied to adjust for observed covariates. Weighted Cox models were estimated to analyze mortality and hospitalization. Weighted cost differences with bootstrapped 95% confidence intervals (CI) were applied for cost analysis. Results: We compared 840 patients treated with pirfenidone and 713 patients treated with nintedanib. Both groups were similar regarding two-year all-cause mortality (HR: 0.90 95% CI: 0.76; 1.07), one-year all cause (HR: 1.09, 95% CI: 0.95; 1.25) and respiratory-related hospitalization (HR: 0.89, 95% CI: 0.72; 1.08). No significant differences were observed regarding total (€− 807, 95% CI: €− 2977; €1220) and respiratory-related (€− 1282, 95% CI: €− 3423; €534) costs. Conclusion: Our analyses suggest that the patient-related outcomes mortality, hospitalization, and costs do not differ between the two currently available antifibrotic drugs pirfenidone and nintedanib. Hence, the decision on treatment with pirfenidone versus treatment with nintedanib ought to be made case-by-case taking clinical characteristics, comorbidities, comedications, individual risk of side effects, and patients' preferences into account.
Respiratory Research

Krack, G.; Kirsch, F.; Schwarzkopf, L.; Schramm, A.; Leidl, R.
Can adherence to and persistence with inhaled long-acting bronchodilators improve the quality of life in patients with chronic obstructive pulmonary disease? Results from a German disease management program.
Clin. Drug Invest. 41, 989–998 (2021)
Background and Objective: Adherence to and persistence with inhaled long-acting bronchodilators (ILAB), is commonly considered to be a relevant driver of perceived health-related quality of life (HRQoL) in chronic obstructive pulmonary disease (COPD), but the topic is rarely studied with real-world data. Using survey and health insurance claims data, this study investigates the effect of adherence to and persistence with ILAB on EQ-5D-5L visual analog scale (VAS) in ILAB users who were enrolled in the German disease management programs (DMP) for COPD. Methods: Included ILAB users were aged ≥ 18 years, continuously insured with AOK Bavaria and enrolled in the DMP for COPD. Adherence to ILAB [proportion of days covered (PDC); PDC ≥ 80%], and persistence (days of uninterrupted ILAB therapy) were assessed in the year preceding the study's HRQoL questionnaire. In a cross-sectional design we applied quasi-Poisson models with log link function and subgroup analyses. The robustness of results was analyzed with comprehensive sensitivity analyses. Results: Patients with PDC ≥ 80% had 2.96% higher VAS scores than patients with lower PDCs. From all analyses, patients with GOLD stage III had the highest effects from PDC ≥ 80% (5.33% increased VAS). Patients without heart failure profited significantly more from PDC ≥ 80% (+ 4.34% vs − 2.88%) and from an additional persistent day (+ 0.01% vs – 0.01%) than patients with heart failure. Conclusions: Overall, ILAB users significantly profited from PDC ≥ 80%, but not from continuous PDC or persistent days. In secondary subgroup analyses, patients with GOLD stage III and patients without heart failure particularly profited from PDC ≥ 80%. Only patients without heart failure particularly profited from more persistent days. Because identified effects were small and often not robust, advancing adherence and persistence alone may not improve the German DMP for COPD substantially.
Clinical Drug Investigation

Teni, F.S.; Gerdtham, U.G.; Leidl, R.; Henriksson, M.; Åström, M.; Sun, S.; Burström, K.
Inequality and heterogeneity in health-related quality of life: Findings based on a large sample of cross-sectional EQ-5D-5L data from the Swedish general population.
Qual. Life Res., DOI: 10.1007/s11136-021-02982-3 (2021)
PURPOSE: This study aimed to investigate inequality and heterogeneity in health-related quality of life (HRQoL) and to provide EQ-5D-5L population reference data for Sweden. METHODS: Based on a large Swedish population-based survey, 25,867 respondents aged 30–104 years, HRQoL is described by sex, age, education, income, economic activity, health-related behaviours, self-reported diseases and conditions. Results are presented by EQ-5D-5L dimensions, respondents rating of their overall health on the EQ visual analogue scale (EQ VAS), VAS index value and TTO (time trade-off) index value allowing for calculation of quality-adjusted life years (QALYs). Ordinary Least Squares and multivariable logistic regression analyses were used to study inequalities in observed EQ VAS score between socioeconomic groups and the likelihood to report problems on the dimensions, respectively, adjusted for confounders. RESULTS: In total, 896 different health states were reported; 24.1% did not report any problems. Most problems were reported with pain/discomfort. Women reported worse HRQoL than men, and health deteriorated with age. The strongest association between diseases and conditions and EQ VAS score was seen for depression and mental health problems. There was a socioeconomic gradient in HRQoL; adjusting for health-related behaviours, diseases and conditions slightly reduced the differences between educational groups and income groups, but socioeconomic inequalities largely remained. CONCLUSION: EQ-5D-5L population reference (norms) data are now available for Sweden, including socioeconomic differentials. Results may be used for comparisons with disease-specific populations and in health economic evaluations. The observed socioeconomic inequality in HRQoL should be of great importance for policy makers concerned with equity aspects.
Quality of Life Research

Stöber, A.; Lutter, J.; Schwarzkopf, L.; Kirsch, F.; Schramm, A.; Vogelmeier, C.F.; Leidl, R.
Impact of lung function and exacerbations on health-related quality of life in copd patients within one year: Real-world analysis based on claims data.
Int. J. Chron. Obstruct. Pulmon. Dis. 16, 2637-2651 (2021)
Purpose: Real-world evidence on the impact of forced expiratory volume in one second (FEV1) and exacerbations on health-related quality of life (HRQoL) in patients with chronic obstructive pulmonary disease (COPD) is sparse especially with regard to GOLD ABCD groups. This study investigates how changes in FEV1 and exacerbations affect generic and disease-specific HRQoL in COPD patients over one year. Methods: Using German claims data and survey data, we classified 3016 COPD patients and analyzed their health status by GOLD groups AB

and CD. HRQoL was measured with the disease-specific COPD assessment test (CAT) and the visual analog scale (VAS) from the generic Euro-Qol 5D-5L. We applied change score models to assess associations between changes in FEV1 (≥100 mL decrease/no change/≥100 mL increase) or the development of severe exacerbations with change in HRQoL. Results: FEV1 decrease was associated with a significant but not minimal important difference (MID) deterioration in disease-specific HRQoL (mean change [95% CI]: CAT +0.74 [0.15 to 1.33]), while no significant change was observed in the generic VAS. Experiencing at least one severe exacerbation also had a significant impact on CAT deterioration (+1.58 [0.52 to 2.64]), but again not on VAS. Here, GOLD groups AB showed not only a statistically but also a clinically relevant MID deterioration in CAT (+2.1 [0.88 to 3.32]). These particular patient groups were further characterized by a higher probability of being male, having a higher mMRC and Charlson index, and a lower probability of having higher FEV1 or BMI values. Conclusion: FEV1 decline and the occurrence of ≥1 severe exacerbation are significantly associated with overall deterioration in disease-specific HRQoL. Preventing severe exacerbations particularly in patients without previous severe exacerbations (ABCD groups A and B) may help to stabilize the key patient-reported outcome HRQoL.
International Journal of Chronic Obstructive Pulmonary Disease

Teni, F.S.; Rolfson, O.; Berg, J.; Leidl, R.; Burström, K.
Concordance among Swedish, German, Danish, and UK EQ-5D-3L value sets: Analyses of patient-reported outcomes in the swedish hip arthroplasty register.
J. Clin. Med. 10:4205 (2021)
Background: Application of different value sets to health-related quality of life (HRQoL) measured with the EQ-5D-3L may lead to different results due to differences in methods, perspectives, and countries used. Focusing on concordance, this study aimed at understanding the implications of applying EQ-5D-3L value sets from Sweden, Germany, Denmark, and the UK to evaluate HRQoL of patients undergoing total hip replacement (THR) in Sweden before and after surgery. Methods: We performed a longitudinal study of patients in the Swedish Hip Arthroplasty Register from preoperative stage to 1-year follow-up (n = 73,523) using data collected from 2008 to 2016. Eight EQ-5D-3L value sets from the four countries were compared based on a valuation method (visual analogue scale (VAS) or time trade-off (TTO)), perspective (experience-based or hypothetical), and country. Concordance among the value sets with patient-reported EQ VAS score was also assessed. Longitudinal changes in EQ-5D-3L index over the 1-year follow-up were compared across value sets by method, perspective, and country. Results: Value sets based on the same method and perspective showed higher concordance in EQ-5D-3L index at both measurement time points than other comparisons. In the comparisons by perspective, VAS value sets showed higher concordance than TTO value sets. The Swedish VAS and the Danish TTO value sets showed the highest levels of concordance with patient-reported EQ VAS scores. Generally, value sets based on the same method and perspective had the smallest mean differences between changes in EQ-5D-3L indices from preoperative to 1-year postoperative follow-up. Conclusion: Among THR patients value sets based on the same method and perspective, a direct transfer of results across countries could be meaningful. In cases of differences in methods and perspectives among value sets, transfer of value sets across settings would have to consider conversion through crosswalk.
Journal of Clinical Medicine

Kabiri, Y.; Fuhrmann, A.; Becker, A.; Jedermann, L.; Eberhagen, C.; König, A.; Silva, T.B.; Borges, F.; Hauck, S.M.; Michalke, B.; Knolle, P.; Zischka, H.
Mitochondrial impairment by MitobloCK-6 inhibits liver cancer cell proliferation.
Front. Cell Dev. Biol. 9:725474 (2021)
Augmenter of liver regeneration (ALR) is a critical multi-isoform protein with its longer isoform, located in the mitochondrial intermembrane space, being part of the mitochondrial disulfide relay system (DRS). Upregulation of ALR was observed in multiple forms of cancer, among them hepatocellular carcinoma (HCC). To shed light into ALR function in HCC, we used MitoBloCK-6 to pharmacologically inhibit ALR, resulting in profound mitochondrial impairment and cancer cell proliferation deficits. These effects were mostly reversed by supplementation with bioavailable hemin b, linking ALR function to mitochondrial iron homeostasis. Since many tumor cells are known for their increased iron demand and since increased iron levels in cancer are associated with poor clinical outcome, these results help to further advance the intricate relation between iron and mitochondrial homeostasis in liver cancer.
Frontiers in cell and developmental biology

Kellerer, C.; Jörres, R.A.; Schneider, A.; Alter, P.; Kauczor, H.U.; Jobst, B.; Biederer, J.; Bals, R.; Watz, H.; Behr, J.; Kauffmann-Guerrero, D.; Lutter, J.; Hapfelmeier, A.; Magnussen, H.; Trudzinski, F.C.; Welte, T.; Vogelmeier, C.F.; Kahnert, K.
Prediction of lung emphysema in COPD by spirometry and clinical symptoms: Results from COSYCONET.
Respir. Res. 22:242 (2021)
Background: Lung emphysema is an important phenotype of chronic obstructive pulmonary disease (COPD), and CT scanning is strongly recommended to establish the diagnosis. This study aimed to identify criteria by which physicians with limited technical resources can improve the diagnosis of emphysema. Methods: We studied 436 COPD patients with prospective CT scans from the COSYCONET cohort. All items of the COPD Assessment Test (CAT) and the St George's Respiratory Questionnaire (SGRQ), the modified Medical Research Council (mMRC) scale, as well as data from spirometry and CO diffusing capacity, were used to construct binary decision trees. The importance of parameters was checked by the Random Forest and AdaBoost machine learning algorithms. Results: When relying on questionnaires only, items CAT 1 & 7 and SGRQ 8 & 12 sub-item 3 were most important for the emphysema- versus airway-dominated phenotype, and among the spirometric measures FEV1/FVC. The combination of CAT item 1 (≤ 2) with mMRC (> 1) and FEV1/FVC, could raise the odds for emphysema by factor 7.7. About 50% of patients showed combinations of values that did not markedly alter the likelihood for the phenotypes, and these could be easily identified in the trees. Inclusion of CO diffusing capacity revealed the transfer coefficient as dominant measure. The results of machine learning were consistent with those of the single trees. Conclusions: Selected items (cough, sleep, breathlessness, chest condition, slow walking) from comprehensive COPD questionnaires in combination with FEV1/FVC could raise or lower the likelihood for lung emphysema in patients with COPD.

The simple, parsimonious approach proposed by us might help if diagnostic resources regarding respiratory diseases are limited. Trial registration ClinicalTrials.gov, Identifier: NCT01245933, registered 18 November 2010, https://clinicaltrials.gov/ct2/show/record/NCT01245933.
Respiratory Research

Grau, A.J.; Dienlin, S.; Bartig, D.; Maier, W.; Buggle, F.; Becher, H.
Urban villages' redevelopment in cities of migration through the lens of cultural identity: A comparative study of Singapore and Shenzhen.
Trop. Geography 41, 397-402 (2021)
With a strong emphasis on historical heritage and culture-making, culture-led redevelopment has become an important policy in many megacities to revitalize declining areas, such as urban villages. However, local governments have different understandings of cultural development and historic preservation and often take them at face value while ignoring the internal mechanisms. For cities of migration, cultural identity has richer connotations. The time-space nexus between the origins and destinations of migrants is highly significant for fostering a diverse and more inclusive urban culture. Taking three urban villages in Singapore and Shenzhen as empirical cases and using the theoretical perspective of cultural identity, this paper explores the culture-making process in the redevelopment of urban villages. We argue that the essence of cultural identity lies in social relations, not merely in visual symbols and images, and understanding cultural identity requires comprehending the relations between the global and the local, as well as between the past and the present embedded in places. The paper starts with an interpretation of the culture-led macro policy, followed by an analysis of urban redevelopment's internal political and economic driving forces. Based on data from participant observation and semi-structured interviews in both cities, a qualitative analysis on the modality, mechanism, and influences of identity-making in urban village redevelopment was conducted. Research findings include differences in the dominant stakeholders' attitudes toward cultural identity, especially migrants' identity, in the redevelopment modalities in the two aforementioned cities. These differences have led to different outcomes. The case of Singapore's Geylang Serai Village centered on the living needs and activities of Malay migrants, who were the main residents there, to conduct the regeneration. Further, the Housing and Development Board (HDB) issued a policy to ensure residents' housing rights. Therefore, the program maintained the continuity of the existing community by protecting the spontaneously formed identity while developing the showcase economy based on simultaneous market activities. Regarding Shenzhen, developers of Nantou Ancient City and Gankeng Hakka Town focused on specific historical periods and designated the architectural style as the local characteristic in order to develop the tourism economy. However, the top-down imposed identity had little to do with the migrants' community, which led to their exclusion and broke down their established social networks, indicating that the mere focus on beautifying the physical environment will lead to gentrification catering to middle-class aesthetics. The study findings point to the conclusion that the designation of the cultural identity of a place is, effectively, the use of cultural capital. The voice of identity in cultural discourses represents the social right of a community to urban spaces. Therefore, culture-led urban village redevelopment should focus more on local communities' social relations and actual needs in order to promote a more just, inclusive, and sustainable urban redevelopment.
Tropical Geography

Kahnert, K.; Lutter, J.; Welte, T.; Alter, P.; Behr, J.; Herth, F.; Kauczor, H.U.; Söhler, S.; Pfeifer, M.; Watz, H.; Vogelmeier, C.F.; Bals, R.; Jörres, R.A.; Trudzinski, F.C.
Impact of the COVID-19 pandemic on the behaviour and health status of patients with COPD: Results from the German COPD cohort COSYCONET.
ERJ Open Res. 7:00242-2021 (2021)
Background: Infection control measures for coronavirus disease 2019 (COVID-19) might have affected management and clinical state of patients with COPD. We analysed to which extent this common notion is fact-based. Methods: Patients of the COSYCONET cohort were contacted with three recurring surveys (COVID1, 2 and 3 at 0, 3 and 6 months, respectively). The questionnaires comprised behaviour, clinical and functional state, and medical treatment. The responses to the questionnaires were compared amongst themselves and with pre-COVID information from the last visit of COSYCONET. Results: Overall, 594 patients were contacted and 375 patients (58% males, forced expiratory volume in 1 s (FEV1) 61±22% predicted) provided valid data in COVID1 and COVID2. Five patients reported infections with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Most patients - except for patients with higher education - reported compliance with recommended protective measures, whereby compliance to hygiene, contact and access to physicians slightly improved between COVID1 and COVID2. Also, patients obtained more information from physicians than from public media. In the majority of cases, the personal physician could not be substituted by remote consultation. Over time, symptoms slightly increased and self-assessed physical capacity decreased. Results of COVID3 were similar. Women and patients with more exacerbations and dyspnoea avoided medical consultations, whereas Global Initiative for Chronic Obstructive Lung Disease (GOLD) D patients were more amenable to tele-consultation. Conclusion: In well-characterised COPD patients, we observed on average slight deteriorations of clinical state during the period of COVID-19 restrictions, with high and partially increasing adherence to protective measures. The data suggest that in particular, women and GOLD D patients should be actively contacted by physicians to identify deteriorations.
ERJ Open Research

Koletzko, L.; Klucker, E.; Le Thi, T.G.; Breiteneicher, S.; Rubio-Acero, R.; Neuhaus, L.; Stark, R.G.; Standl, M.; Wieser, A.; Török, H.; Koletzko, S.; Schwerd, T.
Following pediatric and adult ibd patients through the COVID-19 pandemic: Changes in psychosocial burden and perception of infection risk and harm over time.
J. Clin. Med. 10:4124 (2021)
Background: COVID-19-associated restrictions impact societies. We investigated the impact in a large cohort of inflammatory bowel disease (IBD) patients. Methods: Pediatric (pIBD) and adult patients and pIBD parents completed validated questionnaires for self-perceived stress (Perceived Stress Questionnaire, PSQ) and quality of life from July to October 2020 (1st survey) and March to April 2021 (2nd survey). Analyses

were stratified by age groups (6–20, >20–40, >40–60, >60 years). Perceived risk of infection and harm from COVID-19 were rated on a 1–7 scale. An index for severe outcome (SIRSCO) was calculated. Multivariable logistic regression analysis was performed. Results: Of 820 invited patients, 504 (62%, 6–85 years) patients and 86 pIBD parents completed the 1st, thereof 403 (80.4%) the 2nd survey. COVID-19 restrictions resulted in cancelled doctoral appointments (26.7%), decreased physical activity, increased food intake, unintended weight gain and sleep disturbance. PSQ increased with disease activity. Elderly males rated lower compared to females or younger adults. PSQ in pIBD mothers were comparable to moderate/severe IBD adults. Infection risk and harm were perceived high in 36% and 75.4%. Multivariable logistic models revealed associations of higher perceived risk with >3 household members, job conditions and female gender, and of perceived harm with higher SIRSCO, unintended weight change, but not with gender or age. Cancelled clinic-visits were associated with both. SARS-CoV-2 antibodies prior 2nd infection wave were positive in 2/472 (0.4%). Conclusions: IBD patients report a high degree of stress and self-perceived risk of complications from COVID-19 with major differences related to gender and age. Low seroprevalence may indicate altered immune response.
Journal of Clinical Medicine

Fritsche, A.#; Wagner, R.#; Heni, M.; Kantartzis, K.; Machann, J.; Schick, F.; Lehmann, R.; Peter, A.; Dannecker, C.; Fritsche, L.; Valenta, V.; Nawroth, P.P.; Kopf, S.; Pfeiffer, A.F.; Kabisch, S.; Dambeck, U.; Stumvoll, M.; Blüher, M.; Birkenfeld, A.L.; Schwarz, P.; Hauner, H.; Clavel, J.; Seißler, J.; Lechner, A.; Müssig, K.; Weber, K.; Laxy, M.; Bornstein, S.; Schürmann, A.; Roden, M.; Hrabě de Angelis, M.; Stefan, N.; Häring, H.-U.
Different effects of lifestyle intervention in high- and low-risk prediabetes.
Diabetes 70, 2785-2795:2785-2795 (2021)
Lifestyle intervention (LI) can prevent type 2 diabetes, but response to LI varies depending on risk subphenotypes. We tested if prediabetic individuals with low risk benefit from conventional LI and individuals with high risk benefit from an intensification of LI in a multi-center randomized controlled intervention over 12 months with 2 years follow up. 1105 prediabetic individuals based on ADA glucose criteria were stratified into a high- and low-risk phenotype, based on previously described thresholds of insulin secretion, insulin sensitivity and liver fat content. Low-risk individuals were randomly assigned to conventional LI according to the DPP protocol or control (1:1), high-risk individuals to conventional or intensified LI with doubling of required exercise (1:1). A total of 908 (82%) participants completed the study. In high-risk individuals, the difference between conventional and intensified LI in post-challenge glucose change was -0.29 mmol/l [CI:-0.54;-0.04], p=0.025. Liver fat (-1.34 percentage points [CI:-2.17;-0.50], p=0.002) and cardiovascular risk (-1.82[CI:-3.13-0.50],p=0.007) underwent larger reductions with intensified than with conventional LI. During a follow up of 3 years, intensified compared to conventional LI had a higher probability to normalize glucose tolerance (p=0.008). In conclusion, it is possible in high-risk individuals with prediabetes to improve glycemic and cardiometabolic outcomes by intensification of LI. Individualized, risk-phenotype-based LI may be beneficial for the prevention of diabetes.
Diabetes

Huber, M.B.; Schneider, N.; Kirsch, F.; Schwarzkopf, L.; Schramm, A.; Leidl, R.
Long-term weight gain in obese COPD patients participating in a disease management program: A risk factor for reduced health-related quality of life.
Respir. Res. 22:226 (2021)
Background: Little is known about how long-term weight gain affects the health perception of COPD patients. Objectives: The aim is to evaluate the long-term association of BMI change and health-related quality of life (HRQoL) in obese COPD patients. Methods: Claims and survey data from a COPD disease management program were used to match two groups of COPD patients with BMI ≥ 30 who have differing weight trajectories over a 5-year timespan via propensity score and genetic matching. EQ-5D-5L, including visual analog scale (VAS) and COPD Assessment Test (CAT), were used as outcomes of interest. Sociodemographic and disease-based variables were matched. Results: Out of 1202 obese COPD patients, 126 with a weight increase of four or more BMI points were matched separately with 252 (propensity score matching) and 197 (genetic matching) control subjects who had relatively stable BMI. For the EQ-5D-5L, patients with BMI increase reported significantly worse health perception for VAS and all descriptive dimensions except pain/discomfort. For the CAT, especially the perception of ability to complete daily activities and overall energy results were significantly worse. VAS differences reach the range of minimal important differences. Stopping smoking and already being in obesity class II were the most influential risk factors for BMI increase. Conclusion: Obese COPD patients who gain four or more BMI points over 5 years report significantly lower results in different dimensions of generic and disease-specific HRQoL than their peers with stable BMI. To improve real-world outcomes, tracking and preventing specific BMI trajectories could constitute a clinically relevant aspect of managing COPD patients.
Respiratory Research

Maqhuzu, P.N.; Kreuter, M.; Bahmer, T.; Kahn, N.; Claussen, M.; Holle, R.; Schwarzkopf, L.
Cost drivers in the pharmacological treatment of interstitial lung disease.
Respir. Res. 22:218 (2021)
INTRODUCTION: Treatments of interstitial lung diseases (ILDs) mainly focus on disease stabilization and relief of symptoms by managing inflammation or suppressing fibrosis by (in part costly) drugs. To highlight economic burden of drug treatment in different ILD-subtypes we assessed cost trends and therewith-associated drivers. METHODS: Using data from the German, observational HILDA study we estimated adjusted mean medication costs over 36-month intervals using one- and two-part Generalized Estimating Equation (GEE) regression models with a gamma distribution and log link. Next, we determined factors associated with costs. RESULTS: In Idiopathic pulmonary fibrosis (IPF) mean per capita medication costs increased from €1442 before to €11,000€ at the end of study. In non-IPF subtypes, the increase took place at much lower level. Mean per capita ILD-specific medication costs at the end of the study ranged between €487 (other ILD) and €9142 (IPF). At baseline, higher FVC %predicted values were associated with lower medication costs in IPF (-9%) and sarcoidosis (-1%). During follow up higher comorbidity burden escalated costs in

progressive fibrosing ILD (PF-ILD) (+52%), sarcoidosis (+60%) and other ILDs (+24%). The effect of disease duration was not uniform, with cost savings in PF-ILD (-8%) and sarcoidosis (-6%), but increased spending in IPF (+11%). CONCLUSION: Pharmacological management of ILD, in particular of IPF imposes a substantial economic burden on the healthcare system. Strategies to reduce comorbidity burden and early treatment may reduce the impact of ILDs on the healthcare system.
Respiratory Research

Steinbeisser, K.; Schwarzkopf, L.; Grill, E.; Schwettmann, L.; Peters, A.; Seidl, H.
Gender-linked determinants for utilization of long-term care in community-dwelling adults 65+ in Germany: Results from the population-based KORA-Age study.
Exp. Gerontol. 153:111500 (2021)
BACKGROUND: The number of people using long-term care (LTC) is increasing steadily, hence, demand for adequate services is rising. The purpose of this exploratory study was to identify relevant gender-linked determinants for utilization of LTC in community-dwelling older adults. METHODS: We examined 4077 females (52.7%) and males ≥ 65 years old (range: 65-97 years) between 2011/12 (t1) and 2016 (t2). Data originated from the population-based Cooperative Health Research in the Region of Augsburg (KORA)-Age study in southern Germany. A descriptive analysis assessed the amount of LTC used. Cross-sectional generalized estimating equation logistic models identified determinants for utilization of (in)formal LTC. Determinants for transition to LTC between t1 and t2 were examined using a longitudinal logistic regression model. Potential determinants were chosen according to Andersen's Behavioral Model of Health Services Use. RESULTS: At t2, 820 (20.1%) were LTC users with 527 (64.3%) being female. The average amount of informal LTC was higher in males, whereas the amount of formal LTC was higher in females. In both genders, higher age, multimorbidity, and disability were associated with utilization of and transition to LTC. Living alone was significantly associated with utilization of LTC in both genders, but its effect was two times stronger in males. Thus, it is considered the essential gender-linked determinant. CONCLUSIONS: Gender-linked determinants must be considered when establishing demand-oriented policies. Future health programs should specifically target older individuals, especially males, living alone to improve their capabilities in activities of daily living to allow them to remain living longer and independently within community settings.
Experimental Gerontology

Trudzinski, F.C.; Kellerer, C.; Jörres, R.A.; Alter, P.; Lutter, J.; Trinkmann, F.; Herth, F.J.F.; Frankenberger, M.; Watz, H.; Vogelmeier, C.F.; Kauczor, H.U.; Welte, T.; Behr, J.; Bals, R.; Kahnert, K.
Gender-specific differences in COPD symptoms and their impact for the diagnosis of cardiac comorbidities.
Clin. Res. Cardiol., DOI: 10.1007/s00392-021-01915-x (2021)
Background: In chronic obstructive pulmonary disease (COPD), gender-specific differences in the prevalence of symptoms and comorbidity are known. Research question: We studied whether the relationship between these characteristics depended on gender and carried diagnostic information regarding cardiac comorbidities. Study design and methods: The analysis was based on 2046 patients (GOLD grades 1–4, 795 women; 38.8%) from the COSYCONET COPD cohort. Assessments comprised the determination of clinical history, comorbidities, lung function, COPD Assessment Test (CAT) and modified Medical Research Council dyspnea scale (mMRC). Using multivariate regression analyses, gender-specific differences in the relationship between symptoms, single CAT items, comorbidities and functional alterations were determined. To reveal the relationship to cardiac disease (myocardial infarction, or heart failure, or coronary artery disease) logistic regression analysis was performed separately in men and women. Results: Most functional parameters and comorbidities, as well as CAT items 1 (cough), 2 (phlegm) and 5 (activities), differed significantly ($p < 0.05$) between men and women. Beyond this, the relationship between functional parameters and comorbidities versus symptoms showed gender-specific differences, especially for single CAT items. In men, item 8 (energy), mMRC, smoking status, BMI, age and spirometric lung function was related to cardiac disease, while in women primarily age was predictive. Interpretation: Gender-specific differences in COPD not only comprised differences in symptoms, comorbidities and functional alterations, but also differences in their mutual relationships. This was reflected in different determinants linked to cardiac disease, thereby indicating that simple diagnostic information might be used differently in men and women. Clinical trial registration: The cohort study is registered on ClinicalTrials.gov with identifier NCT01245933 and on GermanCTR.de with identifier DRKS00000284, date of registration November 23, 2010. Further information can be obtained on the website http://www.asconet.net.
Clinical Research in Cardiology

Shao, H.; Zhang, P.; Benoit, S.R.; Imperatore, G.; Cheng, Y.J.; Gregg, E.W.; Yang, S.
Trends in total and out-of-pocket payments for insulin among privately insured U.S. adults with diabetes from 2005 to 2018.
Diabetes Care 44, e1-e3 (2021)
Diabetes Care

Auzanneau, M.; Rosenbauer, J.; Maier, W.; von Sengbusch, S.; Hamann, J.; Kapellen, T.; Freckmann, G.; Schmidt, S.; Lilienthal, E.; Holl, R.W.
Heterogeneity of access to diabetes technology depending on area deprivation and demographics between 2016 and 2019 in Germany.
J. Diabetes Sci. Technol., DOI: 10.1177/19322968211028608 (2021)
BACKGROUND: Despite increasing use of technology in type 1 diabetes, persistent ethnic and socio-economic disparities have been reported. We analyzed how the use of insulin pump therapy and continuous glucose monitoring (CGM) evolved over the years in Germany depending on demographics and area deprivation. METHOD: We investigated the use of insulin pump and CGM between 2016 and 2019 in 37,798 patients with type 1 diabetes aged < 26 years from the German Prospective Follow-up Registry (DPV). Associations with federal state, area-deprivation quintile (German Index of Multiple Deprivation 2010 on district level), gender, and migration background were investigated over time using multiple logistic regression. RESULTS: Between 2016 and 2019, the regional distribution of insulin pump use did not change substantially and the association with area deprivation remained non-linear and

statistically non-significant. The effect of area deprivation on CGM use decreased continuously and disappeared in 2019 (OR [95%-CI] Q1 vs Q5: 1.85 [1.63-2.10] in 2016; 0.97 [0.88-1.08] in 2019). The effect of migration background on the use of either technology decreased over the years but remained significant in 2019. Girls had constantly higher odds of using an insulin pump than boys (OR: 1.25 [1.18-1.31] in 2019), whereas no gender difference was identified for CGM use. CONCLUSIONS: Although disparities decreased in Germany, access to diabetes technology still depends on migration background in 2019, and gender differences in pump use persist. As technological advances are made, further research is needed to understand the reasons for these persistent disparities.
Journal of Diabetes Science and Technology

Grau, A.J.; Dienlin, S.; Bartig, D.; Maier, W.; Buggle, F.; Becher, H.
Regional deprivation, stroke incidence, and stroke care.
Dtsch. Arztebl. Int. 118, 397-402 (2021)
BACKGROUND: Regional deprivation can increase the risk of illness and adversely affect care outcomes. In this study, we investigated for the German state of Rhineland-Palatinate whether spatial-structural disadvantages are associated with an increased frequency of ischemic stroke and with less favorable care outcomes. METHODS: We compared billing data from DRG statistics (2008-2017) and quality assurance data (2017) for acute ischemic stroke with the German Index of Multiple Deprivation 2010 (GIMD 2010) for the 36 districts (Landkreise) and independent cities (i.e., cities not belonging to a district) in Rhineland-Palatinate using correlation analyses, a Poisson regression analysis, and logistic regression analyses. RESULTS: The age-standardized stroke rates (ASR) ranged from 122 to 209 per 100 000 inhabitants, while the GIMD 2010 ranged from 4.6 to 47.5; the two values were positively correlated (Spearman's $\rho = 0.47$; 95% confidence interval [0.16; 0.85]). In 2017, mechanical thrombectomies were performed more commonly (5.7%) in the first GIMD 2010 quartile of the regional areas (i.e., in the least deprived areas) than in the remaining quartiles (4.2-4.6%). The intravenous thrombolysis rates showed no differences from one GIMD 2010 quartile to another. Severe neurological deficits (National Institutes of Health Stroke Scale ≥ 5) on admission to the hospital were slightly more common in the fourth quartile (i.e., in the most deprived areas), while antiplatelet drugs and statins were somewhat less commonly ordered on discharge in those areas than in the first quartile. CONCLUSION: These findings document a relationship between regional deprivation and the occurrence of acute ischemic stroke. Poorer GIMD 2010 scores were associated with worse care outcomes in a number of variables, but the absolute differences were small.
Deutsches Ärzteblatt international

Becker, J.; Steckling-Muschack, N.; Mittermeier, I.; Bergmann, K.C.; Böse-O'Reilly, S.; Buters, J.T.M.; Damialis, A.; Heigl, K.; Heinrich, J.; Kabesch, M.; Mertes, H.; Nowak, D.; Schutzmeier, P.; Walser-Reichenbach, S.M.; Weinberger, A.; Korbely, C.; Herr, C.; Heinze, S.; Kutzora, S.
Threshold values of grass pollen (Poaceae) concentrations and increase in emergency department visits, hospital admissions, drug consumption and allergic symptoms in patients with allergic rhinitis: A systematic review.
Aerobiologia, DOI: 10.1007/s10453-021-09720-9 (2021)
Airborne grass (Poaceae) pollen measurements are used in public warning systems to inform people about the risk of allergic symptoms. However, there is no consensus about which exact thresholds of pollen concentrations provoke the allergic symptoms. The aim of this study was to review the relevant scientific information on the relationship between grass pollen concentrations and the occurrence of emergency department (ED) visits, hospital admissions (HA), drug consumption and allergic symptoms. Literature search was conducted by experts' consultation and snowball strategy. Studies meeting the criteria for inclusion were assessed regarding their risk of bias (RoB). A high RoB resulted in exclusion of the study from data synthesis. Extensive data were extracted and qualitatively compared. The review is registered in PROSPERO. 32 Studies were eligible while 18 showed a low RoB and were qualitatively synthesised. Emergency department visits and hospital admissions were mostly investigated. Threshold values of 10 grains/m3 and 12 grains/m3 were reported for ED visits and HA. Evidence exists that an increase of 10 grains/m3 of air leads to a significant increase in adverse health outcomes. Especially at a three-day lag, adverse health effects were shown. Variations in exposure and outcome measurement make the definition of pollen thresholds difficult. As a consequence, no defined pollen threshold values could be identified. Studies with uniform exposure measures and statistical methods are necessary to gain a better understanding of the impact of grass pollen on human health. Determining personal thresholds could be beneficial for affected people.
Aerobiologia

Loidl, V.; Decke, S.; Hamacher, K.; Lang, M.; Laub, O.; Marijic, P.; Murawski, M.; Schwettmann, L.; Grill, E.
Mixed-methods evaluation of a structured primary care programme for children and adolescents with mental health problems (PrimA-QuO): A study protocol.
BMJ Open 11:e052747 (2021)
INTRODUCTION: More than 17% of German children and adolescents have clinically relevant mental health problems (MHP). Typically, general paediatricians are often the first contact for children with MHP, and referrals to specialised care tend to be the standard approach. A statutory health insurance fund developed a programme for children with MHP (Health Coaching (HC)) aiming to offer targeted but low-threshold services. However, little is known about whether HC has the potential for optimising patient care. The aim of the PrimA-QuO study is to examine the effectiveness and the acceptance, barriers and facilitators of all stakeholders of this structured primary care programme for children affected by the most frequently encountered MHP in paediatric practice. METHODS AND ANALYSIS: In this mixed-methods approach, children (n=800; aged 0-17 years) with MHP meeting all inclusion criteria will be identified in the health insurance database according to International Classification of Diseases, 10th Revision diagnoses between 2018 and 2019. The qualitative component uses a series of semistructured interviews with programme developers, paediatricians trained in HC, adolescents with MHP treated according to the programme guidelines and their parents. In addition, a prospective, pragmatic, parallel-group cohort study will be conducted using an online questionnaire to examine the effects of HC on health-related quality of life of affected children and their families as well as on change in MHP. Children treated according to the HC guidelines form the intervention group,

whereas all others serve as controls. Primary data from the cohort study are linked to children's health insurance claims data to calculate the costs of care as proxies for healthcare utilisation. The hypothesis is that HC is an effective and efficient primary care programme with the potential to improve patients' and their families' health outcomes. ETHICS AND DISSEMINATION: The study was approved by the Ethical Committee of Ludwig-Maximilians-Universität München. Grant number 01VSF16032 (funded by the German Innovationsfonds).
BMJ Open

Kurz, C.F.
Augmented inverse probability weighting and the double robustness property.
Med. Decis. Making, DOI: 10.1177/0272989X211027181 (2021)
This article discusses the augmented inverse propensity weighted (AIPW) estimator as an estimator for average treatment effects. The AIPW combines both the properties of the regression-based estimator and the inverse probability weighted (IPW) estimator and is therefore a "doubly robust" method in that it requires only either the propensity or outcome model to be correctly specified but not both. Even though this estimator has been known for years, it is rarely used in practice. After explaining the estimator and proving the double robustness property, I conduct a simulation study to compare the AIPW efficiency with IPW and regression under different scenarios of misspecification. In 2 real-world examples, I provide a step-by-step guide on implementing the AIPW estimator in practice. I show that it is an easily usable method that extends the IPW to reduce variability and improve estimation accuracy.[Box: see text].
Medical Decision Making

Kellerer, C.; Kahnert, K.; Trudzinski, F.C.; Lutter, J.; Berschneider, K.; Speicher, T.; Watz, H.; Bals, R.; Welte, T.; Vogelmeier, C.F.; Jörres, R.A.; Alter, P.
COPD maintenance medication is linked to left atrial size: Results from the COSYCONET cohort.
Respir. Med. 185:106461 (2021)
BACKGROUND: Lung function impairment in COPD is known to be related to reductions of left heart size, while short-term interventional trials with bronchodilators showed positive effects on cardiac parameters. We investigated whether COPD maintenance therapy has analogous long-term effects. METHODS: Pooled data of GOLD grade 1-4 patients from visits 1 and 3 (1.5 y apart) of the COSYCONET cohort were used. Medication was categorized as use of ICS, LABA + ICS, LABA + LAMA and triple therapy (LABA + LAMA + ICS), contrasting "always" versus "never". Echocardiographic parameters comprised left ventricular end-diastolic and -systolic diameter (LVEDD, LVESD), ejection fraction (LVEF) and left atrial diameter (LA). Associations were identified by multiple regression analysis, as well as propensity score analysis. RESULTS: Overall, 846 patients (mean age 64.5 y; 41% female) were included, 53% using ICS at both visits, 51% LABA + ICS, 56% LABA + LAMA, 40% LABA + LAMA + ICS (triple) therapy. Conversely, 30%, 32%, 28% and 42% had no ICS, LABA + ICS, LABA + LAMA or triple therapy, respectively, at both visits. Among echocardiographic measures, only LA showed statistically significant associations (increases) with medication, whereby significant effects were linked to ICS, LABA + ICS and LABA + LAMA ($p < 0.05$ each, "always" versus "never") and propensity score analyses underlined the role of LABA + LAMA. CONCLUSIONS: In this observational study, COPD maintenance therapy, especially LABA + LAMA, was linked to left atrial size, consistent with the results of short-term interventional trials. These findings suggest that maintenance medication for COPD does not only improve lung function and patient reported outcomes but may also have an impact on the cardiovascular system. TRIAL REGISTRATION: NCT01245933.
Respiratory Medicine

Olm, M.; Donnachie, E.; Tauscher, M.; Gerlach, R.; Linde, K.; Maier, W.; Schwettmann, L.; Schneider, A.
Ambulatory specialist costs and morbidity of coordinated and uncoordinated patients before and after abolition of copayment: A cohort analysis.
PLoS ONE 16:e0253919 (2021)
To strengthen the coordinating function of general practitioners (GPs) in the German healthcare system, a copayment of €10 was introduced in 2004. Due to a perceived lack of efficacy and a high administrative burden, it was abolished in 2012. The present cohort study investigates characteristics and differences of GP-coordinated and uncoordinated patients in Bavaria, Germany, concerning morbidity and ambulatory specialist costs and whether these differences have changed after the abolition of the copayment. We performed a retrospective routine data analysis, using claims data of the Bavarian Association of the Statutory Health Insurance Physicians during the period 2011–2012 (with copayment) and 2013–2016 (without copayment), covering 24 quarters. Coordinated care was defined as specialist contact only with referral. Multinomial regression modelling, including inverse probability of treatment weighting, was used for the cohort analysis of 500 000 randomly selected patients. Longitudinal regression models were calculated for cost estimation. Coordination of care decreased substantially after the abolition of the copayment, accompanied by increasing proportions of patients with chronic and mental diseases in the uncoordinated group, and a corresponding decrease in the coordinated group. In the presence of the copayment, uncoordinated patients had €21.78 higher specialist costs than coordinated patients, increasing to €24.94 after its abolition. The results indicate that patients incur higher healthcare costs for specialist ambulatory care when their care is uncoordinated. This effect slightly increased after abolition of the copayment. Beyond that, the abolition of the copayment led to a substantial reduction in primary care coordination, particularly affecting vulnerable patients. Therefore, coordination of care in the ambulatory setting should be strengthened.
PLoS ONE

Steckling-Muschack, N.; Mertes, H.; Mittermeier, I.; Schutzmeier, P.; Becker, J.; Bergmann, K.C.; Böse-O'Reilly, S.; Buters, J.T.M.; Damialis, A.; Heinrich, J.; Kabesch, M.; Nowak, D.; Walser-Reichenbach, S.M.; Weinberger, A.; Zamfir, M.; Herr, C.; Kutzora, S.; Heinze, S.
A systematic review of threshold values of pollen concentrations for symptoms of allergy.
Aerobiologia 37, 395–424 (2021)
Pollen threshold values used in public warning systems are intended to inform people of the risk of developing allergy symptoms. However, there is no consensus about which pollen concentrations provoke allergy symptoms. The aim of this systematic review was the evaluation of studies investigating the

relationship between pollen concentrations (alder, ash, birch, hazel, mugwort and ragweed) and the number of cases in which participants visited a doctor, drug consumption and allergy symptoms. This systematic literature review is registered in PROSPERO (CRD42019112369). A PubMed search was applied and enriched by consultation with experts and a snowball strategy. The included studies were checked for risk of bias (RoB), and extensive data were extracted and compared. Of 511 studies, 22 were eligible according to the previously established inclusion criteria, and 17 from these showed a low RoB. The strongest evidence was reported for ash (Fraxinus) pollen, where an increase of number of doctor's visits at an interquartile range (IQR) of 18–28 grains/m was detected by three studies. Five studies about birch (Betula) pollen showed a threshold value of 45 grains/m for increased drug consumption. The evidence of a threshold value was limited for alder (Alnus), hazel (Corylus), mugwort (Artemisia) and ragweed (Ambrosia) pollen. The inconsistent results concerning all types of pollen, except ash pollen, can be the result of multiple factors, e.g., age, gender, allergen content of pollen and individual sensitivity. These influencing factors should be investigated more closely in future research.
Aerobiologia

Ptushkina, V.; Seidel-Jacobs, E.; Maier, W.; Schipf, S.; Voelzke, H.; Markus, M.R.P.; Nauck, M.; Meisinger, C.; Peters, A.; Herder, C.; Schwettmann, L.; Doerr, M.; Felix, S.B.; Roden, M.; Rathmann, W.
Educational level, but not income or area deprivation, is related to macrovascular disease: Results from two population-based cohorts in Germany.
Int. J. Public Health 66:633909 (2021)
Objectives: An inverse relationship between education and cardiovascular risk has been described, however, the combined association of education, income, and neighborhood socioeconomic status with macrovascular disease is less clear. The aim of this study was to evaluate the association of educational level, equivalent household income and area deprivation with macrovascular disease in Germany.Methods: Cross-sectional data from two representative German population-based studies, SHIP-TREND (n = 3,731) and KORA-F4 (n = 2,870), were analyzed. Multivariable logistic regression models were applied to estimate odds ratios and 95% confidence intervals for the association between socioeconomic determinants and macrovascular disease (defined as self-reported myocardial infarction or stroke).Results: The study showed a higher odds of prevalent macrovascular disease in men with low and middle educational level compared to men with high education. Area deprivation and equivalent income were not related to myocardial infarction or stroke in any of the models.Conclusion: Educational level, but not income or area deprivation, is significantly related to the macrovascular disease in men. Effective prevention of macrovascular disease should therefore start with investing in individual education.
International Journal of Public Health

Huebner, M.; Börnigen, D.; Deckert, A.; Holle, R.; Meisinger, C.; Müller-Nurasyid, M.; Peters, A.; Rathmann, W.; Becher, H.
Genetic variation and cardiovascular risk factors: A cohort study on migrants from the former soviet union and a native german population.
Int. J. Environ. Res. Public Health 18:6215 (2021)
Resettlers are a large migrant group of more than 2 million people in Germany who migrated mainly from the former Soviet Union to Germany after 1989. We sought to compare the distribution of the major risk factors for cardiovascular disease (CVD) and to investigate the overall genetic differences in a study population which consisted of resettlers and native (autochthone) Germans. This was a joint analysis of two cohort studies which were performed in the region of Augsburg, Bavaria, Germany, with 3363 native Germans and 363 resettlers. Data from questionnaires and physical examinations were used to compare the risk factors for cardiovascular diseases between the resettlers and native Germans. A population-based genome-wide association analysis was performed in order to identify the genetic differences between the two groups. The distribution of the major risk factors for CVD differed between the two groups. The resettlers lead a less active lifestyle. While female resettlers smoked less than their German counterparts, the men showed similar smoking behavior. SNPs from three genes (BTNL2, DGKB, TGFBR3) indicated a difference in the two populations. In other studies, these genes have been shown to be associated with CVD, rheumatoid arthritis and osteoporosis, respectively.
International Journal of Environmental Research and Public Health

Böckmann, D.; Szentes, B.L.; Schultz, K.; Nowak, D.; Schuler, M.; Schwarzkopf, L.
Cost-effectiveness of pulmonary rehabilitation in patients with bronchial asthma: An analysis of the EPRA randomized controlled trial.
Value Health 24, 1254-1262 (2021)
Objectives: At 3 months after the intervention, this study evaluates the cost-effectiveness of a 3-week inpatient pulmonary rehabilitation (PR) in patients with asthma compared with usual care alongside the single-center randomized controlled trial—Effectiveness of Pulmonary Rehabilitation in Patients With Asthma. Methods: Adopting a societal perspective, direct medical costs and productivity loss were assessed using the Questionnaire for Health-Related Resource Use-Lung, a modification of the FIM in an Elderly Population. The effect side was operationalized as minimal important differences (MIDs) of the Asthma Control Test (ACT) and the Asthma Quality of Life Questionnaire (AQLQ) and through quality-adjusted life-years (QALYs) gained. Adjusted mean differences in costs (gamma-distributed model) and each effect parameter (Gaussian-distributed model) were simultaneously calculated within 1000 bootstrap replications to determine incremental cost-effectiveness ratios (ICERs) and to subsequently delineate cost-effectiveness acceptability curves. Results: PR caused mean costs per capita of €3544. Three months after PR, we observed higher mean costs (Δ€3673; 95% confidence interval (CI) €2854-€4783) and improved mean effects (ACT Δ1.59 MIDs, 95% CI 1.37-1.81; AQLQ Δ1.76 MIDs, 95% CI 1.46-2.08; QALYs gained Δ0.01, 95% CI 0.01-0.02) in the intervention group. The ICER was €2278 (95% CI €1653-€3181) per ACT-MID, €1983 (95% CI €1430-€2830) per AQLQ-MID, and €312 401 (95% CI €209 206-€504 562) per QALY gained. Conclusions: Contrasting of PR expenditures with ICERs suggests that the intervention, which achieves clinically relevant changes in asthma-relevant parameters, has a high probability to be already cost-effective in the short term. However, in terms of QALYs, extended follow-up periods are likely required to comprehensively judge the added value of a one-time initial investment in PR.

Value in Health

Lutter, J.; Jörres, R.A.; Trudzinski, F.C.; Alter, P.; Kellerer, C.; Watz, H.; Welte, T.; Bals, R.; Kauffmann-Guerrero, D.; Behr, J.; Holle, R.; F Vogelmeier, C.; Kahnert, K.
Treatment of COPD Groups GOLD A and B with inhaled corticosteroids in the COSYCONET cohort - determinants and consequences.
Int. J. Chron. Obstruct. Pulmon. Dis. 16, 987-998 (2021)
Background: In COPD patients of GOLD groups A and B, a high degree of treatment with inhaled corticosteroids (ICS) has been reported, which is regarded as overtreatment according to GOLD recommendations. We investigated which factors predict ICS use and which relationship it has to clinical and functional outcomes, or healthcare costs. Methods: We used pooled data from visits 1 and 3 of the COSYCONET cohort (n=2741, n=2053, interval 1.5 years) including patients categorized as GOLD grades 1-4 and GOLD group A or B at both visits (n=1080). Comparisons were performed using ANOVA, and regression analyses using propensity matching and inverse probability weighting to adjust for differences between ICS groups. These were defined as having ICS at both visits (always) vs no ICS at both visits (never). Measures were divided into predictors of ICS treatment and outcomes. Results: Among 1080 patients, 608 patients were eligible for ICS groups (n=297 never, n=311 always). Prior to matching, patients with ICS showed significantly ($p<0.05$ each) impaired lung function, symptoms and exacerbation history. After matching, the outcomes generic quality of life and CO diffusing capacity were increased in ICS patients ($p<0.05$ each). Moreover, costs for respiratory medication, but not total health care costs, were significantly elevated in the ICS group by 780€ per year. Conclusion: ICS therapy in COPD GOLD A/B patients can have small positive and negative effects on clinical outcomes and health care costs, indicating that the clinical evaluation of ICS over-therapy in COPD requires a multi-dimensional approach.
International Journal of Chronic Obstructive Pulmonary Disease

Emmert-Fees, K.; Karl, F.; von Philipsborn, P.; Rehfuess, E.A.; Laxy, M.
Simulation modeling for the economic evaluation of population-based dietary policies: A systematic scoping review.
Adv. Nutr. 12, 1957-1995 (2021)
Simulation modeling can be useful to estimate the long-term health and economic impacts of population-based dietary policies. We conducted a systematic scoping review following the PRISMA-ScR (Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews) guideline to map and critically appraise economic evaluations of population-based dietary policies using simulation models. We searched Medline, Embase, and EconLit for studies published in English after 2005. Modeling studies were mapped based on model type, dietary policy, and nutritional target, and modeled risk factor-outcome pathways were analyzed. We included 56 studies comprising 136 model applications evaluating dietary policies in 21 countries. The policies most often assessed were reformulation (34/136), taxation (27/136), and labeling (20/136); the most common targets were salt/sodium (60/136), sugar-sweetened beverages (31/136), and fruit and vegetables (15/136). Model types included Markov-type (35/56), microsimulation (11/56), and comparative risk assessment (7/56) models. Overall, the key diet-related risk factors and health outcomes were modeled, but only 1 study included overall diet quality as a risk factor. Information about validation was only reported in 19 of 56 studies and few studies (14/56) analyzed the equity impacts of policies. Commonly included cost components were health sector (52/56) and public sector implementation costs (35/56), as opposed to private sector (18/56), lost productivity (11/56), and informal care costs (3/56). Most dietary policies (103/136) were evaluated as cost-saving independent of the applied costing perspective. An analysis of the main limitations reported by authors revealed that model validity, uncertainty of dietary effect estimates, and long-term intervention assumptions necessitate a careful interpretation of results. In conclusion, simulation modeling is widely applied in the economic evaluation of population-based dietary policies but rarely takes dietary complexity and the equity dimensions of policies into account. To increase relevance for policymakers and support diet-related disease prevention, economic effects beyond the health sector should be considered, and transparent conduct and reporting of model validation should be improved.
Advances in nutrition

Kurz, C.F.; König, A.
The causal impact of sugar taxes on soft drink sales: Evidence from France and Hungary.
Eur. J. Health Econ. 22, 905-915 (2021)
Sugar-sweetened beverages (SSBs) are associated with increased body weight and obesity, which induce a wide array of health impairments such as diabetes or cardiovascular disorders. Excise taxes have been introduced to counteract SSB consumption. We investigated the effect of sugar taxes on SSB sales in Hungary and France using a synthetic control approach. For France, we found a slight decrease in SSB sales after tax implementation while overall soft drink sales increased. For Hungary, there was only a short-term decrease in SSB sales which disappeared after 2 years, leading to an overall increase in SSB sales. However, both effects are characterized by great uncertainty.
The European journal of health economics

Schultz, K.; Wittmann, M.; Wagner, R.; Lehbert, N.; Schwarzkopf, L.; Szentes, B.L.; Nowak, D.; Faller, H.; Schuler, M.
In-patient pulmonary rehabilitation to improve asthma control.
Dtsch. Arztebl. Int. 118, 23-30 (2021)
BACKGROUND: Despite the availability of effective pharmaceutical treatment options, many patients with asthma do not manage to control their illness. This randomized trial with a waiting-list control group examined whether a 3-week course of inpatient pulmonary rehabilitation (PR) improves asthma control (primary endpoint) and other secondary endpoints (e.g., quality of life, cardinal symptoms, mental stress). The subsequent observational segment of the study investigated the long-term outcome after PR. METHODS: After approval of the rehabilitation´ by the insurance providers (T0), 412 adults with uncontrolled asthma (Asthma Control Test [ACT] score < 20 points) undergoing rehabilitation were assigned to either the intervention group (IG) or the waiting-list control group (CG). PR commenced 1 month (T1) after randomization in the IG and 5 months after randomization (T3) in the CG. Asthma control and the secondary endpoints were assessed 3 months after PR in the IG (T3) as an intention-to-treat analysis by means of analyses of covariance. Moreover, both groups were observed

for a period of 12 months after the end of PR. RESULTS: At T3 the mean ACT score was 15.76 points in the CG, 20.38 points in the IG. The adjusted mean difference of 4.71 points was clinically relevant (95% confidence interval [3.99; 5.43]; effect size, Cohen's d = 1.27). The secondary endpoints also showed clinically relevant effects in favor of the IG. A year after the end of rehabilitation the mean ACT score was 19.00 points, still clinically relevant at 3.54 points higher than when rehabilitation began. Secondary endpoints such as quality of life and cardinal symptoms (dyspnea, cough, expectoration, pain) and self-management showed moderate to large effects. CONCLUSION: The trial showed that a 3-week course of PR leads to clinically relevant improvement in asthma control and secondary endpoints. Patients who do not achieve control of their asthma despite outpatient treatment therefore benefit from rehabilitation.
Deutsches Ärzteblatt international

Finke, I.; Behrens, G.; Maier, W.; Schwettmann, L.; Pritzkuleit, R.; Holleczek, B.; Kajüter, H.; Gerken, M.; Mattutat, J.; Emrich, K.; Jansen, L.; Brenner, H.
Small-area analysis on socioeconomic inequalities in cancer survival for 25 cancer sites in Germany.
Int. J. Cancer 149, 561-572 (2021)
Socioeconomic inequalities in cancer survival have been reported in various countries but it is uncertain to what extent they persist in countries with relatively comprehensive health insurance coverage such as Germany. We investigated the association between area-based socioeconomic deprivation on municipality level and cancer survival for 25 cancer sites in Germany. We used data from seven population-based cancer registries (covering 32 million inhabitants). Patients diagnosed in 1998 to 2014 with one of 25 most common cancer sites were included. Area-based socioeconomic deprivation was assessed using the categorized German Index of Multiple Deprivation (GIMD) on municipality level. We estimated 3-month, 1-year, 5-year and 5-year conditional on 1-year age-standardized relative survival using period approach for 2012 to 2014. Trend analyses were conducted for periods between 2003-2005 and 2012-2014. Model-based period analysis was used to calculate relative excess risks (RER) adjusted for age and stage. In total, 2 333 547 cases were included. For all cancers combined, 5-year survival rates by GIMD quintile were 61.6% in Q1 (least deprived), 61.2% in Q2, 60.4% in Q3, 59.9% in Q4 and 59.0% in Q5 (most deprived). For most cancer sites, the most deprived quintile had lower 5-year survival compared to the least deprived quintile even after adjusting for stage (all cancer sites combined, RER 1.16, 95% confidence interval 1.14-1.19). For some cancer sites, this association was stronger during short-term follow-up. Trend analyses showed improved survival from earlier to recent periods but persisting deprivation differences. The underlying reasons for these persisting survival inequalities and strategies to overcome them should be further investigated.
International Journal of Cancer

Burns, J.; Movsisyan, A.; Stratil, J.M.; Biallas, R.L.; Coenen, M.; Emmert-Fees, K.; Geffert, K.; Hoffmann, S.; Horstick, O.; Laxy, M.; Klinger, C.; Kratzer, S.; Litwin, T.; Norris, S.; Pfadenhauer, L.M.; von Philipsborn, P.; Sell, K.; Stadelmaier, J.; Verboom, B.; Voss, S.; Wabnitz, K.; Rehfuess, E.
International travel-related control measures to contain the COVID-19 pandemic: A rapid review.
Cochrane Database Syst. Rev. 3:CD013717 (2021)
BACKGROUND: In late 2019, the first cases of coronavirus disease 2019 (COVID-19) were reported in Wuhan, China, followed by a worldwide spread. Numerous countries have implemented control measures related to international travel, including border closures, travel restrictions, screening at borders, and quarantine of travellers. OBJECTIVES: To assess the effectiveness of international travel-related control measures during the COVID-19 pandemic on infectious disease transmission and screening-related outcomes. SEARCH METHODS: We searched MEDLINE, Embase and COVID-19-specific databases, including the Cochrane COVID-19 Study Register and the WHO Global Database on COVID-19 Research to 13 November 2020. SELECTION CRITERIA: We considered experimental, quasi-experimental, observational and modelling studies assessing the effects of travel-related control measures affecting human travel across international borders during the COVID-19 pandemic. In the original review, we also considered evidence on severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS). In this version we decided to focus on COVID-19 evidence only. Primary outcome categories were (i) cases avoided, (ii) cases detected, and (iii) a shift in epidemic development. Secondary outcomes were other infectious disease transmission outcomes, healthcare utilisation, resource requirements and adverse effects if identified in studies assessing at least one primary outcome. DATA COLLECTION AND ANALYSIS: Two review authors independently screened titles and abstracts and subsequently full texts. For studies included in the analysis, one review author extracted data and appraised the study. At least one additional review author checked for correctness of data. To assess the risk of bias and quality of included studies, we used the Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2) tool for observational studies concerned with screening, and a bespoke tool for modelling studies. We synthesised findings narratively. One review author assessed the certainty of evidence with GRADE, and several review authors discussed these GRADE judgements. MAIN RESULTS: Overall, we included 62 unique studies in the analysis; 49 were modelling studies and 13 were observational studies. Studies covered a variety of settings and levels of community transmission. Most studies compared travel-related control measures against a counterfactual scenario in which the measure was not implemented. However, some modelling studies described additional comparator scenarios, such as different levels of stringency of the measures (including relaxation of restrictions), or a combination of measures. Concerns with the quality of modelling studies related to potentially inappropriate assumptions about the structure and input parameters, and an inadequate assessment of model uncertainty. Concerns with risk of bias in observational studies related to the selection of travellers and the reference test, and unclear reporting of certain methodological aspects. Below we outline the results for each intervention category by illustrating the findings from selected outcomes. Travel restrictions reducing or stopping cross-border travel (31 modelling studies) The studies assessed cases avoided and shift in epidemic development. We found very low-certainty evidence for a reduction in COVID-19 cases in the community (13 studies) and cases exported or imported (9 studies). Most studies reported positive effects, with effect sizes varying widely; only a few studies showed no effect. There was very low-certainty evidence that cross-border travel controls can slow the spread of COVID-19. Most studies predicted positive effects, however, results from

individual studies varied from a delay of less than one day to a delay of 85 days; very few studies predicted no effect of the measure. Screening at borders (13 modelling studies; 13 observational studies) Screening measures covered symptom/exposure-based screening or test-based screening (commonly specifying polymerase chain reaction (PCR) testing), or both, before departure or upon or within a few days of arrival. Studies assessed cases avoided, shift in epidemic development and cases detected. Studies generally predicted or observed some benefit from screening at borders, however these varied widely. For symptom/exposure-based screening, one modelling study reported that global implementation of screening measures would reduce the number of cases exported per day from another country by 82% (95% confidence interval (CI) 72% to 95%) (moderate-certainty evidence). Four modelling studies predicted delays in epidemic development, although there was wide variation in the results between the studies (very low-certainty evidence). Four modelling studies predicted that the proportion of cases detected would range from 1% to 53% (very low-certainty evidence). Nine observational studies observed the detected proportion to range from 0% to 100% (very low-certainty evidence), although all but one study observed this proportion to be less than 54%. For test-based screening, one modelling study provided very low-certainty evidence for the number of cases avoided. It reported that testing travellers reduced imported or exported cases as well as secondary cases. Five observational studies observed that the proportion of cases detected varied from 58% to 90% (very low-certainty evidence). Quarantine (12 modelling studies) The studies assessed cases avoided, shift in epidemic development and cases detected. All studies suggested some benefit of quarantine, however the magnitude of the effect ranged from small to large across the different outcomes (very low- to low-certainty evidence). Three modelling studies predicted that the reduction in the number of cases in the community ranged from 450 to over 64,000 fewer cases (very low-certainty evidence). The variation in effect was possibly related to the duration of quarantine and compliance. Quarantine and screening at borders (7 modelling studies; 4 observational studies) The studies assessed shift in epidemic development and cases detected. Most studies predicted positive effects for the combined measures with varying magnitudes (very low- to low-certainty evidence). Four observational studies observed that the proportion of cases detected for quarantine and screening at borders ranged from 68% to 92% (low-certainty evidence). The variation may depend on how the measures were combined, including the length of the quarantine period and days when the test was conducted in quarantine. AUTHORS' CONCLUSIONS: With much of the evidence derived from modelling studies, notably for travel restrictions reducing or stopping cross-border travel and quarantine of travellers, there is a lack of 'real-world' evidence. The certainty of the evidence for most travel-related control measures and outcomes is very low and the true effects are likely to be substantially different from those reported here. Broadly, travel restrictions may limit the spread of disease across national borders. Symptom/exposure-based screening measures at borders on their own are likely not effective; PCR testing at borders as a screening measure likely detects more cases than symptom/exposure-based screening at borders, although if performed only upon arrival this will likely also miss a meaningful proportion of cases. Quarantine, based on a sufficiently long quarantine period and high compliance is likely to largely avoid further transmission from travellers. Combining quarantine with PCR testing at borders will likely improve effectiveness. Many studies suggest that effects depend on factors, such as levels of community transmission, travel volumes and duration, other public health measures in place, and the exact specification and timing of the measure. Future research should be better reported, employ a range of designs beyond modelling and assess potential benefits and harms of the travel-related control measures from a societal perspective.
Cochrane Database of Systematic Reviews

Sieberts, S.K.; Schaff, J.; Duda, M.; Pataki, B.Á.; Sun, M.; Snyder, P.; Daneault, J.F.; Parisi, F.; Costante, G.; Rubin, U.; Banda, P.; Chae, Y.; Chaibub Neto, E.; Dorsey, E.R.; Aydın, Z.; Chen, A.; Elo, L.L.; Espino, C.; Glaab, E.; Goan, E.; Golabchi, F.N.; Görmez, Y.; Jaakkola, M.K.; Jonnagaddala, J.; Klén, R.; Li, D.; McDaniel, C.; Perrin, D.; Perumal, T.M.; Rad, N.M.; Rainaldi, E.; Sapienza, S.; Schwab, P.; Shokhirev, N.; Venäläinen, M.S.; Vergara-Diaz, G.; Zhang, Y.; Abrami, A.; Adhikary, A.; Agurto, C.; Bhalla, S.; Bilgin, H.; Caggiano, V.; Cheng, J.; Deng, E.; Gan, Q.; Girsa, R.; Han, Z.; Heisig, S.; Huang, K.; Jahandideh, S.; Kopp, W.; Kurz, C.F.; Lichtner, G.; Norel, R.; Raghava, G.P.S.; Sethi, T.; Shawen, N.; Tripathi, V.; Tsai, M.; Wang, T.; Wu, Y.; Zhang, J.; Zhang, X.; Wang, Y.; Guan, Y.; Brunner, D.; Bonato, P.; Mangravite, L.M.; Omberg, L.°
Crowdsourcing digital health measures to predict Parkinson's disease severity: The Parkinson's Disease Digital Biomarker DREAM Challenge.
NPJ Digit. Med. 4:53 (2021)
Consumer wearables and sensors are a rich source of data about patients' daily disease and symptom burden, particularly in the case of movement disorders like Parkinson's disease (PD). However, interpreting these complex data into so-called digital biomarkers requires complicated analytical approaches, and validating these biomarkers requires sufficient data and unbiased evaluation methods. Here we describe the use of crowdsourcing to specifically evaluate and benchmark features derived from accelerometer and gyroscope data in two different datasets to predict the presence of PD and severity of three PD symptoms: tremor, dyskinesia, and bradykinesia. Forty teams from around the world submitted features, and achieved drastically improved predictive performance for PD status (best AUROC = 0.87), as well as tremor- (best AUPR = 0.75), dyskinesia- (best AUPR = 0.48) and bradykinesia-severity (best AUPR = 0.95).
NPJ digital medicine

Sun, D.; Richard, M.A.; Musani, S.K.; Sung, Y.U.; Winkler, T.W.; Schwander, K.; Chai, J.F.; Guo, X.; Kilpeläinen, T.O.; Vojinovic, D.; Aschard, H.; Bartz, T.M.; Bielak, L.F.; Brown, M.R.; Chitrala, K.; Hartwig, F.P.; Horimoto, A.R.V.R.; Liu, Y.; Manning, A.K.; Noordam, R.; Smith, A.V.; Harris, S.E.; Kühnel, B.; Lyytikäinen, L.-P.; Nolte, I.M.; Rauramaa, R.; van der Most, P.J.; Wang, R.; Ware, E.B.; Weiss, S.; Wen, W.; Yanek, L.R.; Arking, D.E.; Arnett, D.K.; Barac, A.; Boerwinkle, E.; Broeckel, U.; Chakravarti, A.; Chen, Y.-C. D.; Cupples, L.A.; Daviglus, M.L.; de Las Fuentes, L.; de Mutsert, R.; de Vries, P.S.; Delaney, J.A.C.; Diez Roux, A.V.; Dörr, M.; Faul, J.D.; Fretts, A.M.; Gallo, L.C.; Grabe, H.J.; Gu, C.C.; Harris, T.B.; Hartman, C.C.A.; Heikkinen, S.; Ikram, M.A.; Isasi, C.; Johnson, W.C.; Jonas, J.B.; Kaplan, R.C.; Komulainen, P.; Krieger, J.E.; Levy, D.; Liu, J.; Lohman, K.; Luik, A.I.; Martin, L.W.; Meitinger, T.; Milaneschi, Y.; O'Connell, J.R.; Palmas, W.R.; Peters, A.; Peyser, P.A.; Pulkki-Råback, L.;

Raffel, L.J.; Reiner, A.P.; Rice, K.; Robinson, J.G.; Rosendaal, F.R.; Schmidt, C.O.; Schreiner, P.J.; Schwettmann, L.; Shikany, J.M.; Shu, X.O.; Sidney, S.; Sims, M.; Smith, J.A.; Sotoodehnia, N.; Strauch, K.; Tai, E.S.; Taylor, K.D.; Uitterlinden, A.G.; van Duijn, C.M.; Waldenberger, M.; Wee, H.L.; Wei, W.B.; Wilson, G.; Xuan, D.; Yao, J.; Zeng, D.; Zhao, W.; Zhu, X.; Zonderman, A.B.; Becker, D.M.; Deary, I.J.; Gieger, C.; Lakka, T.A.; Lehtimäki, T.; North, K.E.; Oldehinkel, A.J.; Penninx, B.W.J.H.; Snieder, H.; Wang, Y.X.; Weir, D.R.; Zheng, W.; Evans, M.K.; Gauderman, W.J.; Gudnason, V.; Horta, B.L.; Liu, C.-T.; Mook-Kanamori, D.O.; Morrison, A.C.; Pereira, A.C.; Psaty, B.M.; Amin, N.; Fox, E.R.; Kooperberg, C.; Sim, X.; Bierut, L.; Rotter, J.I.; Kardia, S.L.R.; Franceschini, N; Rao, D.C.; Fornage, M.
Multi-ancestry genome-wide association study accounting for gene-psychosocial factor interactions identifies novel loci for blood pressure traits.
HGG Advances 2:100013 (2021)
Psychological and social factors are known to influence blood pressure (BP) and risk of hypertension and associated cardiovascular diseases. To identify novel BP loci, we carried out genome-wide association meta-analyses of systolic, diastolic, pulse, and mean arterial BP, taking into account the interaction effects of genetic variants with three psychosocial factors: depressive symptoms, anxiety symptoms, and social support. Analyses were performed using a two-stage design in a sample of up to 128,894 adults from five ancestry groups. In the combined meta-analyses of stages 1 and 2, we identified 59 loci (p value < 5e−8), including nine novel BP loci. The novel associations were observed mostly with pulse pressure, with fewer observed with mean arterial pressure. Five novel loci were identified in African ancestry, and all but one showed patterns of interaction with at least one psychosocial factor. Functional annotation of the novel loci supports a major role for genes implicated in the immune response (PLCL2), synaptic function and neurotransmission (LIN7A and PFIA2), as well as genes previously implicated in neuropsychiatric or stress-related disorders (FSTL5 and CHODL). These findings underscore the importance of considering psychological and social factors in gene discovery for BP, especially in non-European populations.
Human Genetics and Genomics Advances

Polus, S.; Burns, J.; Hoffmann, S.; Mathes, T.; Mansmann, U.; Been, J.V.; Lack, N.; Koller, D.; Maier, W.; Rehfuess, E.A.
Interrupted time series study found mixed effects of the impact of the Bavarian smoke-free legislation on pregnancy outcomes.
Sci. Rep. 11:4209 (2021)
In 2007 the German government passed smoke-free legislation, leaving the details of implementation to the individual federal states. In January 2008 Bavaria implemented one of the strictest laws in Germany. We investigated its impact on pregnancy outcomes and applied an interrupted time series (ITS) study design to assess any changes in preterm birth, small for gestational age (primary outcomes), and low birth weight, stillbirth and very preterm birth. We included 1,236,992 singleton births, comprising 83,691 preterm births and 112,143 small for gestational age newborns. For most outcomes we observed unclear effects. For very preterm births, we found an immediate drop of 10.4% (95%CI − 15.8, − 4.6%; p = 0.0006) and a gradual decrease of 0.5% (95%CI − 0.7, − 0.2%, p = 0.0010) after implementation of the legislation. The majority of subgroup and sensitivity analyses confirm these results. Although we found no statistically significant effect of the Bavarian smoke-free legislation on most pregnancy outcomes, a substantial decrease in very preterm births was observed. We cannot rule out that despite our rigorous methods and robustness checks, design-inherent limitations of the ITS study as well as country-specific factors, such as the ambivalent German policy context have influenced our estimation of the effects of the legislation.
Scientific Reports

Shao, H.; Laxy, M.; Benoit, S.R.; Cheng, Y.J.; Gregg, E.W.; Zhang, P.
Trends in total and out-of-pocket payments for noninsulin glucose-lowering drugs among U.S. adults with large-employer private health insurance from 2005 to 2018.
Diabetes Care 44, 925-934 (2021)
OBJECTIVE: To estimate trends in total payment and patients' out-of-pocket (OOP) payments of noninsulin glucose-lowering drugs by class from 2005 to 2018. RESEARCH DESIGN AND METHODS: We analyzed data for 53 million prescriptions from adults aged >18 years with type 2 diabetes under fee-for-service plans from the 2005-2018 IBM MarketScan Commercial Databases. The total payment was measured as the amount that the pharmacy received, and the OOP payment was the sum of copay, coinsurance, and deductible paid by the beneficiaries. We applied a joinpoint regression to evaluate nonlinear trends in cost between 2005 and 2018. We further conducted a decomposition analysis to explore the drivers for total payment change. RESULTS: Total annual payments for older drug classes, including metformin, sulfonylurea, meglitinide, α-glucosidase inhibitors, and thiazolidinedione, have declined during 2005-2018, ranging from -$271 (-53.8%) (USD) for metformin to -$2,406 (-92.2%) for thiazolidinedione. OOP payments for these drug classes also reduced. In the same period, the total annual payments for the newer drug classes, including dipeptidyl peptidase-4 inhibitors, glucagon-like peptide 1 receptor agonists, and sodium-glucose cotransporter 2 inhibitors, have increased by $2,181 (88.4%), $3,721 (77.6%), and $1,374 (37.0%), respectively. OOP payment for these newer classes remained relatively unchanged. Our study findings indicate that switching toward the newer classes for noninsulin glucose-lowering drugs was the main driver that explained the total payment increase. CONCLUSIONS: Average annual payments and OOP payment for noninsulin glucose-lowering drugs have increased significantly from 2005 to 2018. The uptake of newer drug classes was the main driver.
Diabetes Care

Mayerhofer, B.; Jörres, R.A.; Lutter, J.; Waschki, B.; Kauffmann-Guerrero, D.; Alter, P.; Trudzinski, F.C.; Herth, F.J.F.; Holle, R.; Behr, J.; Bals, R.; Welte, T.; Watz, H.; Vogelmeier, C.F.; Kahnert, K.
Deterioration and mortality risk of COPD patients not fitting into standard GOLD categories: Results of the COSYCONET Cohort.
Respiration 100, 308-317 (2021)
Background: Patients with COPD-specific symptoms and history but FEV1/FVC ratio ≥0.7 are a heterogeneous group (former GOLD grade 0) with uncertainties regarding natural history. Objective: We investigated which lung function measures and cutoff values are predictive for deterioration according to GOLD grades and all-cause mortality. Methods: We used visit 1-4 data of the COSYCONET cohort. Logistic and Cox regression analyses were used to identify relevant parameters. GOLD 0 patients were categorized according to whether they maintained

grade 0 over the following 2 visits or deteriorated persistently into grades 1 or 2. Their clinical characteristics were compared with those of GOLD 1 and 2 patients. Results: Among 2,741 patients, 374 GOLD 0, 206 grade 1, and 962 grade 2 patients were identified. GOLD 0 patients were characterized by high symptom burden, comparable to grade 2, and a restrictive lung function pattern; those with FEV1/FVC above 0.75 were unlikely to deteriorate over time into grades 1 and 2, in contrast to those with values between 0.70 and 0.75. Regarding mortality risk in GOLD 0, FEV1%predicted and age were the relevant determinants, whereby a cutoff value of 65% was superior to that of 80% as proposed previously. Conclusions: Regarding patients of the former GOLD grade 0, we identified simple criteria for FEV1/FVC and FEV1% predicted that were relevant for the outcome in terms of deterioration over time and mortality. These criteria might help to identify patients with the typical risk profile of COPD among those not fulfilling spirometric COPD criteria.
Respiration

Schunk, M.; Le, L.; Syunyaeva, Z.; Haberland, B.; Tänzler, S.; Mansmann, U.; Schwarzkopf, L.; Seidl, H.; Streitwieser, S.; Hofmann, M.; Müller, T.; Weiß, T.; Morawietz, P.; Rehfuess, E.A.; Huber, R.M.; Berger, U.; Bausewein, C.
Effectiveness of a specialised breathlessness service for patients with advanced disease in Germany: A pragmatic fast track randomised controlled trial (BreathEase).
Eur. Respir. J. 58:2002139 (2021)
Background The effectiveness of the Munich Breathlessness Service (MBS), integrating palliative care, respiratory medicine and physiotherapy, was tested in the BreathEase trial in patients with chronic breathlessness in advanced disease and their carers.Methods BreathEase was a single-blinded randomised controlled fast-track trial. The MBS was attended for 5-6 weeks; the control group started the MBS after 8 weeks of standard care. Randomisation was stratified by cancer and the presence of a carer. Primary outcomes were patients' mastery of breathlessness (Chronic Respiratory Disease Questionnaire (CRQ) Mastery), quality of life (CRQ QoL), symptom burden (Integrated Palliative care Outcome Scale (IPOS)) and carer burden (Zarit Burden Interview (ZBI)). Intention-to-treat (ITT) analyses were conducted with hierarchical testing. Effectiveness was investigated by linear regression on change scores, adjusting for baseline scores and stratification variables. Missing values were handled with multiple imputation.Results 92 patients were randomised to the intervention group and 91 patients were randomised to the control group. Before the follow-up assessment after 8 weeks (T1), 17 and five patients dropped out from the intervention and control groups, respectively. Significant improvements in CRQ Mastery of 0.367 (95% CI 0.065-0.669) and CRQ QoL of 0.226 (95% CI 0.012-0.440) score units at Ti in favour of the intervention group were seen in the ITT analyses (n=183), but not in IPOS. Exploratory testing showed nonsignificant improvements in 21311.Conclusions These findings demonstrate positive effects of the MBS in reducing burden caused by chronic breathlessness in advanced illness across a wide range of patients. Further evaluation in subgroups of patients and with a longitudinal perspective is needed.
European Respiratory Journal

Schwarzkopf, L.; Loy, J.K.; Braun-Michl, B.; Grüne, B.; Sleczka, P.; Kraus, L.
Gambling disorder in the context of outpatient counselling and treatment: Background and design of a prospective German cohort study.
Int. J. Methods Psychiatr. Res. 30:e1867 (2021)
OBJECTIVE: The prospective naturalistic study 'Katamnese-Studie' conducted between 2014 and 2019 gathers evidence on the course of gambling disorder in German routine outpatient addiction care. This study elucidates design and methodological advantages and caveats of the study. METHODS: Participants of the multi-centre cohort received written questionnaires at admission and at 6-, 12-, 24- and 36-month follow-up to assess socio-demographic data, gambling behaviour, gambling-related consequences and care offers sought. Subsequently, self-reports were linked to client-individual routine documentation for the German Addiction Care Statistical Service. Furthermore, employees of participating outpatient addiction care facilities were surveyed regarding experiences with and attitudes towards gambling disorder. Multivariate longitudinal regression models will portray changes in the severity of gambling disorder and gambling behaviour and explore associated client- and care-related factors. CONCLUSION: The 'Katamnese-Studie' covers the whole spectrum of outpatient gambling care. Keeping the design-related caveats in mind (reliability of self-reports, loss-to-follow-up and issues regarding causal inference), the study is anticipated to draw a comprehensive picture of routine outpatient gambling care and key factors related to sustained remission. In the medium term, this information might support the development and subpopulation-specific adaptation of recommendations on how to structure process and content of outpatient gambling care.
International Journal of Methods in Psychiatric Research

Jansen, L.; Kanbach, J.; Finke, I.; Arndt, V.; Emrich, K.; Holleczek, B.; Kajüter, H.; Kieschke, J.; Maier, W.; Pritzkuleit, R.; Sirri, E.; Schwettmann, L.; Erb, C.; Brenner, H.
Estimation of the potentially avoidable excess deaths associated with socioeconomic inequalities in cancer survival in Germany.
Cancers 13:357 (2021)
Many countries have reported survival inequalities due to regional socioeconomic deprivation. To quantify the potential gain from eliminating cancer survival disadvantages associated with area-based deprivation in Germany, we calculated the number of avoidable excess deaths. We used population-based cancer registry data from 11 of 16 German federal states. Patients aged ≥15 years diagnosed with an invasive malignant tumor between 2008 and 2017 were included. Area-based socioeconomic deprivation was assessed using the quintiles of the German Index of Multiple Deprivation (GIMD) 2010 on a municipality level nationwide. Five-year age-standardized relative survival for 25 most common cancer sites and for total cancer were calculated using period analysis. Incidence and number of avoidable excess deaths in Germany in 2013-2016 were estimated. Summed over the 25 cancer sites, 4100 annual excess deaths (3.0% of all excess deaths) could have been avoided each year in Germany during the period 2013-2016 if relative survival were in all regions comparable with the least deprived regions. Colorectal, oral and pharynx, prostate, and bladder cancer contributed the largest numbers of avoidable excess deaths. Our results provide a good basis to estimate the potential of intervention programs for reducing socioeconomic inequalities in cancer burden in Germany.
Cancers

Laxy, M.; Becker, J.; Kähm, K.; Holle, R.; Peters, A.; Thorand, B.; Schwettmann, L.; Karl, F.
Utility decrements associated with diabetes and related complications: Estimates from a population-based study in Germany.
Value Health 24, 274-280 (2021)
ISPOR–The Professional Society for Health Economics and Outcomes Research Objectives: Health utility decrement estimates for diabetes and complications are needed for parametrization of simulation models that aim to assess the cost-utility of diabetes prevention and care strategies. Thisstudy estimates health utility decrements associated with diabetes and cardiovascular and microvascular complications from a cross-sectional population-based German study. Methods: Data were obtained from the population based cross-sectional KORA (Cooperative Health Research in the Region of Augsburg) health questionnaire 2016 and comprised n = 1072 individuals with type 2 diabetes and n = 7879 individuals without diabetes. Health utility was assessed through the EQ-5D-5L. We used linear regression models with an interaction term between type 2 diabetes and cardiovascular and microvascular complications while adjusting for demographic and socio-economic factors and other comorbidities. Results: Type 2 diabetes ($\beta = -0.028$, standard error [SE] = 0.014), stroke ($\beta = -0.070$, SE = 0.010), cardiac arrhythmia ($\beta = -0.031$, SE = 0.006), heart failure ($\beta = -0.073$, SE = 0.009), coronary heart disease ($\beta = -0.028$, SE = 0.010), myocardial infarction ($\beta = -0.020$, SE = 0.011, estimates of main effec), and neuropathy ($\beta = -0.067$, SE = 0.020), diabetic foot ($\beta = -0.042$, SE = 0.030), nephropathy ($\beta = -0.032$, SE = 0.025), and blindness ($\beta = -0.094$, SE = 0.056, estimates of interaction terms) were negatively associated with health utility. The interaction term for diabetes x stroke ($\beta = -0.052$, SE = 0.021) showed that the utility decrement for stroke is significantly larger in people with type 2 diabetes than in people without diabetes. Conclusions: Diabetes, cardiovascular, and microvascular conditions are associated with significant health utility decrements. Utility decrements for some conditions differ between people with and without type 2 diabetes. These results are of high relevance for the parametrization of decision analytic simulation models and applied health economic evaluations in the field of prevention and management of diabetes in Germany.
Value in Health

Huang, J.; Covic, M.; Huth, C.; Rommel, M.; Adam, J.; Zukunft, S.; Prehn, C.; Wang, L.; Nano, J.; Scheerer, M.F.; Neschen, S.; Kastenmüller, G.; Gieger, C.; Laxy, M.; Schliess, F.; Adamski, J.; Suhre, K.; Hrabě de Angelis, M.; Peters, A.; Wang-Sattler, R.
Validation of candidate phospholipid biomarkers of chronic kidney disease in hyperglycemic individuals and their organ-specific exploration in leptin receptor-deficient db/db mouse.
Metabolites 11:89 (2021)
Biological exploration of early biomarkers for chronic kidney disease (CKD) in (pre)diabetic individuals is crucial for personalized management of diabetes. Here, we evaluated two candidate biomarkers of incident CKD (sphingomyelin (SM) C18:1 and phosphatidylcholine diacyl (PC aa) C38:0) concerning kidney function in hyperglycemic participants of the Cooperative Health Research in the Region of Augsburg (KORA) cohort, and in two biofluids and six organs of leptin receptor-deficient (db/db) mice and wild type controls. Higher serum concentrations of SM C18:1 and PC aa C38:0 in hyperglycemic individuals were found to be associated with lower estimated glomerular filtration rate (eGFR) and higher odds of CKD. In db/db mice, both metabolites had a significantly lower concentration in urine and adipose tissue, but higher in the lungs. Additionally, db/db mice had significantly higher SM C18:1 levels in plasma and liver, and PC aa C38:0 in adrenal glands. This cross-sectional human study confirms that SM C18:1 and PC aa C38:0 associate with kidney dysfunction in pre(diabetic) individuals, and the animal study suggests a potential implication of liver, lungs, adrenal glands, and visceral fat in their systemic regulation. Our results support further validation of the two phospholipids as early biomarkers of renal disease in patients with (pre)diabetes.
Metabolites

Voss, S.; Schneider, A.E.; Huth, C.; Wolf, K.; Markevych, I.; Schwettmann, L.; Rathmann, W.; Peters, A.; Breitner, S.
Long-term exposure to air pollution, road traffic noise, residential greenness, and prevalent and incident metabolic syndrome: Results from the population-based KORA F4/FF4 cohort in Augsburg, Germany.
Environ. Int. 147:106364 (2021)
Background: A growing number of epidemiological studies show associations between environmental factors and impaired cardiometabolic health. However, evidence is scarce concerning these risk factors and their impact on metabolic syndrome (MetS). This analysis aims to investigate associations between long-term exposure to air pollution, road traffic noise, residential greenness, and MetS. Methods: We used data of the first (F4, 2006–2008) and second (FF4, 2013–2014) follow-up of the population-based KORA S4 survey in the region of Augsburg, Germany, to investigate associations between exposures and MetS prevalence at F4 (N = 2883) and MetS incidence at FF4 (N = 1192; average follow-up: 6.5 years). Residential long-term exposures to air pollution – including particulate matter (PM) with a diameter < 10 µm (PM10), PM < 2.5 µm (PM2.5), PM between 2.5 and 10 µm (PMcoarse), absorbance of PM2.5 (PM2.5abs), particle number concentration (PNC), nitrogen dioxide (NO2), ozone (O3) – and road traffic noise were modeled by land-use regression models and noise maps. For greenness, the Normalized Difference Vegetation Index (NDVI) was obtained. We estimated Odds Ratios (OR) for single and multi-exposure models using logistic regression and generalized estimating equations adjusted for confounders. Joint Odds Ratios were calculated based on the Cumulative Risk Index. Effect modifiers were examined with interaction terms. Results: We found positive associations between prevalent MetS and interquartile range (IQR) increases in PM10 (OR: 1.15; 95% confidence interval [95% CI]: 1.02, 1.29), PM2.5 (OR: 1.14; 95% CI: 1.02, 1.28), PMcoarse (OR: 1.14; 95% CI: 1.02, 1.27), and PM2.5abs (OR: 1.17; 95% CI: 1.03, 1.32). Results further showed negative, but non-significant associations between exposure to greenness and prevalent and incident MetS. No effects were seen for exposure to road traffic noise. Joint Odds Ratios from multi-exposure models were higher than ORs from models with only one exposure.
Environment International

Pedron, S.; Kurz, C.F.; Schwettmann, L.; Laxy, M.
The effect of BMI and type 2 diabetes on socioeconomic status: A two-sample multivariable mendelian randomization study.
Diabetes Care 44, 850-852 (2021)

OBJECTIVE: To assess the independent causal effect of BMI and type 2 diabetes (T2D) on socioeconomic outcomes by applying two-sample Mendelian randomization (MR) analysis. RESEARCH DESIGN AND METHODS: We performed univariable and multivariable two-sample MR to jointly assess the effect BMI and T2D on socioeconomic outcomes. We used overlapping genome-wide significant single nucleotide polymorphisms for BMI and T2D as instrumental variables. Their causal impact on household income and regional deprivation was assessed using summary-level data from the UK Biobank. RESULTS: In the univariable analysis, higher BMI was related to lower income (marginal effect of 1-SD increase in BMI [β = -0.092; 95% CI -0.138; -0.047]) and higher deprivation (β = 0.051; 95% CI 0.022; 0.079). In the multivariable MR, the effect of BMI controlling for diabetes was slightly lower for income and deprivation. Diabetes was not associated with these outcomes. CONCLUSIONS: High BMI, but not diabetes, shows a causal link with socioeconomic outcomes.
Diabetes Care

Pedron, S.; Schmaderer, K.; Murawski, M.; Schwettmann, L.
The association between childhood socioeconomic status and adult health behavior: The role of locus of control.
Soc. Sci. Res. 95:102521 (2021)
The socioeconomic environment in childhood is a powerful determinant for health behavior in adulthood, subsequently influencing health outcomes. However, the underlying mechanisms are insufficiently understood. This study assesses locus of control (LOC) as a mediator linking childhood socioeconomic status (SES) with health behavior (smoking, regular alcohol consumption, unhealthy diet and low physical activity). Drawing on a representative sample from Germany (SOEP), we investigated these relations using structural equations modelling. Results show that externally oriented LOC explains up to 6% of the relationship between childhood SES and health behavior in adulthood, independently from adult SES. Stratification indicates that these results hold in women but not in men, in younger and middle-aged individuals but not in older ones. Hence, control beliefs play a modest yet significant role in shaping the socioeconomic gradient in health behavior and might have far-reaching consequences on how morbidity and mortality arise and persist across generations.
Social Science Research

Stephan, A.J.; Schwettmann, L.; Meisinger, C.; Ladwig, K.-H.; Linkohr, B.; Thorand, B.; Schulz, H.; Peters, A.; Grill, E.
Living longer but less healthy: The female disadvantage in health expectancy. Results from the KORA-Age study.
Exp. Gerontol. 145:111196 (2021)
Objectives: We explored the male-female health-survival paradox in the context of health expectancy (HE) at age 65 and thereafter, using three different morbidity measures and different severity cut-offs with and without adjustments for the share of nursing home residents. Methods: HE at ages 65, 70, 75, 80, and 85 was estimated with the Sullivan method, linking morbidity prevalence from the KORA (Cooperative Health Research in the Region of Augsburg)-Age study to 2016 Bavarian mortality data. Morbidity measures comprised deficit accumulation (Frailty Index, FI, cut-offs 0.08 and 0.25), disability (Health Assessment Questionnaire-Disability Index, HAQ-DI, cut-off >0) and participation (Global Activity Limitation Indicator, GALI, “limited” vs “not limited”). Results: Morbidity data were available for 4083 participants (52.7% female). HE was lower in women than in men at all ages. Differences in morbidity prevalence, absolute HE, and health proportions of life expectancy (relative HE) increased with age for FI ≥ 0.25 and GALI, but not for HAQ-DI > 0 and FI > 0.08. Accounting for the share of nursing home residents resulted in a slight reduction of HE estimates but had no impact on estimated sex differences. Conclusions: In HE at age 65 and thereafter, women's health disadvantage was larger than their life expectancy advantage over men.
Experimental Gerontology

Ng, B.P.; Laxy, M.; Shrestha, S.S.; Soler, R.E.; Cannon, M.J.; Smith, B.D.; Zhang, P.
Prevalence and medical expenditures of diabetes-related complications among adult medicaid enrollees with diabetes in eight U.S. states.
J. Diab. Complic. 35:107814 (2021)
Aims: To estimate the prevalence and medical expenditures of diabetes-related complications (DRCs) among adult Medicaid enrollees with diabetes. Methods: We estimated the prevalence and medical expenditures for 12 diabetes-related complications by Medicaid eligibility category (disability-based vs. non-disability-based) in eight states. We used generalized linear models with log link and gamma distribution to estimate the total per-person annual medical expenditures for DRCs, controlling for demographics, and other comorbidities. Results: Among non-disability-based enrollees (NDBEs), 40.1% (in California) to 47.5% (in Oklahoma) had one or more DRCs, compared to 53.6% (in Alabama) to 64.8% (in Florida) among disability-based enrollees (DBEs). The most prevalent complication was neuropathy (16.1%–27.1% for NDBEs; 20.2%–30.4% for DBEs). Lower extremity amputation (<1% for both eligibilities) was the least prevalent complication. The costliest per-person complication was dialysis (per-person excess annual expenditure of $22,481–$41,298 for NDBEs; $23,569–$51,470 for DBEs in 2012 USD). Combining prevalence and per-person excess expenditures, the three costliest complications were nephropathy, heart failure, and ischemic heart disease (IHD) for DBEs, compared to neuropathy, nephropathy, and IHD for NDBEs. Conclusions: Our study provides data that can be used for assessing the health care resources needed for managing DRCs and evaluating cost-effectiveness of interventions to prevent and management DRCs.
Journal of Diabetes and its Complications

Neuwahl, S.J.; Zhang, P.; Chen, H.; Shao, H.; Laxy, M.; Anderson, A.M.; Craven, T.E.; Hoerger, T.J.
Patient health utility equations for a type 2 diabetes model.
Diabetes Care 44, 381-389 (2021)
OBJECTIVE: To estimate the health utility impact of diabetes-related complications in a large, longitudinal U.S. sample of people with type 2 diabetes. RESEARCH DESIGN AND METHODS: We combined Health Utilities Index Mark 3 data on patients with type 2 diabetes from the Action to Control Cardiovascular Risk in Diabetes (ACCORD) and Look AHEAD (Action for Health in Diabetes) trials and their follow-on studies. Complications were classified as events if they occurred in the year preceding the utility measurement; otherwise, they were classified as a history of the complication. We estimated utility decrements associated with complications using a fixed-effects regression model. RESULTS: Our sample included 15,252 persons with an average follow-up of 8.2 years and a total of

128,873 person-visit observations. The largest, statistically significant ($P < 0.05$) health utility decrements were for stroke (event, -0.109; history, -0.051), amputation (event, -0.092; history, -0.150), congestive heart failure (event, -0.051; history, -0.041), dialysis (event, -0.039), estimated glomerular filtration rate (eGFR) <30 mL/min/1.73 m2 (event, -0.043; history, -0.025), angina (history, -0.028), and myocardial infarction (MI) (event, -0.028). There were smaller effects for laser photocoagulation and eGFR <60 mL/min/1.73 m2. Decrements for dialysis history, angina event, MI history, revascularization event, revascularization history, laser photocoagulation event, and hypoglycemia were not significant ($P \geq 0.05$). CONCLUSIONS: With use of a large study sample and a longitudinal design, our estimated health utility scores are expected to be largely unbiased. Estimates can be used to describe the health utility impact of diabetes complications, improve cost-effectiveness models, and inform diabetes policies.
Diabetes Care

Burns, J.; Hoffmann, S.; Kurz, C.F.; Laxy, M.; Polus, S.; Rehfuess, E.
COVID-19 mitigation measures and nitrogen dioxide - a quasi-experimental study of air quality in Munich, Germany.
Atmos. Environ. 246:118089 (2021)
Background: In response to the COVID-19 pandemic, the Bavarian State government announced several COVID-19 mitigation measures beginning on March 16, 2020, which likely led to a reduction in traffic and a subsequent improvement in air quality. In this study, we evaluated the short-term effect of COVID-19 mitigation measures on NO_2 concentrations in Munich, Germany. Methods: We applied two quasi-experimental approaches, a controlled interrupted time-series (c-ITS) approach and a synthetic control (SC) approach. Each approach compared changes occurring in 2020 to changes occurring in 2014-2019, and accounted for weather-related and other potential confounders. We hypothesized that the largest reductions in NO_2 concentrations would be observed at traffic sites, with smaller reductions at urban background sites, and even small reductions, if any, at background sites. All hypotheses, as well as the main and additional analyses were defined a priori. We also conducted post-hoc analyses to ensure that observed effects were not due to factors other than the intervention. Results: Main analyses largely supported our hypotheses. Specifically, at the two traffic sites, using the c-ITS approach we observed reductions of 9.34 µg/m3 (95% confidence interval: -23.58; 4.90) and 10.02 µg/m3 (-19.25; -0.79). Using the SC approach we observed reductions of 15.65 µg/m3 (-27.58; -4.09) and 15.1 µg/m3 (-24.82; -9.83) at these same sites. We observed effects ranging from smaller in magnitude to no effect at urban background and background sites. Additional analyses showed that the effect was largest in the first two weeks following introduction of measures, and that a 3-day lagged intervention time also showed a larger effect. Post-hoc analyses suggested that at least some of the observed effects may have been attributable to changes in air quality occurring before the intervention, as well as unusually high concentrations in January 2020. Conclusion: We applied two quasi-experimental approaches in assessing the impact of the COVID-19 mitigation measures on NO_2 concentrations in Munich. Taking the 2020 pre-intervention average concentrations as a reference, we observed reductions in NO_2 concentrations of approximately 15-25% and 24-36% at traffic sites, suggesting that reducing traffic may be an effective measure to reduce NO_2 concentrations in heavily trafficked areas by margins which could translate to public health benefits.
Atmospheric Environment

Shao, H.; Laxy, M.; Gregg, E.W.; Albright, A.; Zhang, P.
Cost-effectiveness of the new 2018 American college of physicians glycemic control guidance statements among US adults with type 2 diabetes.
Value Health 24, 227-235 (2021)
Objectives: This study aims to estimate the national impact and cost-effectiveness of the 2018 American College of Physicians (ACP) guidance statements compared to the status quo. Methods: Survey data from the 2011-2016 National Health and Nutrition Examination were used to generate a national representative sample of individuals with diagnosed type 2 diabetes in the United States. Individuals with A1c <6.5% on antidiabetic medications are recommended to deintensify their A1c level to 7.0% to 8.0% (group 1); individuals with A1c 6.5% to 8.0% and a life expectancy of <10 years are recommended to deintensify their A1c level >8.0% (group 2); and individuals with A1c >8.0% and a life expectancy of >10 years are recommended to intensify their A1c level to 7.0% to 8.0% (group 3). We used a Markov-based simulation model to evaluate the lifetime cost-effectiveness of following the ACP recommended A1c level. Results: 14.41 million (58.1%) persons with diagnosed type 2 diabetes would be affected by the new guidance statements. Treatment deintensification would lead to a saving of $363 600 per quality-adjusted life-year (QALY) lost for group 1 and a saving of $118 300 per QALY lost for group 2. Intensifying treatment for group 3 would lead to an additional cost of $44 600 per QALY gain. Nationally, the implementation of the guidance would add 3.2 million life-years and 1.1 million QALYs and reduce healthcare costs by $47.7 billion compared to the status quo. Conclusions: Implementing the new ACP guidance statements would affect a large number of persons with type 2 diabetes nationally. The new guidance is cost-effective.
Value in Health

Jones, A.; Bardram, J.E.; Bækgaard, P.; Cramer-Petersen, C.L.; Skinner, T.; Vrangbæk, K.; Starr, L.; Nørgaard, K.; Lind, N.; Bechmann Christensen, M.; Glümer, C.; Wang-Sattler, R.; Laxy, M.; Brander, E.; Heinemann, L.; Heise, T.; Schliess, F.; Ladewig, K.; Kownatka, D.
Integrated personalized diabetes management goes Europe: A multi-disciplinary approach to innovating type 2 diabetes care in Europe.
Prim. Care Diabetes 15, 360-364 (2021)
Type 2 diabetes mellitus represents a multi-dimensional challenge for European and global societies alike. Building on an iterative six-step disease management process that leverages feedback loops and utilizes commodity digital tools, the PDM-ProValue study program demonstrated that integrated personalized diabetes management, or iPDM, can improve the standard of care for persons living with diabetes in a sustainable way. The novel “iPDM Goes Europe” consortium strives to advance iPDM adoption by (1) implementing the concept in a value-based healthcare setting for the treatment of persons living with type 2 diabetes, (2) providing tools to assess the patient's physical and mental health status, and (3) exploring new avenues to take advantage of emerging big data resources.
Primary Care Diabetes

Seidl, H.; Hein, L.; Scholz, S.; Bowles, D.; Greiner, W.; Brettschneider, C.; König, H.H.; Holle, R.
Validierung des FIMA-Fragebogens zur Inanspruchnahme von Versorgungsleistungen anhand von Routinedaten der Krankenversicherung: Welchen Einfluss hat der Erinnerungszeitraum?
Gesundheitswesen 83, 66-74 (2021)
Ziel Das Ziel der Studie ist die Validierung des Fragebogens zur Inanspruchnahme Medizinischer und nicht-medizinischer Versorgungsleistungen im Alter (FIMA). Methodik Die Selbstangaben von 1552 Teilnehmern wurden mit den Routinedaten der Krankenversicherung abgeglichen. Als Güteparameter wurden Intraklassenkorrelation (ICC), Sensitivität, Spezifität und Kappa-Koeffizienten nach Cohen bestimmt. Der Einfluss von soziodemografischen und gesundheitlichen Faktoren, des Erinnerungszeitraums (3, 6 oder 12 Monate) sowie der Häufigkeit der Inanspruchnahme wurde anhand logistischer Regressionen untersucht. Ergebnisse Die durchschnittlich 74 Jahre alten Teilnehmer stuften den FIMA größtenteils (95%) als einfach auszufüllen ein. Die Anzahl der Arztkontakte wurde je nach Erinnerungszeitraum zwischen 9 bis 28% unterschätzt, der ICC war für jeden Zeitraum mittelmäßig (ICC: 0,46, 0,48, 0,55). Die Anzahl physiotherapeutischer Kontakte wurde insgesamt sehr gut erinnert (ICC>0,75). Bei den Rehabilitations- und Krankenhaustagen gab es Unterschiede zwischen den Erinnerungszeiträumen (3/6/12 Monate): Rehabilitation: ICC=0,88/0,51/0,87; Krankenhaustage: ICC=0,69/0,88/0,66. Die Selbstangaben für die Leistungen aus der Pflegeversicherung zeigten durchgehend sehr hohe Kappa-Koeffizienten (>0,90) während die Hilfsmittel über alle Zeiträume eine schlechte Übereinstimmung (Kappa<0,30) und die Medikamenteneinnahme eine gute Übereinstimmung (Kappa>0,40) zeigten. In der ambulanten (Arzt, Physiotherapeut) und der stationären Versorgung (Rehabilitation, Krankenhaus) sank die Chance der Übereinstimmung pro zusätzlichem Kontakt signifikant. Darüber hinaus führte ein besserer Gesundheitszustand zu einer exakteren Erinnerung an Physiotherapeutenkontakte. Schlussfolgerung Der FIMA weist in weiten Teilen eine gute Reliabilität auf. Er ist sehr gut verständlich und ein valides Instrument, um Kosten der Gesundheitsversorgung in der älteren Bevölkerung zu ermitteln.
Gesundheitswesen, Das

2020
Radon, K.; Saathoff, E.; Pritsch, M.; Guggenbühl Noller, J.M.; Kroidl, I.; Olbrich, L.; Thiel, V.; Diefenbach, M.; Riess, F.; Förster, F.; Theis, F.J.; Wieser, A.; Hoelscher, M.; the KoCo19 collaboration group (Hasenauer, J.; Fuchs, C.; Castelletti, N.; Zeggini, E.; Laxy, M.; Leidl, R.; Schwettmann, L.)
Protocol of a population-based prospective COVID-19 cohort study Munich, Germany (KoCo19) (vol 20, 1036, 2020).
BMC Public Health 20:1335 (2020)
An amendment to this paper has been published and can be accessed via the original article.
BMC Public Health
Herold-Majumdar, A.; Marijic, P.; Stemmer, R.
Organizational culture empowering nurses an residents in nursing homes.
Adv. Soc. Sci. Res. J. 7, 590-611 (2020)
Purpose. If nurses should respect resident´s autonomy, nurses themselves must experience empowerment and respect for their own autonomy in the work environment. The purpose of this study is to get a deeper understanding of nurses' perception of their own empowerment in the organization's culture during an intervention program for strengthening autonomy. Design/methodology/approach. Guided semi-structured interviews and moderated group discussions were conducted before and after the intervention. A structured and evaluative content analysis of the text material were performed. Findings. In total 73 nurses and nurse aids working at frontline with the residents were voluntarily included into the study. New categories for nurses' perceived empowerment and organizational culture could be derived from the text material. Originality/value. The study's results deliver a theoretical model with a sophisticated system of categories for organizational culture as perceived by nurses that can be used for further qualitative and quantitative research and for a sustainable organization development.
Advances in Social Sciences Research Journal (ASSRJ)

Kirsch, F.; Becker, C.; Kurz, C.F.; Schwettmann, L.; Schramm, A.
Effects of adherence to pharmacological secondary prevention after acute myocardial infarction on health care costs – an analysis of real-world data.
BMC Health Serv. Res. 20:1145 (2020)
Background: Acute myocardial infarction (AMI), a major source of morbidity and mortality, is also associated with excess costs. Findings from previous studies were divergent regarding the effect on health care expenditure of adherence to guideline-recommended medication. However, gender-specific medication effectiveness, correlating the effectiveness of concomitant medication and variation in adherence over time, has not yet been considered. Methods: We aim to measure the effect of adherence on health care expenditures stratified by gender from a third-party payer's perspective in a sample of statutory insured Disease Management Program participants over a follow-up period of 3-years. In 3627 AMI patients, the proportion of days covered (PDC) for four guideline-recommended medications was calculated. A generalized additive mixed model was used, taking into account inter-individual effects (mean PDC rate) and intra-individual effects (deviation from the mean PDC rate). Results: Regarding inter-individual effects, for both sexes only anti-platelet agents had a significant negative influence indicating that higher mean PDC rates lead to higher costs. With respect to intra-individual effects, for females higher deviations from the mean PDC rate for angiotensin-converting enzyme (ACE) inhibitors, anti-platelet agents, and statins were associated with higher costs. Furthermore, for males, an increasing positive deviation from the PDC mean increases costs for β-blockers and a negative deviation decreases costs. For anti-platelet agents, an increasing deviation from the PDC-mean slightly increases costs. Conclusion: Positive and negative deviation from the mean PDC rate, independent of how high the mean was, usually negatively affect health care expenditures. Therefore, continuity in intake of guideline-recommended medication is important to save costs.
BMC Health Services Research

Decke, S.°; Deckert, K.; Lang, M.; Laub, O.; Loidl, V.; Schwettmann, L.; Grill, E.°
"We're in good hands there." - Acceptance, barriers and facilitators of a primary care-based health coaching programme

for children and adolescents with mental health problems: A qualitative study (PrimA-QuO).
BMC Fam. Pract. 21:273 (2020)
Background: 11.5 % of girls and 17.8 % of boys are affected by a mental health problem (MHP). The most prevalent problem areas are behavioural problems (girls/boys in %: 11.9/17.9), emotional problems (9.7/8.6) and hyperactivity problems (4.8/10.8). Primary care paediatricians are the first in line to be contacted. Nevertheless, even for less severely affected patients, referral rates to specialised care are constantly high. Therefore, a major statutory health insurance fund introduced a Health Coaching (HC) programme, including a training concept for paediatricians, standardised guidelines for actions and additional payments to strengthen primary care consultation for MHP and to decrease referrals to specialised care. The aim of this study was to examine how the HC is perceived and implemented in daily practice to indicate potential strengths and challenges. Methods: During a one-year period starting in November 2017, a series of guideline-based interviews were conducted by phone with HC-developers, HC-qualified paediatricians, parents and patients (≥14 years) treated according to the HC programme. Paediatricians were selected from a Bavarian practice network with a total of 577 HC qualified paediatricians. Parents of patients with the four most common MHP diagnoses were approached by their health insurance: [World Health Organization, 2013] developmental disorder of speech and language [Wille N, et al., 2008] head/abdominal pain (somatoform) [Holling H, et al., 2003-2006 and 2009-2012] conduct disorder [Plass-Christl A, et al., 2018] non-organic enuresis. 23 paediatricians, 314 parents and 10 adolescents consented to be interviewed. Potential participants were selected based on purposeful sampling, according to principles of maximum variance. All interviews were recorded and transcribed verbatim. Two researchers analysed the transcripts independently of each other. Structuring content analysis derived from Mayring was used for analysis. Results: 11 paediatricians, 3 co-developers, 22 parents and 4 adolescents were included. Families were generally satisfied with paediatric care received in the programme's context. The HC supported paediatricians' essential role as consultants and improved their diagnostic skills. Lack of time, financial restrictions and patients' challenging family structures were reported as major barriers to success. Conclusion: The HC programme is perceived as a facilitator for more patient-centred care. However, structural barriers remain. Starting points for improvement are further options to strengthen families' resources and expanded interdisciplinary networking.
BMC Family Practice

Herder, C.#; Schneider, A.E.#; Zhang, S.; Wolf, K.; Maalmi, H.; Huth, C.; Pickford, R.; Laxy, M.; Bönhof, G.J.; Koenig, W.; Rathmann, W.; Roden, M.; Peters, A.; Thorand, B.; Ziegler, D.
Association of long-term air pollution with prevalence and incidence of distal sensorimotor polyneuropathy: Kora F_4/FF_4 study.
Environ. Health Perspect. 128:127013 (2020)
BACKGROUND: Air pollution contributes to type 2 diabetes and cardiovascular diseases, but its relevance for other complications of diabetes, in partic-ular distal sensorimotor polyneuropathy (DSPN), is unclear. Recent studies have indicated that DSPN is also increasingly prevalent in obesity. OBJECTIVES: We aimed to assess associations of air pollutants with prevalent and incident DSPN in a population-based study of older individuals with high rates of type 2 diabetes and obesity. METHODS: Cross-sectional analyses on prevalent DSPN were based on 1,075 individuals 62–81 years of age from the German Cooperative Health Research in the Region of Augsburg (KORA) F4 survey (2006–2008). Analyses on incident DSPN included 424 individuals without DSPN at base-line (KORA F4), of whom 188 had developed DSPN by the KORA FF4 survey (2013–2014). Associations of annual average air pollutant concentrations at participants' residences with prevalent and incident DSPN were estimated using Poisson regression models with a robust error variance adjusting for multiple confounders. RESULTS: Higher particle number concentrations (PNCs) were associated with higher prevalence [risk ratio (RR) per interquartile range (IQR) increase = 1:10 (95% CI: 1.01, 1.20)] and incidence [1.11 (95% CI: 0.99, 1.24)] of DSPN. In subgroup analyses, particulate (PNC, PM10,PMcoarse, PM2:5, and PM2:5abs) and gaseous (NOx,NO2) pollutants were positively associated with prevalent DSPN in obese participants, whereas corresponding estimates for nonobese participants were close to the null [e.g., for an IQR increase in PNC, RR = 1:17 (95% CI: 1.05, 1.31) vs. 1.06 (95% CI: 0.95, 1.19); pinteraction =0:22]. With the exception of PM2:5abs, corresponding associations with incident DSPN were positive in obese participants but null or inverse for nonobese participants, with pinteraction ≤ 0:13 [e.g., for PNC, RR = 1:28 (95% CI: 1.08, 1.51) vs. 1.03 (95% CI: 0.90, 1.18); pinteraction =0:03]. DISCUSSION: Both particulate and gaseous air pollutants were positively associated with prevalent and incident DSPN in obese individuals. Obesity and air pollution may have synergistic effects on the development of DSPN. https://doi.org/10.1289/EHP7311.
Environmental Health Perspectives

Addala, A.; Auzanneau, M.; Miller, K.; Maier, W.; Foster, N.; Kapellen, T.; Walker, A.; Rosenbauer, J.; Maahs, D.M.; Holl, R.W.
A decade of disparities in diabetes technology use and HbA_{1c} in pediatric type 1 diabetes: A transatlantic comparison.
Diabetes Care 44, 133-140 (2020)
OBJECTIVE: As diabetes technology use in youth increases worldwide, inequalities in access may exacerbate disparities in hemoglobin A1c (HbA1c). We hypothesized that an increasing gap in diabetes technology use by socioeconomic status (SES) would be associated with increased HbA1c disparities. RESEARCH DESIGN AND METHODS: Participants aged <18 years with diabetes duration ≥1 year in the Type 1 Diabetes Exchange (T1DX, U.S., n = 16,457) and Diabetes Prospective Follow-up (DPV, Germany, n = 39,836) registries were categorized into lowest (Q1) to highest (Q5) SES quintiles. Multiple regression analyses compared the relationship of SES quintiles with diabetes technology use and HbA1c from 2010-2012 to 2016-2018. RESULTS: HbA1c was higher in participants with lower SES (in 2010-2012 and 2016-2018, respectively: 8.0% and 7.8% in Q1 and 7.6% and 7.5% in Q5 for DPV; 9.0% and 9.3% in Q1 and 7.8% and 8.0% in Q5 for T1DX). For DPV, the association between SES and HbA1c did not change between the two time periods, whereas for T1DX, disparities in HbA1c by SES increased significantly (P < 0.001). After adjusting for technology use, results for DPV did not change, whereas the increase in T1DX was no longer significant. CONCLUSIONS: Although causal conclusions cannot be drawn, diabetes technology use is lowest and HbA1c is highest in those of the lowest SES quintile in the T1DX, and this difference for

HbA1c broadened in the past decade. Associations of SES with technology use and HbA1c were weaker in the DPV registry.
Diabetes Care

Borgmann, S.; Gontscharuk, V.; Sommer, J.; Laxy, M.; Ernstmann, N.; Karl, F.; Rückert-Eheberg, I.-M.; Schwettmann, L.; Ladwig, K.-H.; Peters, A.; Icks, A.
Different information needs in subgroups of people with diabetes mellitus: A latent class analysis.
BMC Public Health 20:1901 (2020)
BACKGROUND: Current evidence suggests that the information needs of people with diabetes mellitus differ across patient groups. With a view to being able to provide individualized information, this study aims to identify (i) the diabetes-related information needs of people with diabetes mellitus; (ii) different subgroups of people with specific information needs; and (iii) associated characteristics of the identified subgroups, such as sociodemographic characteristics, diabetes-related comorbidities, and well-being. METHODS: This cross-sectional study was based on data from 837 respondents with diabetes mellitus who participated in the population-based KORA (Cooperative Health Research in the Augsburg Region) Health Survey 2016 in Southern Germany (KORA GEFU 4 study) (45.6% female, mean age 71.1 years, 92.8% Type 2 diabetes). Diabetes-related information needs were assessed with a questionnaire asking about patients' information needs concerning 11 diabetes-related topics, e.g. 'long-term complications' and 'treatment/therapy'. Subgroups of people with different information needs and associated characteristics were identified using latent class analysis. RESULTS: We identified the following four classes of people with different information needs: 'high needs on all topics', 'low needs on all topics', 'moderate needs with a focus on complications and diabetes in everyday life', and 'advanced needs with a focus on social and legal aspects and diabetes research'. The classes differed significantly in age, years of education, type of diabetes, diabetes duration, diabetes-related comorbidities, smoking behaviour, diabetes education, current level of information, and time preference. CONCLUSIONS: Knowledge about different patient subgroups can be useful for tailored information campaigns or physician-patient interactions. Further research is needed to analyse health care needs in these groups, changes in information needs over the course of the disease, and prospective health outcomes.
BMC Public Health

Lutter, J.; Jörres, R.A.; Welte, T.; Watz, H.; Waschki, B.; Alter, P.; Trudzinski, F.C.; Ohlander, J.; Behr, J.; Bals, R.; Studnicka, M.; Holle, R.; Vogelmeier, C.F.; Kahnert, K.
Impact of education on COPD severity and all-cause mortality in lifetime never-smokers and longtime ex-smokers: Results of the COSYCONET cohort.
Int. J. Chron. Obstruct. Pulmon. Dis. 15, 2787-2798 (2020)
Background: Beyond smoking, several risk factors for the development of chronic obstructive pulmonary disease (COPD) have been described, among which socioeconomic status including education is of particular interest. We studied the contribution of education to lung function and symptoms relative to smoking in a group of never-smokers with COPD compared to a group of long-time ex-smokers with COPD. Methods: We used baseline data of the COSYCONET cohort, including patients of GOLD grades 1-4 who were either never-smokers (n=150, age 68.5y, 53.3% female) or ex-smokers (≥10 packyears) for at least 10 years (n=616, 68.3y, 29.9% female). Socioeconomic status was analyzed using education level and mortality was assessed over a follow-up period of 4.5 years. Analyses were performed using ANOVA and regression models. Results: Spirometric lung function did not differ between groups, whereas CO diffusing capacity and indicators of lung hyperinflation/air-trapping showed better values in the never-smoker group. In both groups, spirometric lung function depended on the education level, with better values for higher education. Quality of life and 6-MWD were significantly different in never-smokers as well as patients with higher education. Asthma, alpha-1-antitrypsin deficiency, and bronchiectasis were more often reported in never-smokers, and asthma was more often reported in patients with higher education. Higher education was also associated with reduced mortality (hazard ratio 0.46; 95% CI 0.22-0.98). Conclusion: Overall, in the COSYCONET COPD cohort, differences in functional status between never-smokers and long-time ex-smokers were not large. Compared to that, the dependence on education level was more prominent, with higher education associated with better outcomes, including mortality. These data indicate that non-smoking COPD patients' socioeconomic factors are relevant and should be taken into account by clinicians.
International Journal of Chronic Obstructive Pulmonary Disease

Huber, M.B.; Kurz, C.F.; Kirsch, F.; Schwarzkopf, L.; Schramm, A.; Leidl, R.
The relationship between body mass index and health-related quality of life in COPD: Real-world evidence based on claims and survey data.
Respir. Res. 21:291 (2020)
Background Body mass index (BMI) is an important parameter associated with mortality and health-related quality of life (HRQoL) in chronic obstructive pulmonary disease (COPD). However, informed guidance on stratified weight recommendations for COPD is still lacking. This study aims to determine the association between BMI and HRQoL across different severity grades of COPD to support patient management. Methods We use conjunct analysis of claims and survey data based on a German COPD disease management program from 2016 to 2017. The EQ-5D-5L visual analog scale (VAS) and COPD Assessment Test (CAT) are used to measure generic and disease-specific HRQoL. Generalized additive models with smooth functions are implemented to evaluate the relationship between BMI and HRQoL, stratified by COPD severity. Results 11,577 patients were included in this study. Mean age was 69.4 years and 59% of patients were male. In GOLD grades 1-3, patients with BMI of around 25 had the best generic and disease-specific HRQoL, whereas in GOLD grade 4, obese patients had the best HRQoL using both instruments when controlled for several variables including smoking status, income, COPD severity, comorbidities, emphysema, corticosteroid use, and days spent in hospital. Conclusion This real-world analysis shows the non-linear relationship between BMI and HRQoL in COPD. HRQoL of obese patients with mild to severe COPD might improve following weight reduction. For very severe COPD, a negative association of obesity and HRQoL could not be confirmed. The results hint at the need to stratify COPD patients by disease stage for optimal BMI management.
Respiratory Research

König, A.

Domain-specific risk attitudes and aging—a systematic review.
J. Behav. Decis. Mak., DOI: 10.1002/bdm.2215 (2020)
Risk attitudes have a significant impact on human decision making. In contrast to the conventional assumption of stable, universal risk attitudes, previous research has found domain-specific and age-related differences in risk attitudes. For this reason, a systematic review including 19 studies was conducted to evaluate the relationship between self-reported risk attitudes and aging in different domains of decision making. The results suggest a negative relationship between aging and self-reported risk attitudes. Age-related differences in risk attitudes also vary between different domains. Nine studies examined general risk attitudes, with eight finding a negative relationship with aging. Eight out of 11 studies found a negative relationship in the financial domain. All nine studies in the health domain identified a negative association as well. The seven studies included in the social domain showed mixed results. All six studies in the recreational domain identified a negative association. Four out of five studies in the ethical domain found a negative relationship. The three studies included in the driving and career domain also showed negative relationships between risk attitudes and aging. Potential policy implications are discussed.
Journal of Behavioral Decision Making

Bauer, J.; Klingelhöfer, D.; Maier, W.; Schwettmann, L.; Groneberg, D.A.
Spatial accessibility of general inpatient care in Germany: An analysis of surgery, internal medicine and neurology.
Sci. Rep. 10:19157 (2020)
Improving spatial accessibility to hospitals is a major task for health care systems which can be facilitated using recent methodological improvements of spatial accessibility measures. We used the integrated floating catchment area (iFCA) method to analyze spatial accessibility of general inpatient care (internal medicine, surgery and neurology) on national level in Germany determining an accessibility index (AI) by integrating distances, hospital beds and morbidity data. The analysis of 358 million distances between hospitals and population locations revealed clusters of lower accessibility indices in areas in north east Germany. There was a correlation of urbanity and accessibility up to $r = 0.31$ ($p < 0.001$). Furthermore, 10% of the population lived in areas with significant clusters of low spatial accessibility for internal medicine and surgery (neurology: 20%). The analysis revealed the highest accessibility for heart failure (AI = 7.33) and the lowest accessibility for stroke (AI = 0.69). The method applied proofed to reveal important aspects of spatial accessibility i.e. geographic variations that need to be addressed. However, for the majority of the German population, accessibility of general inpatient care was either high or at least not significantly low, which suggests rather adequate allocation of hospital resources for most parts of Germany.
Scientific Reports

Kirsch, F.; Schramm, A.; Kurz, C.F.; Schwarzkopf, L.; Lutter, J.; Huber, M.B.; Leidl, R.
Effect of BMI on health care expenditures stratified by COPD GOLD severity grades: Results from the LQ-DMP study.
Respir. Med. 175:106194 (2020)
Chronic Obstructive Pulmonary Disease (COPD) is characterized by persistent respiratory symptoms and airflow limitation, which is progressive and not fully reversible. In patients with COPD, body mass index (BMI) is an important parameter associated with health outcomes, e.g. mortality and health-related quality of life. However, so far no study evaluated the association of BMI and health care expenditures across different COPD severity grades. We used claims data and documentation data of a Disease Management Program (DMP) from a statutory health insurance fund (AOK Bayern). Patients were excluded if they had less than 4 observations in the 8 years observational period. Generalized additive mixed models with smooth functions were used to evaluate the association between BMI and health care expenditures, stratified by severity of COPD, indicated by GOLD grades 1–4. We included 30,682 patients with overall 188,725 observations. In GOLD grades 1–3 we found an u-shaped relation of BMI and expenditures, where patients with a BMI of 30 or slightly above had the lowest and underweight and obese patients had the highest health care expenditures. Contrarily, in GOLD grade 4 we found an almost linear decline of health care expenditures with increasing BMI. In terms of expenditures, the often reported obesity paradox in patients with COPD was clearly reflected in GOLD grade 4, while in all other severity grades underweight as well as severely obese patients caused the highest health care expenditures. Reduction of obesity may thus reduce health care expenditures in GOLD grades 1–3.
Respiratory Medicine

Tarricone, R.; Ciani, O.; Torbica, A.; Brouwer, W.; Chaloutsos, G.; Drummond, M.F.; Martelli, N.; Persson, U.; Leidl, R.; Levin, L.; Sampietro-Colom, L.; Taylor, R.S.
Lifecycle evidence requirements for high-risk implantable medical devices: A European perspective.
Expert Rev. Med. Devices 17, 993-1006 (2020)
IntroductionThe new European Union (EU) Regulations on medical devices and on in vitro diagnostics provide manufacturers and Notified Bodies with new tools to improve pre-market and post-market clinical evidence generation especially for high-risk products but fail to indicate what type of clinical evidence is appropriate at each stage of the whole lifecycle of medical devices. In this paper we address: i) the appropriate level and timing of clinical evidence throughout the lifecycle of high-risk implantable medical devices; and ii) how the clinical evidence generation ecosystem could be adapted to optimize patient access.Areas coveredThe European regulatory and health technology assessment (HTA) contexts are reviewed, in relation to the lifecycle of high-risk medical devices and clinical evidence generation recommended by international network or endorsed by regulatory and HTA agencies in different jurisdictions.Expert opinionFour stages are relevant for clinical evidence generation: i) pre-clinical, pre-market; ii) clinical, pre-market; iii) diffusion, post-market; and iv) obsolescence & replacement, post-market. Each stage has its own evaluation needs and specific studies are recommended to generate the appropriate evidence. Effective lifecycle planning requires anticipation of what evidence will be needed at each stage.
Expert review of medical devices

Yang, W.; Cintina, I.; Hoerger, T.; Neuwahl, S.J.; Shao, H.; Laxy, M.; Zhang, P.
Estimating costs of diabetes complications in people <65 years in the U.S. using panel data.
J. Diab. Complic. 34:107735 (2020)
Aims: To estimate the cost of diabetes complications in the United States (U.S.). Methods: We constructed longitudinal

panel data using one of the largest claims databases in the U.S. for privately insured Type 1 (T1DM) and type 2 (T2DM) diabetes patients with a follow-up time of one to ten years. Complication costs were estimated both in years of the first occurrence and in subsequent years, using individual fixed-effects models. All costs were in 2016 dollars. Results: 47,166 people with T1DM and 608,237 with T2DM were included in our study. Aside from organ transplants, which were rare, the estimated average costs for the top three most costly conditions in the first vs. subsequent years were: end stage renal disease ($73,534 vs. $97,431 for T1DM; $94,231 vs. $98,981 for T2DM), congestive heart failure ($41,681 vs. $14,855 for T1DM; $31,202 vs. $7062 for T2DM), and myocardial infarction ($40,899 vs. $9496 for T1DM; $45,251 vs. $8572 for T2DM). For both diabetes types, retinopathy and neuropathy tend to have the lowest cost estimates. Conclusions: Our study provides the latest and most comprehensive cost estimates for a broad set of diabetes complications needed to evaluate the long-term cost-effectiveness of interventions for preventing and managing diabetes.
Journal of Diabetes and its Complications

Kurz, C.F.; Stafford, S.
Isolating cost drivers in interstitial lung disease treatment using nonparametric Bayesian methods.
Biom. J. 62, 1896-1908 (2020)
Mixture modeling is a popular approach to accommodate overdispersion, skewness, and multimodality features that are very common for health care utilization data. However, mixture modeling tends to rely on subjective judgment regarding the appropriate number of mixture components or some hypothesis about how to cluster the data. In this work, we adopt a nonparametric, variational Bayesian approach to allow the model to select the number of components while estimating their parameters. Our model allows for a probabilistic classification of observations into clusters and simultaneous estimation of a Gaussian regression model within each cluster. When we apply this approach to data on patients with interstitial lung disease, we find distinct subgroups of patients with differences in means and variances of health care costs, health and treatment covariates, and relationships between covariates and costs. The subgroups identified are readily interpretable, suggesting that this nonparametric variational approach to inference can discover valid insights into the factors driving treatment costs. Moreover, the learning algorithm we employed is very fast and scalable, which should make the technique accessible for a broad range of applications.
Biometrical Journal

Maqhuzu, P.N.; Szentes, B.L.; Kreuter, M.; Bahmer, T.; Kahn, N.; Claussen, M.; Holle, R.; Schwarzkopf, L.
Determinants of health-related quality of life decline in interstitial lung disease.
Health Qual. Life Outcomes 18:334 (2020)
BackgroundHealth-related quality of life (HRQL) in interstitial lung disease (ILD) patients is impaired. We aimed to identify baseline predictors for HRQL decline within a 12-month observation period. MethodsWe analyzed 194 ILD patients from two German ILD-centers in the observational HILDA study. We employed the disease-specific King's Brief Interstitial Lung Disease questionnaire (K-BILD) with the subdomains 'psychological impact', 'chest symptoms' and 'breathlessness and activities', and the generic EQ-5D Visual Analog Scale (VAS). We evaluated how many patients experienced a clinically meaningful decline in HRQL. Subsequently, we investigated medical and sociodemographic factors as potential predictors of HRQL deterioration.ResultsWithin the study population (34.0% male, O age 61.7) mean HRQL scores hardly changed between baseline and follow up (K-BILD: 52.8 vs. 52.5 | VAS: 60.0 vs. 57.3). On the intra-individual level, 30.4% (n=59) experienced a clinically relevant deterioration in K-BILD total score and 35.4% (n=68) in VAS. Lower baseline forced vital capacity (FVC) % predicted determined HRQL decline in K-BILD total score (ss -coefficient: - 0.02, p=0.007), VAS (ss -coefficient: - 0.03, p<0.0001), and in the subdomain 'psychological impact' (-coefficient: - 0.02, p=0.014). Lower baseline diffusing capacity of carbon monoxide (DLCO) % predicted determined deterioration in 'breathlessness and activities' (ss -coefficient: - 0.04, p=0.003) and 'chest symptoms' (ss -coefficient: - 0.04, p=0.002). Additionally, increasing age predicted decline in 'psychological impact' (ss -coefficient: 0.06, p<0.007).ConclusionAround a third of ILD patients experienced a clinically relevant HRQL deterioration in a 12-month period, which was associated with baseline lung function values in all K-BILD domains. As lung function values are time-dependent variables with possible improvements, in contrast to age and ILD subtype, it, thus, seems important to improve lung function and prevent its decline in order to maintain HRQL on the possibly highest level.
Health and Quality of Life Outcomes

Burns, J.; Movsisyan, A.; Stratil, J.M.; Coenen, M.; Emmert-Fees, K.; Geffert, K.; Hoffmann, S.; Horstick, O.; Laxy, M.; Pfadenhauer, L.M.; von Philipsborn, P.; Sell, K.; Voss, S.; Rehfuess, E.
Travel-related control measures to contain the COVID-19 pandemic: A rapid review.
Cochrane Database Syst. Rev. 2020:CD013717 (2020)
BackgroundIn late 2019, first cases of coronavirus disease 2019, or COVID-19, caused by the novel coronavirus SARS-CoV-2, were reported in Wuhan, China. Subsequently COVID-19 spread rapidly around the world. To contain the ensuing pandemic, numerous countries have implemented control measures related to international travel, including border closures, partial travel restrictions, entry or exit screening, and quarantine of travellers.ObjectivesTo assess the effectiveness of travel-related control measures during the COVID-19 pandemic on infectious disease and screening-related outcomes.Search methodsWe searched MEDLINE, Embase and COVID-19-specific databases, including the WHO Global Database on COVID-19 Research, the Cochrane COVID-19 Study Register, and the CDC COVID-19 Research Database on 26 June 2020. We also conducted backward-citation searches with existing reviews.Selection criteriaWe considered experimental, quasi-experimental, observational and modelling studies assessing the effects of travel-related control measures affecting human travel across national borders during the COVID-19 pandemic. We also included studies concerned with severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS) as indirect evidence. Primary outcomes were cases avoided, cases detected and a shift in epidemic development due to the measures. Secondary outcomes were other infectious disease transmission outcomes, healthcare utilisation, resource requirements and adverse effects if identified in studies assessing at least one primary outcome.Data collection and analysisOne review author screened titles and abstracts; all

excluded abstracts were screened in duplicate. Two review authors independently screened full texts. One review author extracted data, assessed risk of bias and appraised study quality. At least one additional review author checked for correctness of all data reported in the 'Risk of bias' assessment, quality appraisal and data synthesis. For assessing the risk of bias and quality of included studies, we used the Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2) tool for observational studies concerned with screening, ROBINS-1 for observational ecological studies and a bespoke tool for modelling studies. We synthesised findings narratively. One review author assessed certainty of evidence with GRADE, and the review author team discussed ratings.Main resultsWe included 40 records reporting on 36 unique studies. We found 17 modelling studies, 7 observational screening studies and one observational ecological study on COVID-19, four modelling and six observational studies on SARS, and one modelling study on SARS and MERS, covering a variety of settings and epidemic stages.Most studies compared travel-related control measures against a counterfactual scenario in which the intervention measure was not implemented. However, some modelling studies described additional comparator scenarios, such as different levels of travel restrictions, or a combination of measures.There were concerns with the quality of many modelling studies and the risk of bias of observational studies. Many modelling studies used potentially inappropriate assumptions about the structure and input parameters of models, and failed to adequately assess uncertainty. Concerns with observational screening studies commonly related to the reference test and the flow of the screening process.Studies on COVID-19Travel restrictions reducing cross-border travelEleven studies employed models to simulate a reduction in travel volume;one observational ecological study assessed travel restrictions in response to the COVID-19 pandemic.Very low-certainty evidence from modelling studies suggests that when implemented at the beginning of the outbreak, cross-border travel restrictions may lead to a reduction in the number of new cases of between 26% to 90% (4studies), the number of deaths(1study),the time to outbreak of between 2 and 26 days (2 studies),the risk of outbreak of between 1% to 37% (2 studies), and the effective reproduction number (1 modelling and 1 observational ecological study). Low-certainty evidence from modelling studies suggests a reduction in the number of imported or exported cases of between 70% to 81% (5 studies), and in the growth acceleration of epidemic progression (1study).Screening at borders with or without quarantineEvidence from three modelling studies of entry and exit symptom screening without quarantine suggests delays in the time to outbreak of between 1 to 183 days (very low-certainty evidence) and a detection rate of infected travellers of between 10% to 53% (low-certainty evidence).Six observational studies of entry and exit screening were conducted in specific settings such as evacuation flights and cruise ship outbreaks. Screening approaches varied but followed a similar structure, involving symptom screening of all individuals at departure or upon arrival, followed by quarantine, and different procedures for observation and PCR testing over a period of at least 14 days. The proportion of cases detected ranged from 0% to 91% (depending on the screening approach), and the positive predictive value ranged from 0% to 100% (very low-certainty evidence). The outcomes, however, should be interpreted in relation to both the screening approach used and the prevalence of infection among the travellers screened; for example, symptom-based screening alone generally performed worse than a combination of symptom-based and PCR screening with subsequent observation during quarantine.Quarantine of travellersEvidence from one modelling study simulating a 14-day quarantine suggests a reduction in the number of cases seeded by imported cases; larger reductions were seen with increasing levels of quarantine compliance ranging from 277 to 19 cases with rates of compliance modelled between 70% to 100% (very low-certainty evidence).Authors' conclusionsWith much of the evidence deriving from modelling studies, notably for travel restrictions reducing cross-border travel and quarantine of travellers, there is a lack of 'real-life' evidence for many of these measures. The certainty of the evidence for most travel-related control measures is very low and the true effects may be substantially different from those reported here. Nevertheless, some travel-related control measures during the COVID-19 pandemic may have a positive impact on infectious disease outcomes. Broadly, travel restrictions may limit the spread of disease across national borders. Entry and exit symptom screening measures on their own are not likely to be effective in detecting a meaningful proportion of cases to prevent seeding new cases within the protected region; combined with subsequent quarantine, observation and PCR testing, the effectiveness is likely to improve. There was insufficient evidence to draw firm conclusions about the effectiveness of travel-related quarantine on its own. Some of the included studies suggest that effects are likely to depend on factors such as the stage of the epidemic, the interconnectedness of countries, local measures undertaken to contain community transmission, and the extent of implementation and adherence.
Cochrane Database of Systematic Reviews

Walter, J.; Tufman, A.; Holle, R.; Schwarzkopf, L.
Differences in therapy and survival between lung cancer patients treated in hospitals with high and low patient case volume.
Health Policy 124, 1217-1225 (2020)
Background: In light of political discussions about minimum case volumes and certified lung cancer centers, this observational study investigates differences in therapy and survival between high vs. low patient volume hospitals (HPVH vs. LPVH).Methods: We identified 12,374 lung cancer patients treated in HPVH (>67 patients) and LPVH in 2013 from German health insurance claims. Stratified by metastasis status (no metastases, nodal metastases, systemic metastases), we compared HPVHs and LPVHs regarding likelihood of resection and systemic therapy, type of systemic therapy, and surgical outcomes, using multivariate logistic models. Three-year survival was modeled using Cox regression. We adjusted all regression models for age, gender, comorbidity, and residence area, and included a cluster variable for the hospital.Results: Around 24 % of patients were treated in HPVHs. Irrespective of stratum and subgroup, three-year survival was significantly better in HPVHs. In patients with systemic metastases (OR = 1.84, CI=[1.22,2.76]) and without metastases (OR = 3.28, CI=2.13, 5.04]), resection was more likely in HPVHs. Among patients with systemic therapy, the odds of receiving pemetrexed was higher in HPVHs, in patients with nodal metastases (OR = 1.57, CI=1.01,2.45]). In resected patients without metastases the odds ratio of receiving a thoracoscopic lobectomy was 2.28 (CI=1.04,4.99]) in HPVHs.Conclusion: Our data suggests that case volume is clinically relevant in resected and non-resected lung cancer

patients, but optimal minimum case volumes may differ for subgroups. (C) 2020 Published by Elsevier B.V.
Health Policy

Bauer, J.; Brüggmann, D.; Klingelhöfer, D.; Maier, W.; Schwettmann, L.; Weiss, D.J.; Groneberg, D.A.
Access to intensive care in 14 European countries: A spatial analysis of intensive care need and capacity in the light of COVID-19.
Intensive Care Med. 46, 2026-2034 (2020)
Purpose The coronavirus disease 2019 (COVID-19) poses major challenges to health-care systems worldwide. This pandemic demonstrates the importance of timely access to intensive care and, therefore, this study aims to explore the accessibility of intensive care beds in 14 European countries and its impact on the COVID-19 case fatality ratio (CFR). Methods We examined access to intensive care beds by deriving (1) a regional ratio of intensive care beds to 100,000 population capita (accessibility index, AI) and (2) the distance to the closest intensive care unit. The cross-sectional analysis was performed at a 5-by-5 km spatial resolution and results were summarized nationally for 14 European countries. The relationship between AI and CFR was analyzed at the regional level. Results We found national-level differences in the levels of access to intensive care beds. The AI was highest in Germany (AI = 35.3), followed by Estonia (AI = 33.5) and Austria (AI = 26.4), and lowest in Sweden (AI = 5) and Denmark (AI = 6.4). The average travel distance to the closest hospital was highest in Croatia (25.3 min by car) and lowest in Luxembourg (9.1 min). Subnational results illustrate that capacity was associated with population density and national-level inventories. The correlation analysis revealed a negative correlation of ICU accessibility and COVID-19 CFR ($r = -0.57; p < 0.001$). Conclusion Geographical access to intensive care beds varies significantly across European countries and low ICU accessibility was associated with a higher proportion of COVID-19 deaths to cases (CFR). Important differences in access are due to the sizes of national resource inventories and the distribution of health-care facilities relative to the human population. Our findings provide a resource for officials planning public health responses beyond the current COVID-19 pandemic, such as identifying potential locations suitable for temporary facilities or establishing logistical plans for moving severely ill patients to facilities with available beds.
Intensive Care Medicine

Kahnert, K.; Jörres, R.A.; Kauczor, H.U.; Biederer, J.; Jobst, B.; Alter, P.; Biertz, F.; Mertsch, P.; Lucke, T.; Lutter, J.; Trudzinski, F.C.; Behr, J.; Bals, R.; Watz, H.; Vogelmeier, C.F.; Welte, T.
Relationship between clinical and radiological signs of bronchiectasis in COPD patients: Results from COSYCONET.
Respir. Med. 172:106117 (2020)
Bronchiectasis (BE) might be frequently present in COPD but masked by COPD symptoms. We studied the relationship of clinical signs of bronchiectasis to the presence and extent of its radiological signs in patients of different COPD severity.Visit 4 data (GOLD grades 1-4) of the COSYCONET cohort was used. Chest CT scans were evaluated for bronchiectasis in 6 lobes using a 3-point scale (0: absence, 1: <= 50%, 2: >50% BE-involvement for each lobe).1176 patients were included (61%male, age 67.3y), among them 38 (3.2%) with reported physicians' diagnosis of bronchiectasis and 76 (6.5%) with alpha1-antitrypsin deficiency (AA1D). CT scans were obtained in 429 patients. Within this group, any signs of bronchiectasis were found in 46.6% of patients, whereby <= 50% BE occurred in 18.6% in <= 2 lobes, in 10.0% in 3-4 lobes, in 15.9% in 5-6 lobes; >50% bronchiectasis in at least 1 lobe was observed in 2.1%. Scores >= 4 correlated with an elevated ratio FRC/RV. The clinical diagnosis of bronchiectasis correlated with phlegm and cough and with radiological scores of at least 3, optimally >= 5.In COPD patients, clinical diagnosis and radiological signs of BE showed only weak correlations. Correlations became significant with increasing BE-severity implying radiological alterations in several lobes. This indicates the importance of reporting both presence and extent of bronchiectasis on CT. Further research is warranted to refine the criteria for CT scoring of bronchiectasis and to determine the relevance of radiologically but not clinically detectible bronchiectasis and their possible implications for therapy in COPD patients.
Respiratory Medicine

Olm, M.; Donnachie, E.; Tauscher, M.; Gerlach, R.; Linde, K.; Maier, W.; Schwettmann, L.; Schneider, A.
Impact of the abolition of copayments on the GP-centred coordination of care in Bavaria, Germany: Analysis of routinely collected claims data.
BMJ Open 10:e035575 (2020)
Objectives In 2012, Germany abolished copayment for consultations in ambulatory care. This study investigated the effect of the abolition on general practitioner (GP)-centred coordination of care. We assessed how the proportion of patients with coordinated specialist care changed over time when copayment to all specialist services were removed. Furthermore, we studied how the number of ambulatory emergency cases and apparent 'doctor shopping' changed after the abolition. Design A retrospective routine data analysis of the Bavarian Association of Statutory Health Insurance Physicians, comparing the years 2011 and 2012 (with copayment), with the period from 2013 to 2016 (without copayment). Therefore, time series analyses covering 24 quarters were performed. Setting Primary care in Bavaria, Germany. Participants All statutorily insured patients in Bavaria, aged >= 18 years, with at least one ambulatory specialist contact between 2011 and 2016. Primary and secondary outcome measures Primary outcome was the percentage of patients with GP-coordinated care (every regular specialist consultation within a quarter was preceded by a GP referral). Secondary outcomes were the number of ambulatory emergency cases and apparent 'doctor shopping'. Results After the abolition, the proportion of coordinated patients decreased from 49.6% (2011) to 15.5% (2016). Overall, younger patients and those living in areas with lower levels of deprivation showed the lowest proportions of coordination, which further decreased after abolition. Additionally, there were concomitant increases in the number of ambulatory emergency contacts and to a lesser extent in the number of patients with apparent 'doctor shopping'. Conclusions The abolition of copayment in Germany was associated with a substantial decrease in GP coordination of specialist care. This suggests that the copayment was a partly effective tool to support coordinated care. Future studies are required to investigate how the gatekeeping function of GPs in Germany can best be strengthened while minimising the associated administrative overhead.
BMJ Open

Ali, M.K.; Chwastiak, L.; Poongothai, S.; Emmert-Fees, K.; Patel, S.A.; Anjana, R.M.; Sagar, R.; Shankar, R.; Sridhar, G.R.; Kosuri, M.; Sosale, A.R.; Sosale, B.; Rao, D.; Tandon, N.; Narayan, K.M.V.; Mohan, V.
Effect of a collaborative care model on depressive symptoms and glycated hemoglobin, blood pressure, and serum cholesterol among patients with depression and diabetes in India. The INDEPENDENT randomized clinical trial.
JAMA 324, 651-662 (2020)
Importance Mental health comorbidities are increasing worldwide and worsen outcomes for people with diabetes, especially when care is fragmented. Objective To assess whether collaborative care vs usual care lowers depressive symptoms and improves cardiometabolic indices among adults with diabetes and depression. Design, Setting, and Participants Parallel, open-label, pragmatic randomized clinical trial conducted at 4 socioeconomically diverse clinics in India that recruited patients with type 2 diabetes; a Patient Health Questionnaire-9 score of at least 10 (range, 0-27); and hemoglobin A(1c)(HbA(1c)) of at least 8%, systolic blood pressure (SBP) of at least 140 mm Hg, or low-density lipoprotein (LDL) cholesterol of at least 130 mg/dL. The first patient was enrolled on March 9, 2015, and the last was enrolled on May 31, 2016; the final follow-up visit was July 14, 2018. Interventions Patients randomized to the intervention group (n = 196) received 12 months of self-management support from nonphysician care coordinators, decision support electronic health records facilitating physician treatment adjustments, and specialist case reviews; they were followed up for an additional 12 months without intervention. Patients in the control group (n = 208) received usual care over 24 months. Main Outcomes and Measures The primary outcome was the between-group difference in the percentage of patients at 24 months who had at least a 50% reduction in Symptom Checklist Depression Scale (SCL-20) scores (range, 0-4; higher scores indicate worse symptoms) and a reduction of at least 0.5 percentage points in HbA(1c), 5 mm Hg in SBP, or 10 mg/dL in LDL cholesterol. Prespecified secondary outcomes were percentage of patients at 12 and 24 months who met treatment targets (HbA(1c)<7.0%, SBP <130 mm Hg, LDL cholesterol <100 mg/dL [<70 mg/dL if prior cardiovascular disease]) or had improvements in individual outcomes (>= 50% reduction in SCL-20 score, >= 0.5-percentage point reduction in HbA(1c), >= 5-mm Hg reduction in SBP, >= 10-mg/dL reduction in LDL cholesterol); percentage of patients who met all HbA(1c), SBP, and LDL cholesterol targets; and mean reductions in SCL-20 score, Patient Health Questionnaire-9 score, HbA(1c), SBP, and LDL cholesterol. Results Among 404 patients randomized (mean [SD] age, 53 [8.6] years; 165 [40.8%] men), 378 (93.5%) completed the trial. A significantly greater percentage of patients in the intervention group vs the usual care group met the primary outcome (71.6% vs 57.4%; risk difference, 16.9% [95% CI, 8.5%-25.2%]). Of 16 prespecified secondary outcomes, there were no statistically significant between-group differences in improvements in 10 outcomes at 12 months and in 13 outcomes at 24 months. Serious adverse events in the intervention and usual care groups included cardiovascular events or hospitalizations (4 [2.0%] vs 7 [3.4%]), stroke (0 vs 3 [1.4%]), death (2 [1.0%] vs 7 [3.4%]), and severe hypoglycemia (8 [4.1%] vs 0). Conclusions and Relevance Among patients with diabetes and depression in India, a 12-month collaborative care intervention, compared with usual care, resulted in statistically significant improvements in a composite measure of depressive symptoms and cardiometabolic indices at 24 months. Further research is needed to understand the generalizability of the findings to other low- and middle-income health care settings.This randomized clinical trial compares the effect of a collaborative care model that integrates management of depression and enhanced diabetes care on depressive symptoms and HbA(1c), SBP, and LDL cholesterol measures among individuals with depression and diabetes in India.Question Among patients with diabetes and depression in India, does a 12-month collaborative care intervention that includes nonphysician care coordinators, decision support functions in electronic health records, and specialist case reviews improve depressive symptoms and measures of cardiometabolic health more than usual care at 24 months? Findings In this randomized clinical trial that included 404 patients at urban clinics in India with poorly controlled diabetes and depression, patients in the collaborative care intervention group, compared with the usual care group, were significantly more likely to achieve the composite outcome of at least a 50% reduction in the 20-item Symptom Checklist Depression Scale score and at least 1 of the following: reduction of at least 0.5 percentage points in hemoglobin A(1c), reduction of at least 5 mm Hg in systolic blood pressure, or reduction of at least 10 mg/dL in low-density lipoprotein cholesterol at 24 months (71.6% vs 54.7%). Meaning Among patients with diabetes and depressive symptoms in urban India, a multicomponent collaborative care intervention resulted in statistically significantly greater improvements in a composite measure of depressive symptoms and cardiometabolic indices compared with usual care.
JAMA: Journal of the American Medical Association

Perna, L.; Zhang, Y.; Matias-Garcia, P.R.; Ladwig, K.-H.; Wiechmann, T.; Wild, B.; Waldenberger, M.; Schöttker, B.; Mons, U.; Ihle, A.; Kliegel, M.; Schwettmann, L.; Peters, A.; Brenner, H.
Subjective mental health, incidence of depressive symptoms in later life, and the role of epigenetics: Results from two longitudinal cohort studies.
Transl. Psychiatry 10:323 (2020)
The role of self-perceived general health in predicting morbidity and mortality among older people is established. The predictive value of self-perceived mental health and of its possible biological underpinnings for future depressive symptoms is unexplored. This study aimed to assess the role of mental health-related quality of life (HRQOL) and of its epigenetic markers in predicting depressive symptoms among older people without lifetime history of depression. Data were based on a subgroup (n = 1 492) of participants of the longitudinal ESTHER study. An epigenome-wide association study (EWAS) of mental HRQOL was conducted using DNA from baseline whole blood samples and logistic regression analyses were performed to assess the predictive value of methylation beta values of EWAS identified CpGs for incidence of depressive symptoms in later life. The methylation analyses were replicated in the independent KORA cohort (n = 890) and a meta-analysis of the two studies was conducted. Results of the meta-analysis showed that participants with beta values of cg27115863 within quartile 1 (Q(1)) had nearly a two-fold increased risk of developing depressive symptoms compared to participants with beta values within Q(4) (ORQ1vsQ4 = 1.80; CI 1.25-2.61). In the ESTHER study the predictive value of subjective mental health for future depressive symptoms was also assessed and for 10-unit

increase in mental HRQOL scores the odds for incident depressive symptoms were reduced by 54% (OR 0.46; CI 0.40-0.54). These findings suggest that subjective mental health and hypomethylation at cg27115863 are predictive of depressive symptoms, possibly through the activation of inflammatory signaling pathway.
Translational Psychiatry

Huang, J.; Huth, C.; Covic, M.; Troll, M.; Adam, J.; Zukunft, S.; Prehn, C.; Wang, L.; Nano, J.; Scheerer, M.F.; Neschen, S.; Kastenmüller, G.; Suhre, K.; Laxy, M.; Schliess, F.; Gieger, C.; Adamski, J.; Hrabě de Angelis, M.; Peters, A.; Wang-Sattler, R.
Machine learning approaches reveal metabolic signatures of incident chronic kidney disease in individuals with prediabetes and type 2 diabetes.
Diabetes 69, 2756-2765 (2020)
Early and precise identification of individuals with pre-diabetes and type 2 diabetes (T2D) at risk for progressing to chronic kidney disease (CKD) is essential to prevent complications of diabetes. Here, we identify and evaluate prospective metabolite biomarkers and the best set of predictors of CKD in the longitudinal, population-based Cooperative Health Research in the Region of Augsburg (KORA) cohort by targeted metabolomics and machine learning approaches. Out of 125 targeted metabolites, sphingomyelin C18:1 and phosphatidylcholine diacyl C38:0 were identified as candidate metabolite biomarkers of incident CKD specifically in hyperglycemic individuals followed during 6.5 years. Sets of predictors for incident CKD developed from 125 metabolites and 14 clinical variables showed highly stable performances in all three machine learning approaches and outperformed the currently established clinical algorithm for CKD. The two metabolites in combination with five clinical variables were identified as the best set of predictors, and their predictive performance yielded a mean area value under the receiver operating characteristic curve of 0.857. The inclusion of metabolite variables in the clinical prediction of future CKD may thus improve the risk prediction in people with prediabetes and T2D. The metabolite link with hyperglycemia-related early kidney dysfunction warrants further investigation.
Diabetes

Becker, J.; Bose-O'Reilly, S.; Shoko, D.; Singo, J.; Steckling-Muschack, N.
Comparing the self-reported health-related quality of life (HRQoL) of artisanal and small-scale gold miners and the urban population in Zimbabwe using the EuroQol (EQ-5D-3L+C) questionnaire: A cross-sectional study.
Health Qual. Life Outcomes 18:253 (2020)
Background The role of artisanal and small-scale gold mining (ASGM) as a source of income is rapidly gaining importance in the economically difficult times in Zimbabwe. Besides limited epidemiological data, no data about the self-reported health-related quality of life (HRQoL) of artisanal and small-scale gold miners exist. The aim of the project was to access HRQoL of ASGM workers to improve the data base and compare the data to the urban Zimbabwean population. Methods Data from 83 artisanal and small-scale gold miners in Kadoma, Zimbabwe was analysed. The HRQoL was assessed using the EuroQol dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) accompanied by the cognition add-on questionnaire (EQ-5D-3L+C) and associated visual analogue scale (VAS). We described the EQ-5D dimensions and VAS values and computed health utility (HU) values using the Zimbabwean tariff. The proportions of miners reporting no problem in each EQ-5D dimension were compared with corresponding proportions reporting any problem (moderate or severe), and mean HU and VAS values were analysed across subgroups of the sample. To test differences between subgroups, Fisher's exact test was used and between urban and mining population, Student's t-test was used. Results The reported health states of miners were homogenous, with a large amount (42%) reporting 'full health'. Mean (SD) VAS and HU values were 81.0 (17.5) and 0.896 (0.13), respectively. Subgroup analysis showed that miners with a lower education reported significantly more problems in the dimension of daily activities and miners with mercury contact had more problems in the dimensions of pain/discomfort and cognition. Comparison between mining and urban population showed that in the oldest age group, self-rated VAS values of miners were significantly higher than of their urban counterparts. Conclusions There were no significant differences in the HRQoL of mining and urban populations. However, the reason might be adverse health effects faced by the urban population that do not apply to rural mining areas. A higher education level of miners can improve the HRQoL, which is especially impaired by problems in the cognition dimension.
Health and Quality of Life Outcomes

Greiner, G.; Emmert-Fees, K.; Becker, J.; Rathmann, W.; Thorand, B.; Peters, A.; Quante, A.S.; Schwettmann, L.; Laxy, M.
Toward targeted prevention: Risk factors for prediabetes defined by impaired fasting glucose, impaired glucose tolerance and increased HbA1c in the population-based KORA study from Germany.
Acta Diabetol. 57, 1481-1491 (2020)
Aims To identify socioeconomic, behavioral and clinical factors that are associated with prediabetes according to different prediabetes definition criteria. Methods Analyses use pooled data of the population-based Cooperative Health Research in the Region of Augsburg (KORA) studies (n = 5312 observations aged >= 38 years without diabetes). Prediabetes was defined through either impaired fasting glucose (IFG), impaired glucose tolerance (IGT) or elevated HbA1c according to thresholds of the American Diabetes Association. Explanatory variables were regressed on prediabetes using generalized estimating equations. Results Mean age was 58.4 years; 50% had prediabetes (33% had IFG, 16% IGT, and 26% elevated HbA1c, 10% fulfilled all three criteria). Age, obesity, hypertension, low education, unemployment, statutory health insurance, urban residence and physical inactivity were associated with prediabetes. Male sex was a stronger risk factor for IFG (OR = 2.5; 95%-CI: 2.2-2.9) than for IGT or elevated HbA1c, and being unemployed was a stronger risk factor for IGT (OR = 3.2 95%-CI: 2.6-4.0) than for IFG or elevated HbA1c. Conclusions The overlap of people with IFG, IGT and elevated HbA1c is small, and some factors are associated with only one criterion. Knowledge on sociodemographic and socioeconomic risk factors can be used to effectively target interventions to people at high risk for type 2 diabetes.
Acta Diabetologica

Islek, D.; Weber, M.B.; Ranjit Mohan, A.; Mohan, V.; Staimez, L.R.; Harish, R.; Narayan, K.M.V.; Laxy, M.; Ali, M.K.

Cost-effectiveness of a Stepwise Approach vs Standard Care for Diabetes Prevention in India.
JAMA net. open 3:e207539 (2020)
Question Is a stepwise approach to identifying, delaying, and preventing diabetes in individuals with high risk in a low-income to middle-income country setting cost-effective? Findings In this economic evaluation study, conducted within a randomized clinical trial during a 3-year period, it would cost 145 international dollars to screen for and reduce diabetes incidence by 1 percentage point, 14 & x202f;539 international dollars per diabetes case prevented and/or delayed, and 14 & x202f;986 international dollars per quality-adjusted life-year gained. Meaning The findings of this study suggest that a stepwise approach for identification of high-risk individuals and diabetes prevention is likely cost-effective, even in a low-income to middle-income country setting.This economic evaluation estimates the cost-effectiveness of a stepwise approach to diabetes prevention among adults in India participating in the Diabetes Community Lifestyle Improvement Program.Importance A stepwise approach that includes screening and lifestyle modification followed by the addition of metformin for individuals with high risk of diabetes is recommended to delay progression to diabetes; however, there is scant evidence regarding whether this approach is cost-effective. Objective To estimate the cost-effectiveness of a stepwise approach in the Diabetes Community Lifestyle Improvement Program. Design, Setting, and Participants This economic evaluation study included 578 adults with impaired glucose tolerance, impaired fasting glucose, or both. Participants were enrolled in the Diabetes Community Lifestyle Improvement Program, a randomized clinical trial with 3-year follow-up conducted at a diabetes care and research center in Chennai, India. Interventions The intervention group underwent a 6-month lifestyle modification curriculum plus stepwise addition of metformin; the control group received standard lifestyle advice. Main Outcomes and Measures Cost, health benefits, and incremental cost-effectiveness ratios (ICERs) were estimated from multipayer (including direct medical costs) and societal (including direct medical and nonmedical costs) perspectives. Costs and ICERs were reported in 2019 Indian rupees (INR) and purchasing power parity-adjusted international dollars (INT $). Results The mean (SD) age of the 578 participants was 44.4 (9.3) years, and 364 (63.2%) were men. Mean (SD) body mass index was 27.9 (3.7), and the mean (SD) glycated hemoglobin level was 6.0% (0.5). Implementing lifestyle modification and metformin was associated with INR 10 & x202f;549 (95% CI, INR 10 & x202f;134-10 & x202f;964) (INT $803 [95% CI, INT $771-834]) higher direct costs; INR 5194 (95% CI, INR 3187-INR 7201) (INT $395; 95% CI, INT $65-147) higher direct nonmedical costs, an absolute diabetes risk reduction of 10.2% (95% CI, 1.9% to 18.5%), and an incremental gain of 0.099 (95% CI, 0.018 to 0.179) quality-adjusted life-years per participant. From a multipayer perspective (including screening costs), mean ICERs were INR 1912 (INT $145) per 1 percentage point diabetes risk reduction, INR 191 & x202f;090 (INT $14 & x202f;539) per diabetes case prevented and/or delayed, and INR 196 & x202f;960 (INT $14 & x202f;986) per quality-adjusted life-year gained. In the scenario of a 50% increase or decrease in screening and intervention costs, the mean ICERs varied from INR 855 (INT $65) to INR 2968 (INT $226) per 1 percentage point diabetes risk reduction, from INR 85 & x202f;495 (INT $6505) to INR 296 & x202f;681 (INT $22 & x202f;574) per diabetes case prevented, and from INR 88 & x202f;121 (INT $6705) to INR 305 & x202f;798 (INT $23 & x202f;267) per quality-adjusted life-year gained. Conclusions and Relevance The findings of this study suggest that a stepwise approach for diabetes prevention is likely to be cost-effective, even if screening costs for identifying high-risk individuals are added.
JAMA network open

Milivojevic, M.; Che, X.; Bateman, L.; Cheng, A.; Garcia, B.A.; Hornig, M.; Huber, M.B.; Klimas, N.G.; Lee, B.; Lee, H.; Levine, S.; Montoya, J.G.; Peterson, D.L.; Komaroff, A.L.; Lipkin, W.I.
Plasma proteomic profiling suggests an association between antigen driven clonal B cell expansion and ME/CFS.
PLoS ONE 15:e0236148 (2020)
Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) is an unexplained chronic, debilitating illness characterized by fatigue, sleep disturbances, cognitive dysfunction, orthostatic intolerance and gastrointestinal problems. Using ultra performance liquid chromatography-tandem mass spectrometry (UPLC-MS/MS), we analyzed the plasma proteomes of 39 ME/CFS patients and 41 healthy controls. Logistic regression models, with both linear and quadratic terms of the protein levels as independent variables, revealed a significant association between ME/CFS and the immunoglobulin heavy variable (IGHV) region 3-23/30. Stratifying the ME/CFS group based on self-reported irritable bowel syndrome (sr-IBS) status revealed a significant quadratic effect of immunoglobulin lambda constant region 7 on its association with ME/CFS with sr-IBS whilst IGHV3-23/30 and immunoglobulin kappa variable region 3-11 were significantly associated with ME/CFS without sr-IBS. In addition, we were able to predict ME/CFS status with a high degree of accuracy (AUC = 0.774-0.838) using a panel of proteins selected by 3 different machine learning algorithms: Lasso, Random Forests, and XGBoost. These algorithms also identified proteomic profiles that predicted the status of ME/CFS patients with sr-IBS (AUC = 0.806-0.846) and ME/CFS without sr-IBS (AUC = 0.754-0.780). Our findings are consistent with a significant association of ME/CFS with immune dysregulation and highlight the potential use of the plasma proteome as a source of biomarkers for disease.
PLoS ONE

Bauer, J.; Klingelhöfer, D.; Maier, W.; Schwettmann, L.; Groneberg, D.A.
Prediction of hospital visits for the general inpatient care using floating catchment area methods: A reconceptualization of spatial accessibility.
Int. J. Health Geogr. 19:29 (2020)
Background The adequate allocation of inpatient care resources requires assumptions about the need for health care and how this need will be met. However, in current practice, these assumptions are often based on outdated methods (e.g. Hill-Burton Formula). This study evaluated floating catchment area (FCA) methods, which have been applied as measures of spatial accessibility, focusing on their ability to predict the need for health care in the inpatient sector in Germany. Methods We tested three FCA methods (enhanced (E2SFCA), modified (M2SFCA) and integrated (iFCA)) for their accuracy in predicting hospital visits regarding six medical diagnoses (atrial flutter/fibrillation, heart failure, femoral fracture, gonarthrosis, stroke, and epilepsy) on national level in Germany. We further used the closest provider approach for benchmark purposes.

The predicted visits were compared with the actual visits for all six diagnoses using a correlation analysis and a maximum error from the actual visits of +/- 5%, +/- 10% and +/- 15%. Results The analysis of 229 million distances between hospitals and population locations revealed a high and significant correlation of predicted with actual visits for all three FCA methods across all six diagnoses up to rho = 0.79 (p < 0.001). Overall, all FCA methods showed a substantially higher correlation with actual hospital visits compared to the closest provider approach (up to rho = 0.51; p < 0.001). Allowing a 5% error of the absolute values, the analysis revealed up to 13.4% correctly predicted hospital visits using the FCA methods (15% error: up to 32.5% correctly predicted hospital). Finally, the potential of the FCA methods could be revealed by using the actual hospital visits as the measure of hospital attractiveness, which returned very strong correlations with the actual hospital visits up to rho = 0.99 (p < 0.001). Conclusion We were able to demonstrate the impact of FCA measures regarding the prediction of hospital visits in non-emergency settings, and their superiority over commonly used methods (i.e. closest provider). However, hospital beds were inadequate as the measure of hospital attractiveness resulting in low accuracy of predicted hospital visits. More reliable measures must be integrated within the proposed methods. Still, this study strengthens the possibilities of FCA methods in health care planning beyond their original application in measuring spatial accessibility.
International journal of health geographics

Lutter, J.; Lukas, M.; Schwarzkopf, L.; Jörres, R.A.; Studnicka, M.; Kahnert, K.; Karrasch, S.; Bewig, B.; Vogelmeier, C.F.; Holle, R.
Utilization and determinants of use of non-pharmacological interventions in COPD: Results of the COSYCONET cohort.
Respir. Med. 171:106087 (2020)
Background: Guidelines for chronic obstructive pulmonary disease (COPD) recommend supplementing pharmacotherapy with non-pharmacological interventions. Little is known about the use of such interventions by patients. We analyzed the utilization of a number of non-pharmacological interventions and identified potential determinants of use.Methods: Based on self-reports, use of interventions (smoking cessation, influenza vaccination, physiotherapy, sports program, patient education, pulmonary rehabilitation) and recommendation to use were assessed in 1410 patients with COPD. The utilization was analyzed according to sex and severity of disease. Potential determinants of utilization included demographic variables and disease characteristics and were analyzed using logistic regression models.Results: Influenza vaccination in the previous autumn/winter was reported by 73% of patients. About 19% were currently participating in a reimbursed sports program, 10% received physiotherapy, 38% were ever enrolled in an educational program, and 34% had ever participated in an outpatient or inpatient pulmonary rehabilitation program. Out of 553 current or former smokers, 24% had participated in a smoking cessation program. While reports of having received a recommendation to use mainly did not differ according to sex, women showed significantly (p < 0.05) higher utilization rates than men for all interventions except influenza vaccination. Smoking was a predictor for not having received a recommendation for utilization and also significantly associated with a reduced odds of utilization. We found a correlation between recommendation to use and utilization.Conclusions: Utilization of non-pharmacological interventions was lower in men and smokers. A recommendation or offer to use by the physician could help to increase uptake.
Respiratory Medicine

Beyerlein, A.; Lack, N.; Maier, W.
Associations of area-level deprivation with adverse obstetric and perinatal outcomes in Bavaria, Germany: Results from a cross-sectional study.
PLoS ONE 15:e0236020 (2020)
Background We investigated associations of area-level deprivation with obstetric and perinatal outcomes in a large population-based routine dataset. Methods We used the data of n = 827,105 deliveries who were born in hospitals between 2009 to 2016 in Bavaria, Germany. The Bavarian Index of Multiple Deprivation (BIMD) on district level was assigned to each mother by the zip code of her residential address. We calculated odds ratios (ORs) with 95% confidence intervals (CIs) for preterm deliveries, Caesarian sections (CS), stillbirths, small for gestational age (SGA) births and low 5-minute Apgar scores by BIMD quintiles with and without adjustment for potential confounders. Results We observed a significantly increased risk for preterm deliveries in mothers from the most deprived compared to the least deprived districts (e.g. OR [95% CI] for highest compared to lowest deprivation quintile: 1.06 [1.03, 1.09]) in adjusted analyses. Increased deprivation was also associated with higher SGA and secondary CS rates, but with lower proportions of stillbirths, primary CS and low Apgar scores. When one large clinic with an unusually high stillbirth rate was excluded, the association of BIMD with stillbirths was attenuated and almost disappeared. Conclusions We found that area-level deprivation in Bavaria was positively associated with preterm and SGA births, confirming previous studies. In contrast, the finding of an inverse association between deprivation and both stillbirth rates and low Apgar score came somewhat surprising. However, we conclude that the stillbirths finding is spurious and reflects regional bias due to a clinic which seems to specialize in termination of pregnancies.
PLoS ONE

Teni, F.S.; Burström, K.; Berg, J.; Leidl, R.; Rolfson, O.
Predictive ability of the American Society of Anaesthesiologists physical status classification system on health-related quality of life of patients after total hip replacement: Comparisons across eight EQ-5D-3L value sets.
BMC Musculoskelet. Disord. 21:441 (2020)
Background American Society of Anaesthesiologists (ASA) physical status classification system and its association with postoperative outcomes has been studied in different diseases. However, there is a paucity of studies on the relationship between ASA class and postoperative health-related quality of life (HRQoL) outcomes following total hip replacement (THR).The aim of this study was to assess the discriminative abilities of EQ-5D-3L value sets from Sweden, Germany, Denmark and the United Kingdom in relation to ASA classes and these value sets' abilities to show the predictive performance of ASA classes on HRQoL among THR patients in Sweden.MethodsA longitudinal study was conducted using data of patients in the Swedish Hip Arthroplasty Register who underwent THR between 2008 and 2016. We included 69,290 pre- and 1-year postoperative records and 21,305 6-year postoperative records. The study examined three experience-

based EQ-5D-3L value sets (the Swedish VAS and TTO and the German VAS) and five hypothetical value sets (TTO from Germany and VAS and TTO value sets from Denmark and the UK each). Using linear models, the abilities of the value sets to discriminate among ASA classes and to show the predictive performance of ASA classes on HRQoL score were assessed.ResultsAll value sets differentiated among ASA classes and showed the predictive effect of ASA classes on HRQoL. ASA classes were found to predict HRQoL consistently for all value sets investigated, with small variations in prediction error among the models.ConclusionASA classes of patients undergoing THR predicted HRQoL scores significantly and consistently, indicating their importance in tailoring care for patients.
BMC Musculoskeletal Disorders

Laxy, M.; Zhang, P.; Ng, B.P.; Shao, H.; Ali, M.K.; Albright, A.L.; Gregg, E.W.
Implementing lifestyle change interventions to prevent type 2 diabetes in US medicaid programs: Cost effectiveness, and cost, health, and health equity impact.
Appl. Health Econ. Health Policy 18, 713-726 (2020)
Background Lifestyle change interventions (LCI) for prevention of type 2 diabetes are covered by Medicare, but rarely by US Medicaid programs that constitute the largest public payer system in the USA. We estimate the long-term health and economic implications of implementing LCIs in state Medicaid programs. Methods We compared LCIs modeled after the intervention of the Diabetes Prevention Program versus routine care advice using a decision analytic simulation model and best available data from representative surveys, cohort studies, Medicaid claims data, and the published literature. Target population were non-disability-based adult Medicaid beneficiaries aged 19-64 years at high risk for type 2 diabetes (BMI >= 25 kg/m(2)and HbA1c >= 5.7% or fasting plasma glucose >= 110 mg/dl) from eight study states (Alabama, California, Connecticut, Florida, Iowa, Illinois, New York, Oklahoma) that represent around 50% of the US Medicaid population. Incremental cost-effectiveness ratios (ICERs) measured in cost per quality-adjusted life years (QALYs) gained, and population cost and health impact were modeled from a healthcare system perspective and a narrow Medicaid perspective. Results In the eight selected study states, 1.9 million or 18% of non-disability-based adult Medicaid beneficiaries would belong to the eligible high-risk target population - 66% of them Hispanics or non-Hispanic black. In the base-case analysis, the aggregated 5- and 10-year ICERs are US$226 k/QALY and US$34 k/QALY; over 25 years, the intervention dominates routine care. The 5-, 10-, and 25-year probabilities that the ICERs are below US$50 k (US$100 k)/QALY are 6% (15%), 59% (82%) and 96% (100%). From a healthcare system perspective, initial program investments of US$800 per person would be offset after 13 years and translate to US$548 of savings after 25 years. With a 20% LCI uptake in eligible beneficiaries, this would translate to upfront costs of US$300 million, prevent 260 thousand years of diabetes and save US$205 million over a 25-year time horizon. Cost savings from a narrow Medicaid perspective would be much smaller. Minorities and low-income groups would over-proportionally benefit from LCIs in Medicaid, but the impact on population health and health equity would be marginal. Conclusions In the long-term, investments in LCIs for Medicaid beneficiaries are likely to improve health and to decrease healthcare expenditures. However, population health and health equity impact would be low and healthcare expenditure savings from a narrow Medicaid perspective would be much smaller than from a healthcare system perspective.
Applied Health Economics and Health Policy

Mason, M.J.; Schinke, C.; Eng, C.L.P.; Towfic, F.; Gruber, F.; Dervan, A.; White, B.S.; Pratapa, A.; Guan, Y.; Chen, H.; Cui, Y.; Li, B.; Yu, T.; Chaibub Neto, E.; Mavrommatis, K.; Ortiz, M.; Lyzogubov, V.; Bisht, K.; Dai, H.Y.; Schmitz, F.; Flynt, E.; Dan Rozelle; Danziger, S.A.; Ratushny, A.; Dalton, W.S.; Goldschmidt, H.P.; Avet-Loiseau, H.; Samur, M.; Hayete, B.; Sonneveld, P.; Shain, K.H.; Munshi, N.; Auclair, D.; Hose, D.; Morgan, G.; Trotter, M.; Bassett, D.; Goke, J.; Walker, B.A.; Thakurta, A.; Multiple Myeloma DREAM Consortium (Kurz, C.F.)
Multiple Myeloma DREAM Challenge reveals epigenetic regulator PHF19 as marker of aggressive disease.
Leukemia 34, 1866–1874 (2020)
While the past decade has seen meaningful improvements in clinical outcomes for multiple myeloma patients, a subset of patients does not benefit from current therapeutics for unclear reasons. Many gene expression-based models of risk have been developed, but each model uses a different combination of genes and often involves assaying many genes making them difficult to implement. We organized the Multiple Myeloma DREAM Challenge, a crowdsourced effort to develop models of rapid progression in newly diagnosed myeloma patients and to benchmark these against previously published models. This effort lead to more robust predictors and found that incorporating specific demographic and clinical features improved gene expression-based models of high risk. Furthermore, post-challenge analysis identified a novel expression-based risk marker, PHF19, which has recently been found to have an important biological role in multiple myeloma. Lastly, we show that a simple four feature predictor composed of age, ISS, and expression of PHF19 and MMSET performs similarly to more complex models with many more gene expression features included.
Leukemia

Pedron, S.[#]; Maier, W.[#]; Peters, A.; Linkohr, B.; Meisinger, C.; Rathmann, W.; Eibich, P.; Schwettmann, L.
The effect of retirement on biomedical and behavioral risk factors for cardiovascular and metabolic disease.
Econ. Hum. Biol. 38:100893 (2020)
Retirement is a major life event potentially associated with changes in relevant risk factors for cardiovascular and metabolic conditions. This study analyzes the effect of retirement on behavioral and biomedical risk factors for chronic disease, together with subjective health parameters using Southern German epidemiological data. We used panel data from the KORA cohort study, consisting of 11,168 observations for individuals 45–80 years old. Outcomes included health behavior (alcohol, smoking, physical activity), biomedical risk factors (BMI, waist-to-hip ratio (WHR), glycosylated hemoglobin (HbA1c), total cholesterol/HDL quotient, systolic/diastolic blood pressure), and subjective health (SF12 mental and physical, self-rated health). We applied a parametric regression discontinuity design based on age thresholds for pension eligibility. Robust results after p-value corrections for multiple testing showed an increase in BMI in early retirees (at the age of 60) [β = 1.11, corrected p-

val. < 0.05] and an increase in CHO/HDL in regular retirees (age 65) [β = 0.47, corrected p-val. < 0.05]. Stratified analyses indicate that the increase in BMI might be driven by women and low-educated individuals retiring early, despite increases in the level of physical activity. The increase in CHO/HDL might be driven by men retiring regularly, alongside an increase in subjective physical health. Blood pressure also increased, but the effect differs by retirement timing and sex and is not always robust to sensitivity analysis checks. Our study indicates that retirement has an impact on different risk factors for chronic disease, depending on timing, gender and education. Regular male, early female, and low-educated retirees should be further investigated as potential high-risk groups for worsening risk factors after retirement. Future research should investigate if and how these results are linked: in fact, especially in the last two groups, the increases in leisure time physical activity might not be enough to compensate for the loss of work related physical activity, leading thus to an increase in BMI.
Economics and Human Biology

Beller, J.; Bauersachs, J.; Schäfer, A.; Schwettmann, L.; Heier, M.; Peters, A.; Meisinger, C.; Geyer, S.
Diverging trends in age at first myocardial infarction: Evidence from two German population-based studies.
Sci. Rep. 10:9610 (2020)
Little is known about trends in the age of onset of first myocardial infarction. Thus, we examined trends in the age of onset distribution of first myocardial infarction using two population-based datasets from Germany. First, we used German claims data based on an annual case number of approximately 2 million women and men covering the period from 2006 to 2016. Second, we used data from the KORA (Cooperative Health Research in the Region of Augsburg) Myocardial Infarction Registry covering the period from 2000-2016. Analyses were performed by means of quantile regression to estimate trends across the whole distribution of age of onset. Overall, N-Sample 1=69627 and N-Sample 2=9954 first myocardial infarctions were observed. In both samples, we found highly heterogeneous trends in age of onset. In men, we consistently found that age of onset increased before 50 and after 70 but decreased within this age bracket. For women, on the other hand, we consistently found that age of onset decreased for first myocardial infarctions before 70 but increased slightly or remained relatively stable thereafter. Therefore, late myocardial infarctions tended to occur later in life, while regular myocardial infarctions tended to occur earlier. These results suggest that in myocardial infarction, both morbidity compression and morbidity expansion might have occurred at the same time but for different parts of the age at onset distribution.
Scientific Reports

Maqhuzu, P.N.; Szentes, B.L.; Kreuter, M.; Bahmer, T.; Kahn, N.C.; Claussen, M.; Holle, R.; Schwarzkopf, L.
Predictors of health-related quality of life decline in intersitial lung disease using the K-bild questionnaire.
Value Health 23, S360-S360 (2020)
Value in Health
Meeting abstract

Jansen, L.; Behrens, G.; Finke, I.; Maier, W.; Gerken, M.; Pritzkuleit, R.; Holleczek, B.; Brenner, H.
Area-based socioeconomic inequalities in colorectal cancer survival in Germany: Investigation based on population-based clinical cancer registration.
Front. Oncol. 10:857 (2020)
Background:Socioeconomic inequalities in colorectal cancer survival have been observed in many countries. To overcome these inequalities, the underlying reasons must be disclosed. Methods:Using data from three population-based clinical cancer registries in Germany, we investigated whether associations between area-based socioeconomic deprivation and survival after colorectal cancer depended on patient-, tumor- or treatment-related factors. Patients with a diagnosis of colorectal cancer in 2000-2015 were assigned to one of five deprivation groups according to the municipality of the place of residence using the German Index of Multiple Deprivation. Cox proportional hazards regression models with various levels of adjustment and stratifications were applied. Results:Among 38,130 patients, overall 5-year survival was 4.8% units lower in the most compared to the least deprived areas. Survival disparities were strongest in younger patients, in rectal cancer patients, in stage I cancer, in the latest period, and with longer follow-up. Disparities persisted after adjustment for stage, utilization of surgery and screening colonoscopy uptake rates. They were mostly still present when restricting to patients receiving treatment according to guidelines. Conclusion:We observed socioeconomic inequalities in colorectal cancer survival in Germany. Further studies accounting for potential differences in non-cancer mortality and exploring treatment patterns in detail are needed.
Frontiers in Oncology

Szentes, B.L.; Schultz, K.; Nowak, D.; Schüler, M.; Schwarzkopf, L.
How does the EQ-5D-5L perform in asthma patients compared with an asthma-specific quality of life questionnaire?
BMC Pulm. Med. 20:168 (2020)
Background: Asthma patients experience impairments in health-related quality of life (HRQL). Interventions are available to improve HRQL. EQ-5D-5L is a common generic tool used to evaluate health interventions. However, there is debate over whether the use of this measure is adequate in asthma patients.Methods: We used data from 371 asthma patients participating in a pulmonary rehabilitation (PR) program from the EPRA randomized controlled trial. We used four time points: T0 randomization, T1 start PR, T2 end PR, T3 3 months follow-up. We calculated floor and ceiling effects, intra-class correlation (ICC), Cohen's d, and regression analysis to measure the sensitivity to changes of EQ-5D-5 L (EQ-5D index and Visual Analog Scale (VAS)) and the disease-specific Asthma Quality of Life Questionnaire (AQLQ). Furthermore, we estimated the minimally important difference (MID). Based on the Asthma Control Test (ACT) scores, we defined three groups: 1. ACT-A (ACT> 19) controlled asthma, 2. ACT-B (14 < ACT <= 19) not well-controlled asthma, and 3. ACT-C (ACT <= 14) very poorly controlled asthma.Results: Only the EQ-5D index showed ceiling effects at T2 and T3 (32%). ICC (between T0 and T1) was moderate or good for all measures. Cohen's d at T2 and T3 was better at differentiating between ACT-A and ACT-B than between ACT-B and ACT-C. The EQ-5D index showed moderate effect sizes (0.63-0.75), while AQLQ showed large effect sizes (0.74-1,48). VAS was responsive to pronounced positive and negative ACT changes in every period, and AQLQ mostly to the positive changes, whereas the EQ-5D index was less responsive. We

estimated a MID of 0.08 for the EQ-5D index, 12.3 for VAS, and 0.65 for AQLQ.Conclusion: All presented HRQL tools had good discriminatory power and good reliability. However, EQ-5D-5 L did not react very sensitively to small changes in asthma control. Therefore, we would suggest using supplementary measures in addition to EQ-5D-5 L to evaluate asthma-specific interventions more comprehensively.
BMC Pulmonary Medicine

Lutter, J.; Jörres, R.A.; Kahnert, K.; Schwarzkopf, L.; Studnicka, M.; Karrasch, S.; Schulz, H.; Vogelmeier, C.F.; Holle, R.
Health-related quality of life associates with change in FEV1 in COPD: Results from the COSYCONET cohort.
BMC Pulm. Med. 20:148 (2020)
BackgroundForced expiratory volume in one second (FEV1) characterizes the pathophysiology of COPD and different trajectories of FEV1 decline have been observed in patients with COPD (e.g. gradual or episodic). There is limited information about the development of patient-reported health-related quality of life (HRQL) over the full range of the natural history of COPD. We examined the longitudinal association between change in FEV1 and change in disease-specific and generic HRQL.MethodsWe analysed data of 1734 patients with COPD participating in the COSYCONET cohort with up to 3 years of follow-up. Patients completed the Saint George's Respiratory Questionnaire (SGRQ) and the EQ-5D Visual Analog Scale (EQ VAS). Change score models were used to investigate the relationship between HRQL and FEV1 and to calculate mean changes in HRQL per FEV1 change categories [decrease (<= -100ml), no change, increase (>= 100ml)] after 3 years. Applying hierarchical linear models (HLM), we estimated the cross-sectional between-subject difference and the longitudinal within-subject change of HRQL as related to a FEV1 difference or change.ResultsWe observed a statistically significant deterioration in SGRQ (total score+1.3units) after 3 years, which was completely driven by the activity component (+4units). No significant change was found for the generic EQ VAS. Over the same period, 58% of patients experienced a decrease in FEV1, 28% were recorded as no change in FEV1, and 13% experienced an increase. The relationship between HRQL and FEV1 was found to be approximately linear with decrease in FEV1 being statistically significantly associated with a deterioration in SGRQ (+3.20units). Increase in FEV1 was associated with improvements in SGRQ (-3.81units). The associations between change in FEV1 and the EQ VAS were similar. Results of the HLMs were consistent and highly statistically significant, indicating cross-sectional and longitudinal associations. The largest estimates were found for the association between FEV1 and the SGRQ activity domain.ConclusionsDifference and change in FEV1 over time correlate with difference and change in disease-specific and generic HRQL. We conclude, that deterioration of HRQL should induce timely re-examination of physical status and lung function and possibly reassessment of therapeutic regimes.Trial registrationNCT01245933. Date of registration: 18 November 2010.
BMC Pulmonary Medicine

Galiè, F.; Rospleszcz, S.; Keeser, D.; Beller, E.; Illigens, B.; Lorbeer, R.; Grosu, S.; Selder, S.; Auweter, S.; Schlett, C.L.; Rathmann, W.; Schwettmann, L.; Ladwig, K.-H.; Linseisen, J.; Peters, A.; Bamberg, F.; Ertl-Wagner, B.; Stoecklein, S.
Machine-learning based exploration of determinants of gray matter volume in the KORA-MRI study.
Sci. Rep. 10:8363 (2020)
To identify the most important factors that impact brain volume, while accounting for potential collinearity, we used a data-driven machine-learning approach. Gray Matter Volume (GMV) was derived from magnetic resonance imaging (3T, FLAIR) and adjusted for intracranial volume (ICV). 93 potential determinants of GMV from the categories sociodemographics, anthropometric measurements, cardio-metabolic variables, lifestyle factors, medication, sleep, and nutrition were obtained from 293 participants from a population-based cohort from Southern Germany. Elastic net regression was used to identify the most important determinants of ICV-adjusted GMV. The four variables age (selected in each of the 1000 splits), glomerular filtration rate (794 splits), diabetes (323 splits) and diabetes duration (122 splits) were identified to be most relevant predictors of GMV adjusted for intracranial volume. The elastic net model showed better performance compared to a constant linear regression (mean squared error = 1.10 vs. 1.59, p<0.001). These findings are relevant for preventive and therapeutic considerations and for neuroimaging studies, as they suggest to take information on metabolic status and renal function into account as potential confounders.
Scientific Reports

Schwander, B.; Nuijten, M.; Hiligsmann, M.; Queally, M.; Leidl, R.; Joore, M.; Oosterhoff, M.; Frew, E.; Van Wilder, P.; Postma, M.; Evers, S.
Identification and expert panel rating of key structural approaches applied in health economic obesity models.
Health Policy Technol. 9, 314-322 (2020)
Objectives: This study aims to assess the key structural modelling approaches applied in published obesity models, and to provide an expert consensus to improve the methodology and consistency of the application of decision-analytic modelling in obesity research. Methods: Using a previously published systematic literature search as basis, ten individual interviews, and a face-to-face expert panel meeting were conducted. Within the expert panel meeting, the interview findings were presented and discussed, rated and where possible consensus statements were obtained. In particular, five topics of interest were assessed: time horizon, model type, obesity-related clinical events simulated, event simulation approaches and external event validation. Results: In addition to generic modelling standards, several obesity-specific recommendations were generated: Simulating a lifetime horizon was regarded as optimal (100% agreement); Ideally, both short and long-term results should be presented (100%); Using a risk equation approach for simulating the clinical events was the most preferred approach (60%) followed by applying a body mass index (BMI) related relative risk to a base risk estimate (30%); Continuous BMI approaches were preferred (100%); An individual patient/microsimulation state transition model was regarded as preferred modelling approach (90%); Discrete event simulation (DES) was regarded as the most flexible approach for building an obesity model but it was recognised as complex, and more difficult to build, populate and to disseminate; Performing an external validation was rated as important (100%). Conclusions: The obtained insights, discussion and consensus can provide valuable information for developing decision-analytic models to

generate high-quality and transparent economic evidence for obesity interventions.
Health policy and technology

Karl, F.; Holle, R.; Schwettmann, L.; Peters, A.; Meisinger, C.; Rückert-Eheberg, I.-M.; Laxy, M.
Association between unrealistic comparative optimism and self-management in individuals with type 2 diabetes: Results from a cross-sectional, population-based study.
Health Sci. Rep. 3:e157 (2020)
Background and aims: Unrealistic comparative optimism (UO), as the erroneous judgement of personal risks to be lower than the risks of others, could help explain differences in diabetes self-management. The present study tested the hypothesis that individuals with type 2 diabetes who underestimate their comparative heart attack risk, have a lower adherence regarding recommended self-management. Methods: We used data from individuals with type 2 diabetes participating in the German KORA (Cooperative Health Research in the Region of Augsburg) GEFU 4 (self-administered health questionnaire 2016) study. UO was estimated by comparing participants' subjective comparative risk for having a heart attack within the next 5-years (ie, "higher than others," "average," "lower than others"), with their objective comparative 10-year cardiovascular disease risk based on the Framingham equations. We estimated binary logistic and linear regression models to analyze which characteristics were associated with UO and to test the association between UO and participants' self-management behaviors (ie, regular self-monitoring of body weight, blood sugar, and blood pressure, regular foot care, keeping a diabetes diary, and having a diet plan), and their sum score, respectively. All models were adjusted for socio-demographic and disease-related variables. Results: The studied sample included n = 633 individuals with type 2 diabetes (mean age 70.7 years, 45% women). Smokers and males were more likely to show UO than nonsmokers and females. Furthermore, a higher blood pressure and a higher body mass index were associated with a higher likelihood of UO regarding heart attack risk. However, UO was not significantly associated with patient self-management. Conclusions: Unfavorable health behavior and risk factors are associated with UO. However, our results suggest that UO with regard to perceived heart attack risk may not be a relevant factor for patient self-management in those with type 2 diabetes.
Health science reports

Kartschmit, N.; Sutcliffe, R.; Sheldon, M.P.; Moebus, S.; Greiser, K.H.; Hartwig, S.; Thürkow, D.; Stentzel, U.; van den Berg, N.; Wolf, K.; Maier, W.; Peters, A.; Ahmed, S.; Köhnke, C.; Mikolajczyk, R.; Wienke, A.; Kluttig, A.; Rudge, G.
Walkability and its association with walking/cycling and body mass index among adults in different regions of Germany: A cross-sectional analysis of pooled data from five German cohorts.
BMC Endocr. Disord. 20:7 (2020)
Objectives To examine three walkability measures (points of interest (POI), transit stations and impedance (restrictions to walking) within 640 m of participant's addresses) in different regions in Germany and assess the relationships between walkability, walking/cycling and body mass index (BMI) using generalised additive models.Setting Five different regions and cities of Germany using data from five cohort studies.Participants For analysing walking/cycling behaviour, there were 6269 participants of a pooled sample from three cohorts with a mean age of 59.2 years (SD: 14.3) and of them 48.9% were male. For analysing BMI, there were 9441 participants of a pooled sample of five cohorts with a mean age of 62.3 years (SD: 12.8) and of them 48.5% were male.Outcomes (1) Self-reported walking/cycling (dichotomised into more than 30 min and 30 min and less per day; (2) BMI calculated with anthropological measures from weight and height.Results Higher impedance was associated with lower prevalence of walking/cycling more than 30 min/day (prevalence ratio (PR): 0.95; 95% CI 0.93 to 0.97), while higher number of POI and transit stations were associated with higher prevalence (PR 1.03; 95% CI 1.02 to 1.05 for both measures). Higher impedance was associated with higher BMI (beta: 0.15; 95% CI 0.04 to 0.25) and a higher number of POI with lower BMI (beta: -0.14; 95% CI -0.24 to 0.04). No association was found between transit stations and BMI (beta: 0.005, 95% CI -0.11 to 0.12). Stratified by cohort we observed heterogeneous associations between BMI and transit stations and impedance.Conclusion We found evidence for associations of walking/cycling with walkability measures. Associations for BMI differed across cohorts.
BMC Endocrine Disorders

Kühnel, M.B.; Marchioro, L.; Deffner, V.; Bausewein, C.; Seidl, H.; Siebert, S.; Fegg, M.
How short is too short? A randomised controlled trial evaluating short-term existential behavioural therapy for informal caregivers of palliative patients.
Palliat. Med. 34, 806-816 (2020)
Background:Informal caregivers of palliative patients show higher levels of depression and distress compared with the general population. Fegg's (2013) existential behavioural therapy was shortened to two individual 1-h sessions (short-term existential behavioural therapy).Aim:Testing the effectiveness of sEBT on psychological symptoms of informal caregivers in comparison with active control.Design:Randomised controlled trial.Setting/participants:Informal caregivers of palliative in-patients.Methods:The primary outcome was depression; secondary outcomes were anxiety, subjective distress and minor mental disorders, positive and negative affect, satisfaction with life, quality of life and direct health care costs. General linear mixed models allow several measurements per participant and change over time. Reasons for declining the intervention were investigated by Rosenstock's Health Belief Model.Results:Overall inclusion rate was 41.0%. Data of 157 caregivers were available (63.1% females; mean age: 54.6 years, standard deviation (SD): 14.1); 127 participants were included in the main analysis. Participation in sEBT or active control was not significantly associated with post-treatment depression. Outcomes showed prevailingly significant association with time of investigation. Self-efficacy, scepticism of benefit of the intervention, belief of better coping alone and support by family and friends were significant factors in declining participation in the randomised controlled trial.Conclusion:Inclusion rate was tripled compared with a previously evaluated longer EBT group intervention. By shortening the intervention, inclusion rate was traded for effectiveness and the intervention could not impact caregivers' psychological state. Early integration of sEBT and combination of individual and group setting and further study of the optimal length for caregiver interventions are suggested.
Palliative medicine

Schwettmann, L.; Wuppermann, A.
Der dggö-Ausschuss Allokation und Verteilung-10-jähriger Jubiläumsworkshop.
Gesundheitsökon. Qualitätsmanag. 25, 75-77 (2020)
Der 10-jährige Jubiläumsworkshop des dggö-Ausschusses Allokation und Verteilung fand am 15. und 16. November 2019 an der Universität Konstanz statt und wurde von Friedrich Breyer (Lehrstuhl für Wirtschafts- und Sozialpolitik) und seinem Lehrstuhlteam ausgerichtet.
Gesundheitsökonomie & Qualitätsmanagement
Sonstiges: Nachrichtenmeldung
Other: News Item
Zhou, Y.; Buck, C.; Maier, W.; von Lengerke, T.; Walter, U.; Dreier, M.
Built environment and childhood weight status: A multi-level study using population-based data in the city of Hannover, Germany.
Int. J. Environ. Res. Public Health 17:2694 (2020)
In recent years, built environmental characteristics have been linked to childhood overweight, but the results remain inconsistent across studies. The present study examines associations between several built environmental features and body weight status (BMI) z-score among a large sample of preschool children in the city of Hannover, Germany. Walkability (Index), green space availability, and playground availability related to preschool children's home environments were measured using data from OpenStreetMap (OSM). These built environment characteristics were linked to the data from the 2010-2014 school entry examinations in the Hannover city (n = 22,678), and analysed using multilevel linear regression models to examine associations between the built environment features and the BMI z-score of these children (4-8 years old). No significant associations of built environmental factors on children's BMI were detected, but the effect between green space availability and BMI was modified by the parental educational level. In children with lower compared to higher educated parents, a higher spatial availability of greenspace was significantly associated with reduced body weight. Future research should continue to monitor the disparities in diverse built environment features and how these are related to children's health.
International Journal of Environmental Research and Public Health

Burström, K.; Teni, F.S.; Gerdtham, U.G.; Leidl, R.; Helgesson, G.; Rolfson, O.; Henriksson, M.
Experience-based Swedish TTO and VAS value sets for EQ-5D-5L health states.
Pharmacoeconomics 38, 839-856 (2020)
Background and Objective Although value sets for the five-level version of the generic health-related quality-of-life instrument EQ-5D are emerging, there is still no value set available in the literature based on time trade-off valuations made by individuals experiencing the valued health states. The aim of this study was to estimate experience-based value sets for the EQ-5D-5L for Sweden using time trade-off and visual analogue scale valuation methods. Methods In a large, cross-sectional, population-based, self-administered postal health survey, the EQ-5D-5L descriptive system, EQ visual analogue scale and a time trade-off question were included. Time trade-off and visual analogue scale valuations of the respondent's current health status were used in statistical modelling to estimate a single-index value of health for each of the 3125 health states. Ordinary least-squares and generalised linear models were estimated with the main effect within each of the five dimensions represented by 20 dummy variables reflecting the additional decrement in value for levels 2-5 when the severity increases by one level sequentially beginning from having no problem. Interaction variables representing the occurrence of severity levels in at least one of the dimensions were tested: severity level 2 or worse (N2); severity level 3 or worse (N3); severity level 4 or worse (N4); severity level 5 (N5). Results A total of 896 health states (28.7% of the 3125 possible EQ-5D-5L health states) were reported by the 25,867 respondents. Visual analogue scale (n = 23,899) and time trade-off (n = 13,381) responders reported valuations of their currently experienced health state. The preferred regression models used ordinary least-squares estimation for both time trade-off and visual analogue scale values and showed consistency in all coefficients after combining certain levels. Levels 4 and 5 for the dimensions of mobility, self-care and usual activities were combined in the time trade-off model. Including the interaction variable N5, indicating severity level 5 in at least one of the five dimensions, made it possible to distinguish between the two worst severity levels where no other dimension is at level 5 as this coefficient is applied only once. In the visual analogue scale regression model, levels 4 and 5 of the mobility dimension were combined. The interaction variables N2-N4 were included, indicating that each of these terms reflect a statistically significant decrement in visual analogue scale value if any of the dimensions is at severity level 2, 3 or 4, respectively. Conclusions Time trade-off and visual analogue scale value sets for the EQ-5D-5L are now available for Sweden. The time trade-off value set is the first such value set based on experience-based time trade-off valuation. For decision makers with a preference for experience-based valuations of health states from a representative population-based sample, the reported value sets may be considered fit for purpose to support resource allocation decision as well as evaluating population health and healthcare performance.
PharmacoEconomics

Lakerveld, J.; Woods, C.; Hebestreit, A.; Brenner, H.; Flechtner-Mors, M.; Harrington, J.M.; Kamphuis, C.B.M.; Laxy, M.; Luszczynska, A.; Mazzocchi, M.; Murrin, C.; Poelman, M.; Steenhuis, I.; Roos, G.; Steinacker, J.M.; Stock, C.C.; van Lenthe, F.; Zeeb, H.; Zukowska, J.; Ahrens, W.
Advancing the evidence base for public policies impacting on dietary behaviour, physical activity and sedentary behaviour in Europe: The Policy Evaluation Network promoting a multidisciplinary approach.
Food Policy 96:101873 (2020)
Non-communicable diseases (NCDs) are the leading cause of global mortality. As the social and economic costs of NCDs have escalated, action is needed to tackle important causes of many NCD's: low physical activity levels and unhealthy dietary behaviours. As these behaviours are driven by upstream factors, successful policy interventions are required that encourage healthy dietary behaviours, improve physical activity levels and reduce sedentary behaviours of entire populations. However, to date, no systematic research on the implementation and evaluation of policy interventions related to these health behaviours has been conducted across Europe. Consequently, no information on the merit, gaps, worth or utility of cross-

European policy interventions is available, and no guidance or recommendations on how to enhance this knowledge across European countries exists. As part of the Joint Programming Initiative "A Healthy Diet for a Healthy Life" (JPI HDHL), 28 research institutes from seven European countries and New Zealand have combined their expertise to form the Policy Evaluation Network (PEN). PEN's aim is to advance tools to identify, evaluate, implement and benchmark policies designed to directly or indirectly target dietary behaviours, physical activity, and sedentary behaviour in Europe, as well as to understand how these policies increase or decrease health inequalities. Using well-defined evaluation principles and methods, PEN will examine the content, implementation and impact of policies addressing dietary behaviour, physical activity levels and sedentary behaviour across Europe. It will realise the first steps in a bespoke health policy monitoring and surveillance system for Europe, and refine our knowledge of appropriate research designs and methods for the quantification of policy impact. It will contribute to our understanding of how to achieve successful transnational policy implementation and monitoring of these policies in different cultural, demographic or socioeconomic settings. PEN will consider equity and diversity aspects to ensure that policy actions are inclusive and culturally sensitive. Finally, based on three policy cases, PEN will illustrate how best to evaluate the implementation and impact of such policies in order to yield healthy diets and activity patterns that result in healthier lives for all European citizens.
Food Policy

Wälscher, J.; Witt, S.; Schwarzkopf, L.; Kreuter, M.
Hospitalisation patterns of patients with interstitial lung disease in the light of comorbidities and medical treatment - a German claims data analysis.
Respir. Res. 21:73 (2020)
Background Interstitial lung disease (ILD) is a heterogeneous group of mainly chronic lung diseases differing in disease course and prognosis. For most subtypes, evidence on relevance and outcomes of hospitalisations is lacking. Methods Using German claims data we investigated number of hospitalisations (zero-inflated-negative-binomial models providing rate ratios (RR)) and time to first hospitalisation (Cox proportional-hazard models providing hazard ratios (RR)) for nine ILD-subtypes. Models were stratified by ILD-related and non-ILD-related hospitalisations. We adjusted for age, gender, ILD-subtype, ILD-relevant comorbidities and ILD-medication (immunosuppressive drugs, steroids, anti-fibrotic drugs). Results Among 36,816 ILD-patients (mean age 64.7 years, 56.2% male, mean observation period 9.3 quarters), 71.2% had non-ILD-related and 56.6% ILD-related hospitalisations. We observed more and earlier non-ILD-related hospitalisations in ILD patients other than sarcoidosis. Medical ILD-treatment was associated with increased frequency and in case of late initiation, earlier (non-)ILD-related hospitalisations. Comorbidities were associated with generally increased hospitalisation frequency except for COPD (RR = 0.90) and PH (RR = 0.94) in non-ILD-related and for lung cancer in ILD-related hospitalisations (RR = 0.89). Coronary heart disease was linked with earlier (ILD-related: HR = 1.17, non-ILD-related HR = 1.19), but most other conditions with delayed hospitalisations. Conclusion Hospitalisations are frequent across all ILD-subtypes. The hospitalisation risk might be reduced independently of the subtype by improved management of comorbidities and improved pharmacological and non-pharmacological ILD therapy.
Respiratory Research

Steinbeisser, K.; Schwarzkopf, L.; Graessel, E.; Seidl, H.
Cost-effectiveness of a non-pharmacological treatment vs. “care as usual” in day care centers for community-dwelling older people with cognitive impairment: Results from the German randomized controlled DeTaMAKS-trial.
Eur. J. Health Econ. 21, 825–844 (2020)
Background: Cognitive impairment in older adults causes a high economic and societal burden. This study assesses the cost-effectiveness of the multicomponent, non-pharmacological MAKS treatment vs. “care as usual” in German day care centers (DCCs) for community-dwelling people with mild cognitive impairment (MCI) or mild to moderate dementia over 6 months. Methods: The analysis was conducted from the societal perspective alongside the cluster-randomized controlled, multicenter, prospective DeTaMAKS-trial with waitlist group design. Outcomes were Mini-Mental Status Examination (MMSE) and Erlangen Test of Activities of Daily Living in Persons with Mild Dementia or Mild Cognitive Impairment (ETAM) of 433 individuals in 32 DCCs. Incremental differences in MMSE and ETAM were calculated via a Gaussian-distributed and incremental cost difference via a Gamma-distributed Generalized Linear Model. Cost-effectiveness was assessed via cost-effectiveness planes and cost-effectiveness acceptability curves (CEAC). Results: At 6 months, MMSE (adjusted mean difference = 0.92; 95% confidence interval (CI): 0.17 to 1.67; p = 0.02) and ETAM (adjusted mean difference = 1.00; CI: 0.14 to 1.85; p = 0.02) were significantly better in the intervention group. The adjusted cost difference was − €938.50 (CI: − 2733.65 to 763.13; p = 0.31). Given the CEAC, MAKS was cost-effective for 78.0% of MMSE and 77.4% for ETAM without a need for additional costs to payers. Conclusions: MAKS is a cost-effective treatment to stabilize the ability to perform activities of daily living and cognitive abilities of people with MCI or mild to moderate dementia in German DCCs. Thus, MAKS should be implemented in DCCs.
The European journal of health economics

Schwettmann, L.
A simple vote won’t do it - Empirical social choice and the fair allocation of health care resources.
In: Empirical Research And Normative Theory. 2020. 295-316
Felix, J.; Stark, R.G.; Teuner, C.M.; Leidl, R.; Lennerz, B.; Brandt, S.; von Schnurbein, J.; Moss, A.; Bollow, E.; Sergeyev, E.; Mühlig, Y.; Wiegand, S.; Holl, R.W.; Reinehr, T.; Kiess, W.; Scherag, A.; Hebebrand, J.; Wabitsch, M.; Holle, R.
Health related quality of life associated with extreme obesity in adolescents - results from the baseline evaluation of the YES-study.
Health Qual. Life Outcomes 18:58 (2020)
BackgroundObesity can significantly reduce health-related quality of life (HRQoL) and may lead to numerous health problems even in youths. This study aimed to investigate whether HRQoL varies among youths with obesity depending on grade of obesity and other factors.MethodsFor the Youths with Extreme obesity Study (YES) (2012-2014), a prospective multicenter cohort study, a baseline sample of 431 obese and extremely obese adolescents and young adults (age 14 to 24years, BMI >= 30kg/m(2)) was recruited at four German

university medical centers and one job center. Obesity grade groups (OGG) were defined according to BMI (OGG I: 30-34.9kg/m(2), OGG II: 35-39.9kg/m(2), OGG III (extreme obesity): >= 40kg/m(2)). HRQoL was measured with the Euroqol-5D-3L (EQ-5D-3L), DISABKIDS chronic generic (DCGM-31) and the KINDLR obesity module. Differences between OGGs were assessed with logistic and linear regression models, adjusting for age, sex, and study center in the base model. In a second regression analysis, we included other characteristics to identify possible determinants of HRQoL.ResultsThree hundred fifty-two adolescents (mean age: 16.6 (2.4), mean BMI: 39.1 (7.5) kg/m(2)) with available HRQoL data were analysed. HRQoL of youths in all OGGs was markedly lower than reference values of non-obese adolescents. Adjusting for age and sex, HRQoL of youths in OGG III significantly impaired compared to OGG I. Youths in OGG III were 2.15 times more likely to report problems with mobility in the EQ-5D-3L than youths in OGG I. A mean difference of 9.7 and 6.6 points between OGG III and I were found for DCGM-31 and KINDL respectively and 5.1 points between OGG II and I for DCGM-31. Including further variables into the regression models, showed that HRQoL measured by DCGM-31 was significantly different between OGGs. Otherwise, female sex and having more than 4h of daily screen time were also associated with lower HRQoL measured by DCGM-31 and KINDL.Conclusion HRQoL of adolescents with obesity is reduced, but HRQoL of adolescents with extreme obesity is particularly affected. Larger and longitudinal studies are necessary to understand the relation of extreme obesity and HRQoL, and the impact of other lifestyle or socioeconomic factors.
Health and Quality of Life Outcomes

Hindelang, M.; Kirsch, F.; Leidl, R.
Effectiveness of non-pharmacological COPD management on health-related quality of life-a systematic review.
Expert Rev. Pharmacoecon. Outcomes Res. 20, 79-91 (2020)
Introduction: Chronic obstructive pulmonary disease (COPD) is the third leading cause of mortality worldwide. The chronic progressive disease is accompanied by a high loss of health-related quality of life (HRQoL). The available drugs usually only have symptomatic effects; therefore, non-pharmacological therapies are essential too. Areas covered: This systematic review examines non-pharmacological interventions consisting of pulmonary rehabilitation, physical activity, and training versus usual care or no intervention in COPD using at least one of the following HRQoL measuring instruments: St. George's Respiratory Questionnaire, Clinical COPD Questionnaire, COPD Assessment Test, and EuroQol-5D. Of 1532 identified records from CENTRAL, MEDLINE, and EMBASE, 15 randomized controlled trials met the inclusion criteria. Pulmonary rehabilitation programs were investigated in nine studies, education and counseling-based training programs in three studies, and breathing exercises in three studies. Ten studies were found that investigated non-pharmacological treatment programs that led to a significant and clinically relevant improvement in HRQoL compared with usual care or no treatment. Expert opinion: Non-pharmacological interventions consisting of pulmonary rehabilitation, education and counseling-based training programs, and breathing exercises can improve the HRQoL of COPD patients.
Expert Review of Pharmacoeconomics and Outcomes Research

Kurz, C.F.; Laxy, M.
Application of mendelian randomization to investigate the association of body mass index with health care costs.
Med. Decis. Making 40, 156-169 (2020)
Causal effect estimates for the association of obesity with health care costs can be biased by reversed causation and omitted variables. In this study, we use genetic variants as instrumental variables to overcome these limitations, a method that is often called Mendelian randomization (MR). We describe the assumptions, available methods, and potential pitfalls of using genetic information and how to address them. We estimate the effect of body mass index (BMI) on total health care costs using data from a German observational study and from published large-scale data. In a meta-analysis of several MR approaches, we find that models using genetic instruments identify additional annual costs of euro280 for a 1-unit increase in BMI. This is more than 3 times higher than estimates from linear regression without instrumental variables (euro75). We found little evidence of a nonlinear relationship between BMI and health care costs. Our results suggest that the use of genetic instruments can be a powerful tool for estimating causal effects in health economic evaluation that might be superior to other types of instruments where there is a strong association with a modifiable risk factor.
Medical Decision Making

Stephan, A.J.; Strobl, R.; Schwettmann, L.; Meisinger, C.; Ladwig, K.-H.; Linkohr, B.; Thorand, B.; Peters, A.; Grill, E.
The times we are born into and our lifestyle choices determine our health trajectories in older age - Results from the KORA(1)-Age study.
Prev. Med. 133:106025 (2020)
Health projections often extrapolate from observations in current ageing cohorts, but health in older age may depend not only on individual characteristics but also on a person's historical context. Our objective was to investigate how health deficit accumulation trajectories after age 65 differed in five adjacent birth cohorts and according to individual life course characteristics.Data originate from the 2008/09 KORA (Cooperative Health Research in the Region of Augsburg)-Age cohort study from Southern Germany and their 2012 and 2016 follow-ups. Deficit accumulation was assessed using a Frailty Index. The effects of birth cohort membership and individual life course characteristics on deficit accumulation trajectories were analyzed using generalized linear mixed models.Out of 2701 participants (49% male) from five birth cohorts (1919-23, 1924-28, 1929-33, 1934-38, 1939-43), we included 2512 individuals with 5560 observations. Frailty Index levels were higher for women, smokers, alcohol abstainers, obese participants and persons with a sedentary lifestyle or living below the poverty threshold. We found higher age-specific Frailty Index levels for the two most recent birth cohorts (e.g. 61%, CI: [13%; 130%] for the 1934-38 as compared to the 1919-23 cohort), but the rate of deficit accumulation with age (7% per life year, (CI: [5%, 9%]) was cohort-independent. Results indicate that the historical context (birth cohort membership) may influence the number of accumulated health deficits after age 65 in addition to poverty and other individual life course characteristics, but BMI, physical activity and smoking remain the modifiable risk factors offering the highest prevention potential.
Preventive Medicine

Kartschmit, N.; Sutcliffe, R.; Sheldon, M.P.; Moebus, S.; Greiser, K.H.; Hartwig, S.; Thürkow, D.; Stentzel, U.; van den Berg, N.; Wolf, K.; Maier, W.; Peters, A.; Ahmed, S.; Köhnke, C.; Mikolajczyk, R.; Wienke, A.; Kluttig, A.; Rudge, G.
Walkability and its association with prevalent and incident diabetes among adults in different regions of Germany: Results of pooled data from five German cohorts.
BMC Endocr. Disord. 20:7 (2020)
Background Highly walkable neighbourhoods may increase transport-related and leisure-time physical activity and thus decrease the risk for obesity and obesity-related diseases, such as type 2 diabetes (T2D). Methods We investigated the association between walkability and prevalent/incident T2D in a pooled sample from five German cohorts. Three walkability measures were assigned to participant's addresses: number of transit stations, points of interest, and impedance (restrictions to walking due to absence of intersections and physical barriers) within 640 m. We estimated associations between walkability and prevalent/incident T2D with modified Poisson regressions and adjusted for education, sex, age at baseline, and cohort. Results Of the baseline 16,008 participants, 1256 participants had prevalent T2D. Participants free from T2D at baseline were followed over a mean of 9.2 years (SD: 3.5, minimum: 1.6, maximum: 14.8 years). Of these, 1032 participants developed T2D. The three walkability measures were not associated with T2D. The estimates pointed toward a zero effect or were within 7% relative risk increase per 1 standard deviation with 95% confidence intervals including 1. Conclusion In the studied German settings, walkability differences might not explain differences in T2D.
BMC Endocrine Disorders

Kahnert, K.; Föhrenbach, M.; Lucke, T.; Alter, P.; Trudzinski, F.T.; Bals, R.; Lutter, J.; Timmermann, H.; Söhler, S.; Förderreuther, S.; Nowak, D.; Watz, H.; Waschki, B.; Behr, J.; Welte, T.; Vogelmeier, C.F.; Jörres, R.A.
The impact of COPD on polyneuropathy: Results from the German COPD cohort COSYCONET.
Respir. Res. 21:28 (2020)
Background Peripheral neuropathy is a common comorbidity in COPD. We aimed to investigate associations between alterations commonly found in COPD and peripheral neuropathy, with particular emphasize on the distinction between direct and indirect effects. Methods We used visit 4 data of the COPD cohort COSYCONET, which included indicators of polyneuropathy (repeated tuning fork and monofilament testing), excluding patients with diabetes a/o increased HbA1c. These indicators were analysed for the association with COPD characteristics, including lung function, blood gases, 6-min walk distance (6-MWD), timed-up-and-go-test (TUG), exacerbation risk according to GOLD, C-reactive protein (CRP), and ankle-brachial index (ABI). Based on the results of conventional regression analyses adjusted for age, BMI, packyears and gender, we utilized structural equation modelling (SEM) to quantify the network of direct and indirect relationships between parameters. Results 606 patients were eligible for analysis. The indices of polyneuropathy were highly correlated with each other and related to base excess (BE), ABI and TUG. ABI was linked to neuropathy and 6-MWD, exacerbations depended on FEV1, 6-MWD and CRP. The associations could be summarized into a SEM comprising polyneuropathy as a latent variable (PNP) with three measured indicator variables. Importantly, PNP was directly dependent on ABI and particularly on BE. When also including patients with diabetes and/or elevated values of HbA1c (n = 742) the SEM remained virtually the same. Conclusion We identified BE and ABI as major determinants of peripheral neuropathy in patients with COPD. All other associations, particularly those with lung function and physical capacity, were indirect. These findings underline the importance of alterations of the micromilieu in COPD, in particular the degree of metabolic compensation and vascular status.
Respiratory Research

Kirsch, F.; Becker, C.; Schramm, A.; Maier, W.; Leidl, R.
Patients with coronary artery disease after acute myocardial infarction: Effects of continuous enrollment in a structured Disease Management Program on adherence to guideline-recommended medication, health care expenditures, and survival.
Eur. J. Health Econ. 21, 607–619 (2020)
Objective: Acute myocardial infarction (AMI) carries increased risk of mortality and excess costs. Disease Management Programs (DMPs) providing guideline-recommended care for chronic diseases seem an intuitively appealing way to enhance health outcomes for patients with chronic conditions such as AMI. The aim of the study is to compare adherence to guideline-recommended medication, health care expenditures and survival of patients enrolled and not enrolled in the German DMP for coronary artery disease (CAD) after an AMI from the perspective of a third-party payer over a follow-up period of 3 years. Methods: The study is based on routinely collected data from a regional statutory health insurance fund (n = 15,360). A propensity score matching with caliper method was conducted. Afterwards guideline-recommended medication, health care expenditures, and survival between patients enrolled and not enrolled in the DMP were compared with generalized linear and Cox proportional hazard models. Results: The propensity score matching resulted in 3870 pairs of AMI patients previously and continuously enrolled and not enrolled in the DMP. In the 3-year follow-up period the proportion of days covered rates for ACE-inhibitors (60.95% vs. 58.92%), anti-platelet agents (74.20% vs. 70.66%), statins (54.18% vs. 52.13%), and β-blockers (61.95% vs. 52.64%) were higher in the DMP group. Besides that, DMP participants induced lower health care expenditures per day (€58.24 vs. €72.72) and had a significantly lower risk of death (HR: 0.757). Conclusion: Previous and continuous enrollment in the DMP CAD for patients after AMI is a promising strategy as it enhances guideline-recommended medication, reduces health care expenditures and the risk of death.
The European journal of health economics

Finke, I.; Behrens, G.; Schwettmann, L.; Gerken, M.; Pritzkuleit, R.; Holleczek, B.; Brenner, H.; Jansen, L.
Socioeconomic differences and lung cancer survival in Germany: Investigation based on population-based clinical cancer registration.
Lung Cancer 142, 1-8 (2020)
Objectives: Studies from several countries reported socioeconomic inequalities in lung cancer survival. Hypothesized reasons are differences in cancer care or tumor characteristics. We investigated associations of small-area deprivation and lung cancer survival in Germany and the possible impact of differences in patient, tumor or treatment factors.Materials and Methods: Patients registered with a primary tumor of the lung

between 2000-2015 in three German population-based clinical cancer registries were included. Area-based socioeconomic deprivation on municipality level was measured with the categorized German Index of Multiple Deprivation. Association of deprivation with overall survival was investigated with Cox regression models.Results: Overall, 22,905 patients were included. Five-year overall survival from the least to the most deprived quintile were 17.2%, 15.9%, 16.7%, 15.7%, and 14.4%. After adjustment for patient and tumor factors, the most deprived group had a lower survival compared to the least deprived group (Hazard Ratio (HR) 1.06, 95% confidence interval (CI) 1.01-1.11). Subgroup analyses revealed lower survival in the most deprived compared to the least deprived quintile in patients with stage I-III [HR: 1.14, 95% CI: 1.06-1.22]. The association persisted when restricting to patients receiving surgery but was attenuated for subgroups receiving either chemotherapy or radiotherapy.Conclusion: Our results indicate differences in lung cancer survival according to area deprivation in Germany, which were more pronounced in patients with I-III stage cancer. Future research should address in more detail the underlying reasons for the observed inequalities and possible approaches to overcome them.
Lung Cancer

Kurz, C.F.; Maier, W.; Rink, C.
A greedy stacking algorithm for model ensembling and domain weighting.
BMC Res. Notes 13:70 (2020)
OBJECTIVE: Because it is impossible to know which statistical learning algorithm performs best on a prediction task, it is common to use stacking methods to ensemble individual learners into a more powerful single learner. Stacking algorithms are usually based on linear models, which may run into problems, especially when predictions are highly correlated. In this study, we develop a greedy algorithm for model stacking that overcomes this issue while still being very fast and easy to interpret. We evaluate our greedy algorithm on 7 different data sets from various biomedical disciplines and compare it to linear stacking, genetic algorithm stacking and a brute force approach in different prediction settings. We further apply this algorithm on a task to optimize the weighting of the single domains (e.g., income, education) that build the German Index of Multiple Deprivation (GIMD) to be highly correlated with mortality. RESULTS: The greedy stacking algorithm provides good ensemble weights and outperforms the linear stacker in many tasks. Still, the brute force approach is slightly superior, but is computationally expensive. The greedy weighting algorithm has a variety of possible applications and is fast and efficient. A python implementation is provided.
BMC Research Notes

Becker, J.; Emmert-Fees, K.; Greiner, G.; Rathmann, W.; Thorand, B.; Peters, A.; Karl, F.; Laxy, M.; Schwettmann, L.
Associations between self-management behavior and sociodemographic and disease-related characteristics in elderly people with type 2 diabetes - New results from the population-based KORA studies in Germany.
Prim. Care Diabetes 14, 508-514 (2020)
Aims: Self-management behavior (SMB) is an important aspect in the management of diabetes. This study aimed to identify sociodemographic and disease-related factors associated with good SMB in people with type 2 diabetes (T2D).Methods: We used data from 479 people with T2D aged 65 or older from the population-based KORA (Cooperative Health Research in the Area of Augsburg) Health Survey 2016 in Southern Germany. We estimated Poisson and logistic regression models testing the cross-sectional relationship between individual or disease-related characteristics and an established SMB sum index comprising six SMB dimensions stratified according to insulin treatment status.Results: Mean age in the sample was 75 and mean diabetes duration was 13 years. The overall level of SMB was low. Higher SMB index scores were associated with higher age, treatment with insulin, participation in a diabetes education program, and, for people with insulin treatment, with a BMI below 30 kg/m(2). Single item analyses generally supported these findings.Conclusions: SMB in people with T2D needs to be improved with efficient interventions. Targeting obese individuals and those at an early stage of the disease with low-barrier, regular education or self-management programs may be a preferred strategy.
Primary Care Diabetes

Castillo-Reinado, K.; Maier, W.; Holle, R.; Stahl-Pehe, A.; Baechle, C.; Kuss, O.; Hermann, J.; Holl, R.W.; Rosenbauer, J.; The German Pediatric Surveillance Unit (ESPED
Associations of area deprivation and urban/rural traits with the incidence of type 1 diabetes: Analysis at the municipality level in North Rhine-Westphalia, Germany.
Diabetic Med. 37, 2089-2097 (2020)
Aim To analyse the associations of area deprivation and urban/rural traits with the incidence of type 1 diabetes in the German federal state of North Rhine-Westphalia.Methods Data of incident type 1 diabetes cases in children and adolescents aged <20 years between 2007 and 2014 were extracted from a population-based diabetes register. Population data, indicators of area deprivation and urban/rural traits at the municipality level (396 entities) were obtained from official statistics. Area deprivation was assessed in five groups based on quintiles of an index of multiple deprivation and its seven deprivation domains. Poisson regression accounting for spatial dependence was applied to investigate associations of area deprivation and urban/rural traits with type 1 diabetes incidence.Results Between 2007 and 2014, 6143 incident cases were reported (99% completeness); the crude incidence was 22.3 cases per 100 000 person-years. The incidence decreased with increasing employment and environmental deprivation (relative risk of the most vs. the least deprived municipalities: 0.905 [95% CI: 0.813, 1.007] and 0.839 [0.752, 0.937], respectively) but was not associated with the composite deprivation index. The incidence was higher in more peripheral, rural, smaller and less densely populated municipalities, and the strongest association was estimated for the location trait (relative risk of peripheral/very peripheral compared with very central location: 1.231 [1.044, 1.452]).Conclusions The results suggest that the type 1 diabetes risk is higher in more remote, more rural, less densely populated and less deprived areas. Urban/rural traits were stronger predictors of type 1 diabetes risk than area deprivation indicators.
Diabetic Medicine

Islam, S.M.S.°; Peiffer, R.; Chow, C.K.; Maddison, R.; Lechner, A.; Holle, R.; Niessen, L.; Laxy, M.°
Cost-effectiveness of a mobile-phone text messaging intervention on type 2 diabetes—A randomized-controlled trial.

Health Policy Technol. 9, 79-85 (2020)
Aims: To evaluate the cost-effectiveness of a mobile phone text messaging program for people with type 2 diabetes mellitus. Methods: We performed a generalized cost-effectiveness analysis in a randomized controlled trial in Bangladesh. Patients with type 2 diabetes were randomized (1:1) to a text messaging intervention plus standard-care or standard-care alone. Intervention participants received a text message daily for 6 months encouraging healthy lifestyles. Costs to users and the health systems were measured. The EQ-5D-3L was used to measure improvements in health-related quality-adjusted life years (QALYs). Intervention costs were expressed as average cost-effectiveness ratios (cost-per 1% unit-reduction in glycated haemoglobin HbA1c and cost per QALY gained), based on the World Health Organization cost effectiveness and strategic planning (WHO-CHOICE) method. Results: In 236 patients [mean age 48 (SD9.6) years] the adjusted difference in accumulated QALYs between the intervention and the control group over the 6-month period was 0.010 (95%CI: 0.000; 0.021). Additional costs per-patient averaged 24 international dollars (Intl.$), resulting in incremental cost-effectiveness ratios of 38 Intl.$ per % glycated haemoglobin (HbA1c) reduction and 2406 Intl.$ per QALY gained. The total intervention costs for the mobile phone text messaging program was 2842 Int.$. Conclusion: Text messaging might be a valuable addition to standard treatment for diabetes care in low-resource settings and predicted to lead an overall saving in health systems costs. Studies with longer follow-up and larger samples are needed to draw reliable conclusions.
Health policy and technology

Icks, A.; Haastert, B.; Arend, W.; Konein, J.; Thorand, B.; Holle, R.; Laxy, M.; Schunk, M.; Neumann, A.; Wasem, J.; Chernyak, N.; Dintsios, C.M.
Patient time costs due to self-management in diabetes may be as high as direct medical costs: Results from the population-based KORA survey FF4 in Germany.
Diabetic Med., DOI: 10.1111/dme.14210 (2020)
Time spent on health-related activities is an essential resource in the production of health [1]. Time spent on health care or self-management in chronic diseases cannot be spent on alternative work and leisure activities, and can potentially affect a person's willingness to undertake an intervention [2].
Diabetic Medicine

Kurz, C.F.; König, A.
The causal influence of maternal obesity on preterm birth.
Lancet Diabet. Endocrinol. 8, 101-103 (2020)
Lancet Diabetes and Endocrinology

Olm, M.; Stark, R.G.; Beck, N.; Röger, C.; Leidl, R.
Impact of interventions to reduce overnutrition on healthcare costs related to obesity and type 2 diabetes: a systematic review.
Nutr. Rev. 78, 412-435 (2020)
CONTEXT: In recent decades, obesity and type 2 diabetes mellitus (T2DM) have both become global epidemics associated with substantial healthcare needs and costs. OBJECTIVE: The aim of this review was to critically assess nutritional interventions for their impact on healthcare costs to community-dwelling individuals regarding T2DM or obesity or both, specifically using CHEERS (Consolidated Health Economic Evaluation Reporting Standards) criteria to assess the economic components of the evidence. DATA SOURCES: Searches were executed in Embase, EconLit, AgEcon, PubMed, and Web of Science databases. STUDY SELECTION: Studies were included if they had a nutritional perspective, reported an economic evaluation that included healthcare costs, and focused on obesity or T2DM or both. Studies were excluded if they examined clinical nutritional preparations, dietary supplements, industrially modified dietary components, micronutrient deficiencies, or undernutrition; if they did not report the isolated impact of nutrition in complex or lifestyle interventions; or if they were conducted in animals or attempted to transfer findings from animals to humans. DATA EXTRACTION: A systematic review was performed according to PRISMA guidelines. Using predefined search terms, 21 studies evaluating food habit interventions or taxation of unhealthy foods and beverages were extracted and evaluated using CHEERS criteria. RESULTS: Overall, these studies showed that nutrition interventions and taxation approaches could lead to cost savings and improved health outcomes when compared with current practice. All of the included studies used external sources and economic modeling or risk estimations with population-attributable risks to calculate economic outcomes. CONCLUSIONS: Most evidence supported taxation approaches. The effect of nutritional interventions has not been adequately assessed. Controlled studies to directly measure economic impacts are warranted.
Nutrition reviews

Mühlenbruch, K.; Zhuo, X.; Bardenheier, B.; Shao, H.; Laxy, M.; Icks, A.; Zhang, P.; Gregg, E.W.; Schulze, M.B.
Selecting the optimal risk threshold of diabetes risk scores to identify high-risk individuals for diabetes prevention: A cost-effectiveness analysis.
Acta Diabetol. 57, 447-454 (2020)
Aims Although risk scores to predict type 2 diabetes exist, cost-effectiveness of risk thresholds to target prevention interventions are unknown. We applied cost-effectiveness analysis to identify optimal thresholds of predicted risk to target a low-cost community-based intervention in the USA. Methods We used a validated Markov-based type 2 diabetes simulation model to evaluate the lifetime cost-effectiveness of alternative thresholds of diabetes risk. Population characteristics for the model were obtained from NHANES 2001-2004 and incidence rates and performance of two noninvasive diabetes risk scores (German diabetes risk score, GDRS, and ARIC 2009 score) were determined in the ARIC and Cardiovascular Health Study (CHS). Incremental cost-effectiveness ratios (ICERs) were calculated for increasing risk score thresholds. Two scenarios were assumed: 1-stage (risk score only) and 2-stage (risk score plus fasting plasma glucose (FPG) test (threshold 100 mg/dl) in the high-risk group). Results In ARIC and CHS combined, the area under the receiver operating characteristic curve for the GDRS and the ARIC 2009 score were 0.691 (0.677-0.704) and 0.720 (0.707-0.732), respectively. The optimal threshold of predicted diabetes risk (ICER < $50,000/QALY gained in case of intervention in those above the threshold) was 7% for the GDRS and 9% for the ARIC 2009 score. In the 2-stage scenario, ICERs for all cutoffs >= 5% were below $50,000/QALY gained. Conclusions Intervening in those with >= 7% diabetes risk based on the GDRS or >= 9% on the ARIC 2009 score would be cost-effective. A risk score threshold >= 5% together with elevated FPG would also allow targeting interventions cost-effectively.
Acta Diabetologica

Kiesswetter, E.; Colombo, M.; Meisinger, C.; Peters, A.; Thorand, B.; Holle, R.; Ladwig, K.-H.; Schulz, H.; Grill, E.; Diekmann, R.; Schrader, E.; Stehle, P.; Sieber, C.C.; Volkert, D.
Malnutrition and related risk factors in older adults from different health-care settings: an enable study.
Public Health Nutr. 23, 446-456 (2020)
Objective: The origin of malnutrition in older age is multifactorial and risk factors may vary according to health and living situation. The present study aimed to identify setting-specific risk profiles of malnutrition in older adults and to investigate the association of the number of individual risk factors with malnutrition. Design: Data of four cross-sectional studies were harmonized and uniformly analysed. Malnutrition was defined as BMI < 20 kg/m(2) and/or weight loss of >3 kg in the previous 3-6 months. Associations between factors of six domains (demographics, health, mental function, physical function, dietary intake-related problems, dietary behaviour), the number of individual risk factors and malnutrition were analysed using logistic regression. Setting: Community (CD), geriatric day hospital (GDH), home care (HC), nursing home (NH). Participants: CD older adults (n 1073), GDH patients (n 180), HC receivers (n 335) and NH residents (n 197), all >= 65 years. Results: Malnutrition prevalence was lower in CD (11 %) than in the other settings (16-19 %). In the CD sample, poor appetite, difficulties with eating, respiratory and gastrointestinal diseases were associated with malnutrition; in GDH patients, poor appetite and respiratory diseases; in HC receivers, younger age, poor appetite and nausea; and in NH residents, older age and mobility limitations. In all settings the likelihood of malnutrition increased with the number of potential individual risk factors. Conclusions: The study indicates a varying relevance of certain risk factors of malnutrition in different settings. However, the relationship of the number of individual risk factors with malnutrition in all settings implies comprehensive approaches to identify persons at risk of malnutrition early.
Public Health Nutrition

2019

Maqhuzu, P.N.; Schwarzkopf, L.; Kreuter, M.
Healthcare resource utilization and direct costs of interstitial lung disease management in Germany.
Eur. Respir. J. 54 (2019)
European Respiratory Journal
Meeting abstract

Szentes, B.L.; Schwarzkopf, L.; Schüler, M.; Lehbert, N.; Nowak, D.; Wittmann, M.; Faller, H.; Schultz, K.
How does EQ-5D-5L perform in asthma patients?
Eur. Respir. J. 54 (2019)
European Respiratory Journal
Meeting abstract

Klett-Tammen, C.J.; Lingner, H.; Kuhlmann, A.; Schmidt, T.; Lutter, J.; Von Der Schulenburg, J.M.; Kreuter, M.; Welte, T.
Quality of life in German GP-Patients with COPD- a longitudinal study.
Eur. Respir. J. 54 (2019)
European Respiratory Journal
Meeting abstract

Schultz, K.; Wittmann, M.; Lehbert, N.; Schwarzkopf, L.; Szentes, B.L.; Nowak, D.; Faller, H.; Schüler, M.
Asthma control (AC) and Quality of life (QoL) one year after Pulmonary Rehabilitation (PR).
Eur. Respir. J. 54 (2019)
European Respiratory Journal
Meeting abstract

Murawski, M.; Marijic, P.; Maier, W.; Deckert, K.; Laub, O.; Lang, M.; Schwettmann, L.
Do paediatricians change their coding behaviour regarding mental health problems due to the standardised Health Coaching program (PrimA-QuO)?
Poster: 14. Jahrestagung der Deutschen Gesellschaft für Epidemiologie, 11-13 September 2019, Ulm, Germany. (2019)
Schwarzkopf, L.; Witt, S.; Waelscher, J.; Kreuter, M.
Longitudinal cost of care in individuals with different subtypes of interstitial lung diseases.
Eur. Respir. J. 54 (2019)
European Respiratory Journal
Meeting abstract

Szentes, B.L.; Schwarzkopf, L.; Kirsch, F.; Huber, M.B.; Schramm, A.; Leidl, R.
Different methods to classify COPD patients into the ABCD severity groups - Preliminary results of the LQ-DMP project.
Eur. Respir. J. 54 (2019)
European Respiratory Journal
Meeting abstract

Szentes, B.L.; Maqhuzu, P.N.; Kreuter, M.; Bahmer, T.; Claussen, M.; Schwarzkopf, L.
Health-related quality of life development in IPF versus other ILD - the HILDA study.
Eur. Respir. J. 54 (2019)
European Respiratory Journal
Meeting abstract

Kreuter, M.; Kabitz, H.; Hagmeyer, L.; Hammerl, P.; Esselmann, A.; Wiederhold, C.; Skowasch, D.; Stolpe, C.; Joest, M.; Veitshans, S.; Maqhuzu, P.N.; Schwarzkopf, L.; Hellmann, A.; Pfeifer, M.; Behr, J.; Kauschka, D.; Günther, A.; Herth, F.J.F.; Markart, P.
Treatment and survival diversities in different forms of ILD in Germany - EXCITING registry.
Eur. Respir. J. 54 (2019)
European Respiratory Journal
Meeting abstract

Rohleder, S.; Stock, C.; Maier, W.; Bozorgmehr, K.
Area deprivation and notifiable infectious diseases in Germany: A longitudinal small-area analysis.
Eur. J. Public Health 29, 21-21 (2019)
European Journal of Public Health
Meeting abstract

Kähm, K.; Stark, R.G.; Laxy, M.; Schneider, U.; Leidl, R.
Assessment of excess medical costs for persons with type 2 diabetes according to age groups: An analysis of German health insurance claims data.
Diabetic Med., DOI: 10.1111/dme.14213 (2019)

Aim This cross-sectional study used a large nationwide claims data set to assess the excess medical costs of people with type 2 diabetes according to age group in 2015. Methods Data from 291 709 people with diabetes and 291 709 age- and sex-matched controls were analysed. Total costs (expressed as 2015 euros) of outpatient and inpatient services, medication, rehabilitation, and the provision of aids and appliances were examined. Overall and age-stratified excess costs of people with diabetes were estimated using gamma regression with a log-link. Results Overall, the estimated total direct costs of a person with type 2 diabetes are approximately double those of a person without diabetes: euro4727 vs. euro2196, respectively. Absolute excess costs were approximately the same in all age groups (around euro2500), however, relative excess costs of persons with diabetes were much higher in younger (similar to 334% for < 50 years) than in older age groups (similar to 156% for >= 80 years). Regional costs, both absolute and excess, partly differed from the national level. Conclusions This study complements and updates previous studies on the excess medical costs of people with diabetes in Germany. The results indicate the importance of preventing the development of type 2 diabetes, especially in younger age groups. Longitudinal and regional studies examining changes in prevalence and the development of excess costs in groups with different types of diabetes, and according to age, would be of interest to validate our findings and better understand the avoidable burden of having diabetes.
Diabetic Medicine

Kirsch, F.; Schramm, A.; Schwarzkopf, L.; Szentes, B.L.; Lutter, J.; Huber, M.B.; Leidl, R.
Influence of COPD severity and its comorbidities on direct and indirect costs: Results from the LQ-DMP study.
Value Health 22, S876-S876 (2019)
Value in Health
Meeting abstract

Maqhuzu, P.N.; Kreuter, M.; Schwarzkopf, L.
Cost of healthcare resource utilization in interstitial lung diseases in Germany in 2017.
Value Health 22, S845-S845 (2019)
Value in Health
Meeting abstract

Szentes, B.L.; Schwarzkopf, L.; Schüler, M.; Lehbert, N.; Nowak, D.; Wittmann, M.; Faller, H.; Schultz, K.
The suitablility of the EQ-5D-5L in asthma patients.
Value Health 22, S882-S882 (2019)
Value in Health
Meeting abstract

John, J.; Koerber, F.; Schad, M.
Differential discounting in the economic evaluation of healthcare programs.
Cost Eff. Resour. Alloc. 17:29 (2019)
Background: The question of appropriate discount rates in health economic evaluations has been a point of continuous scientific debate. Today, it is widely accepted that, under certain conditions regarding the social objective of the healthcare decision maker and the fixity of the budget for healthcare, a lower discount rate for health gains than for costs is justified if the consumption value of health is increasing over time. To date, however, there is neither empirical evidence nor a strong theoretical a priori supporting this assumption. Given this lack of evidence, we offer an additional approach to check the appropriateness of differential discounting. Methods: Our approach is based on a two-goods extension of Ramsey's optimal growth model which allows accounting for changing relative values of goods explicitly. Assuming a constant elasticity of substitution (CES) utility function, the growth rate of the consumption value of health depends on three variables: the growth rate of consumption, the growth rate of health, and the income elasticity of the willingness to pay for health. Based on a review of the empirical literature on the monetary value of health, we apply the approach to obtain an empirical value of the growth rate of the consumption value of health in Germany. Results: The empirical literature suggests that the income elasticity of the willingness to pay for health is probably not larger but rather smaller than 1 and probably not smaller but rather larger than 0.2. Combining this finding with reasonable values of the annual growth rates in consumption (1.5-1.6%) and health (0.1%) suggests, for Germany, an annual growth rate of the consumption value of health between 0.3 and 1.5%. Conclusion: In the light of a two-goods extension of Ramsey's optimal growth model, the available empirical evidence makes the case for a growing consumption value of health. Therefore, the current German practice of applying the same discount rate to costs and health gains introduces a systematic bias against healthcare technologies with upfront costs and long-term health effects. Differential discounting with a lower rate for health effects appears to be a more appropriate discounting model.
Cost effectiveness and resource allocation

Felix, J.; Becker, C.; Vogl, M.; Buschner, P.; Plötz, W.; Leidl, R.
Patient characteristics and valuation changes impact quality of life and satisfaction in total knee arthroplasty results from a German prospective cohort study.
Health Qual. Life Outcomes 17:180 (2019)
Background: Evaluation of variations in pre- and postoperative patient reported outcomes (PRO) and the association between preoperative patient characteristics and health and satisfaction outcomes after total knee arthroplasty (TKA) may support shared decision-making in Germany. Since previous research on TKA health outcomes indicated valuation differences in longitudinal data, experienced-based population weights were used for the first time as an external valuation system to measure discrepancies between patient and average population valuation of HRQoL.Methods: Baseline data (n = 203) included sociodemographic and clinical characteristics and PROs, measured by the EQ-5D-3 L and WOMAC. Six-month follow-up data (n = 161) included medical changes since hospital discharge, PROs and satisfaction. A multivariate linear regression analysis was performed to evaluate the relationship between preoperative patient characteristics and PRO scores. Patient acceptable symptom state (PASS) was calculated to provide a satisfaction threshold. Patient-reported health-related quality of life (HRQoL) valuations were compared with average experienced-based population values to detect changes in valuation.Results: One hundred thirty-seven subjects met inclusion criteria. All PRO measures improved significantly. Preoperative WOMAC and EQ-5D VAS, housing situation, marital status, age and asthma were found to be predictors of postoperative outcomes. 73% of study participants valued their preoperative HRQoL higher than the general population valuation, indicating response shift. Preoperatively, patient-

reported EQ-5D VAS was substantially higher than average experienced-based population values. Postoperatively, this difference declined sharply. Approximately 61% of the patients reported satisfactory postoperative health, being mainly satisfied with results if postoperative WOMAC was >= 82.49 (change >= 20.25) and postoperative EQ-5D VAS was >= 75 (change >= 6).Conclusion: On average, patients benefited from TKA. Preoperative WOMAC and EQ-5D VAS were predictors of postoperative outcomes after TKA. Particularly patients with high absolute preoperative PRO scores were more likely to remain unsatisfied. Therefore, outcome prediction can contribute to shared-decision making. Using general population valuations as a reference, this study underlined a discrepancy between population and patient valuation of HRQoL before, but not after surgery, thus indicating a potential temporary response shift before surgery.
Health and Quality of Life Outcomes

von Siemens, S.M.; Perneczky, R.; Vogelmeier, C.F.; Behr, J.; Kauffmann-Guerrero, D.; Alter, P.; Trudzinski, F.C.; Bals, R.; Grohé, C.; Söhler, S.; Waschki, B.; Lutter, J.; Welte, T.; Jörres, R.A.; Kahnert, K.
The association of cognitive functioning as measured by the DemTect with functional and clinical characteristics of COPD: Results from the COSYCONET cohort.
Respir. Res. 20:257 (2019)
Alterations of cognitive functions have been described in COPD. Our study aimed to disentangle the relationship between the degree of cognitive function and COPD characteristics including quality of life (QoL). Data from 1969 COPD patients of the COSYCONET cohort (GOLD grades 1-4; 1216 male/ 753 female; mean (SD) age 64.9 +/- 8.4 years) were analysed using regression and path analysis. The DemTect screening tool was used to measure cognitive function, and the St. George's respiratory questionnaire (SGRQ) to assess disease-specific QoL. DemTect scores were < 9 points in 1.6% of patients and < 13 points in 12% when using the original evaluation algorithm distinguishing between < 60 or > =60 years of age. For statistical reasons, we used the average of both algorithms independent of age in all subsequent analyses. The DemTect scores were associated with oxygen content, 6-min-walking distance (6-MWD), C-reactive protein (CRP), modified Medical Research Council dyspnoea scale (mMRC) and the SGRQ impact score. Conversely, the SGRQ impact score was independently associated with 6-MWD, FVC, mMRC and DemTect. These results were combined into a path analysis model to account for direct and indirect effects. The DemTect score had a small, but independent impact on QoL, irrespective of the inclusion of COPD-specific influencing factors or a diagnosis of cognitive impairment. We conclude that in patients with stable COPD lower oxygen content of blood as a measure of peripheral oxygen supply, lower exercise capacity in terms of 6-MWD, and higher CRP levels were associated with reduced cognitive capacity. Furthermore, a reduction in cognitive capacity was associated with reduced disease-specific quality of life. As a potential clinical implication of this work, we suggest to screen especially patients with low oxygen content and low 6-MWD for cognitive impairment.
Respiratory Research

Finke, I.; Behrens, G.; Schwettmann, L.; Gerken, M.; Pritzkuleit, R.; Holleczek, B.; Brenner, H.; Jansen, L.
Socioeconomic differences and lung cancer survival in Germany: Differences in Therapy and clinical prognostic factors.
J. Epidemiol. Community Health 73, A77-A77 (2019)
Journal of Epidemiology and Community Health
Meeting abstract

Marietta von Siemens, S.; Alter, P.; Lutter, J.; Kauczor, H.U.; Jobst, B.; Bals, R.; Trudzinski, F.C.; Söhler, S.; Behr, J.; Watz, H.; Waschki, B.; Bewig, B.; Jones, P.W.; Welte, T.; Vogelmeier, C.F.; Jörres, R.A.; Kahnert, K.
CAT score single item analysis in patients with COPD: Results from COSYCONET.
Respir. Med. 159:105810 (2019)
The COPD Assessment Test (CAT) is in widespread use for the evaluation of patients with chronic obstructive pulmonary disease (COPD). We assessed whether the CAT items carry additional information beyond the sum score regarding COPD characteristics including emphysema. Patients of GOLD grades 1 to 4 from the COPD cohort COSYCONET (German COPD and Systemic Consequences - Comorbidities Network) with complete CAT data were included (n = 2270), of whom 493 had chest CT evaluated for the presence of emphysema. Comorbidities and lung function were assessed following standardised procedures. Cross-sectional data analysis was based on multiple regression analysis of the single CAT items against a panel of comorbidities, lung function, or CT characteristics (qualitative score, 15th percentile of mean lung density), with age, BMI and gender as covariates. This was supported by exploratory factor analysis. Regarding the relationship to comorbidities and emphysema, there were marked differences between CAT items, especially items 1 and 2 versus 3 to 8. This grouping was basically confirmed by factor analysis. Items 4 and 5, and to a lower degree 1, 2 and 6, appeared to be informative regarding the presence of emphysema, whereas the total score was not or less informative. Regarding comorbidities, similar findings as for the total CAT score were obtained for the modified Medical Research Council scale (mMRC) which was also informative regarding emphysema. Our findings suggest that the usefulness of the CAT can be increased if evaluated on the basis of single items which may be indicating the presence of comorbidities and emphysema.
Respiratory Medicine

Rabel, M.; Mess, F.; Karl, F.; Pedron, S.; Schwettmann, L.; Peters, A.; Heier, M.; Laxy, M.
Change in physical activity after diagnosis of diabetes or hypertension: Results from an observational population-based cohort study.
Int. J. Environ. Res. Public Health 16:4247 (2019)
Background: Chronic diseases like diabetes mellitus or hypertension are a major public health challenge. Irregular physical activity (PA) is one of the most important modifiable risk factors for chronic conditions and their complications. However, engaging in regular PA is a challenge for many individuals. The literature suggests that a diagnosis of a disease might serve as a promising point in time to change health behavior. This study investigates whether a diagnosis of diabetes or hypertension is associated with changes in PA. Methods: Analyses are based on 4261 participants of the population-based KORA S4 study (1999-2001) and its subsequent 7-and 14-year follow-ups. Information on PA and incident diagnoses of diabetes or hypertension was assessed via standardized interviews. Change in PA was

regressed upon diagnosis with diabetes or hypertension, using logistic regression models. Models were stratified into active and inactive individuals at baseline to avoid ceiling and floor effects or regression to the mean. Results: Active participants at baseline showed higher odds (OR = 2.16 [1.20;3.89]) for becoming inactive after a diabetes diagnosis than those without a diabetes diagnosis. No other significant association was observed. Discussion: As PA is important for the management of diabetes or hypertension, ways to increase or maintain PA levels in newly-diagnosed patients are important. Communication strategies might be crucial, and practitioners and health insurance companies could play a key role in raising awareness.
International Journal of Environmental Research and Public Health

Laxy, M.; Kähm, K.
Gesundheitsökonomische Evaluation von Präventions- und Managementstrategien bei Diabetes.
Diabetologie 15, 514-521 (2019)
HintergrundRessourcen im Gesundheitswesen sind knapp, und die Entscheidung für oder gegen eine bestimmte Strategie verursacht Opportunitätskosten. Aufgrund der hohen Versorgungskosten ist die Frage nach der effizienten Verwendung von Ressourcen bei der Betrachtung von Diabetes von besonderer Bedeutung. Mit der systematischen Gegenüberstellung von Kosten und Gesundheitseffekten bietet die gesundheitsökonomische Evaluation (GÖE) einen fundierten Rahmen, der zur Beantwortung dieser Frage beitragen kann.Ziel der ArbeitAnhand des Beispiels Diabetes wird ein Überblick über die Methodik der GÖE präsentiert, um das Verständnis für die Relevanz wissenschaftlicher Studien zu verbessern.Material und MethodenDie Kosten-Nutzwert-Analyse stellt die häufigste Form der Effizienzbewertung in der Literatur dar. Sie sieht für den Vergleich alternativer Handlungsoptionen eine Gegenüberstellung von Kosten und Gesundheitseffekten vor. In der Praxis werden bei der GÖE hierzu oft Daten aus klinischen Studien durch modellbasierte Simulationsstudien ergänzt; wichtig bei Diabetes sind zudem ein langfristiger Zeithorizont unter Berücksichtigung von Diskontierung sowie die vollständige Erfassung aller relevanten Kostenarten.Ergebnisse und DiskussionLaut größtenteils internationaler Evidenz sind eine intensivierte Kontrolle von Blutdruck und Blutzuckerspiegel sowie verhältnispräventive Maßnahmen für die Diabetesprävention mit hoher Wahrscheinlichkeit kosteneffektive bzw. effektive und kostengünstige Strategien. Bei der Allokation von Ressourcen sind auch viele andere Aspekte von Bedeutung, und Effizienzüberlegungen spielen im deutschen Gesundheitssystem nur eine nachgeordnete Rolle. Um das Potenzial der GÖE auszuschöpfen, ist es wichtig, die Gesundheitsökonomie bereits in der Planungsphase von Studien mit einzubeziehen.
Diabetologie, Die

Kirsch, F.; Schramm, A.; Schwarzkopf, L.; Lutter, J.; Szentes, B.L.; Huber, M.B.; Leidl, R.
Direct and indirect costs of COPD progression and its comorbidities in a structured disease management program: Results from the LQ-DMP study.
Respir. Res. 20:215 (2019)
Background: Evidence on the economic impact of chronic obstructive pulmonary disease (COPD) for third-party payers and society based on large real world datasets are still scarce. Therefore, the aim of this study was to estimate the economic impact of COPD severity and its comorbidities, stratified by GOLD grade, on direct and indirect costs for an unselected population enrolled in the structured German Disease Management Program (DMP) for COPD.Methods: All individuals enrolled in the DMP COPD were included in the analysis. Patients were only excluded if they were not insured or not enrolled in the DMP COPD the complete year before the last DMP documentation (at physician visit), had a missing forced expiratory volume in 1 s (FEV1) measurement or other missing values in covariates. The final dataset included 39,307 patients in GOLD grade 1 to 4. We used multiple generalized linear models to analyze the association of COPD severity with direct and indirect costs, while adjusting for sex, age, income, smoking status, body mass index, and comorbidities.Results: More severe COPD was significantly associated with higher healthcare utilization, work absence, and premature retirement. Adjusted annual costs for GOLD grade 1 to 4 amounted to (sic)3809 [(sic)3691-(sic)3935], (sic)4284 [(sic)4176-(sic)4394], (sic)5548 [(sic)5328-(sic)5774], and (sic)8309 [(sic)7583-9065] for direct costs, and (sic)11,784 [(sic)11,257-(sic)12,318], (sic)12, 985 [(sic)12,531-13,443], (sic)15,805 [(sic)15,034-(sic)16,584], and (sic)19,402 [(sic)17,853-(sic)21,017] for indirect costs. Comorbidities had significant additional effects on direct and indirect costs with factors ranging from 1.19 (arthritis) to 1.51 (myocardial infarction) in direct and from 1.16 (myocardial infarction) to 1.27 (cancer) in indirect costs.Conclusion: The findings indicate that more severe GOLD grades in an unselected COPD population enrolled in a structured DMP are associated with tremendous additional direct and indirect costs, with comorbidities significantly increase costs. In direct cost category hospitalization and in indirect cost category premature retirement were the main cost driver. From a societal perspective prevention and interventions focusing on disease control, and slowing down disease progression and strengthening the ability to work would be beneficial in order to realize cost savings in COPD.
Respiratory Research

Königsdorfer, N.#; Jörres, R.A.; Söhler, S.; Welte, T.; Behr, J.; Ficker, J.H.; Bals, R.; Watz, H.; Lutter, J.#; Lucke, T.; Biertz, F.; Alter, P.; Vogelmeier, C.F.; Kahnert, K.
Adherence to respiratory and non-respiratory medication in patients with COPD: Results of the German COSYCONET cohort.
Patient pre. adh. 13, 1711-1721 (2019)
Background: Adherence to COPD medication is often considered to be lower than in other chronic diseases. In view of the frequent comorbidities of COPD, the economic impact of nonadherence and the potential for adverse effects, a direct comparison between the adherence to respiratory and nonrespiratory medication in the same patients seems of particular interest. Objectives: We aimed to investigate the intake of respiratory and nonrespiratory medication in the same patients with COPD and frequent comorbidities. Method: Within the COPD cohort COSYCONET, we contacted 1042 patients, mailing them a list with all medication regarding all their diseases, asking for regular, irregular and nonintake. Results: Valid responses were obtained in 707 patients covering a wide spectrum of drugs. Intake of LABA, LAMA or ICS was regular in 91.9% of patients, even higher for cardiovascular and antidiabetes medication but lower for hyperlipidemia and depression/anxiety medication. Regular intake of respiratory

medication did not depend on GOLD groups A-D or grades 1–4, was highest in patients with concomitant cardiovascular disorders and was lowest for concomitant asthma. It was slightly larger for LAMA and LABA administered via combined compared to single inhalers, and lower when similar compounds were prescribed twice. Most differences did not reach statistical significance owing to the overall high adherence. Conclusion: Our results indicate a high adherence to respiratory medication in participants of a COPD cohort, especially in those with cardiovascular comorbidities. Compared to the lower adherence reported in the literature for COPD patients, our observations still suggest some room for improvement, possibly through disease management programs.
Patient preference and adherence

Gansen, F.; Severin, F.; Schleidgen, S.; Marckmann, G.; Rogowski, W.H.
Lethal privacy: Quantifying life years lost if the right to informational self-determination guides genetic screening for Lynch syndrome.
Health Policy 123, 1004-1010 (2019)
Genetic relatives of hereditary colorectal cancer patients with Lynch syndrome (LS) are at risk of cancer. Testing both colorectal cancer patients and relatives of mutation carriers for LS allows targeted prevention. However, this could mean disclosing sensitive health data to family members. In light of potential trade-offs between cost-effectiveness and patient privacy, this study investigates the implications of increasing test uptake in Germany.Out of 22 screening strategies for LS, the non-dominated and current German strategies were assessed from the perspective of the statutory health insurance. Life years gained by increased prevention were estimated with Markov models. The effects and implications of different test uptake rates in index patients and their relatives were investigated by scenario analysis.Privacy limitations could yield health gains of up to 2500 undiscounted life years for first-degree relatives of index patients and substantially improve cost-effectiveness. However, this approach may contradict the right to informational self-determination.This study demonstrates the effect higher LS test uptakes could have on the lives and rights of colorectal cancer patients and their relatives. It shows potential conflicts between the efficient use of health care resources on the one hand and reasonable consideration of patient autonomy on the other.
Health Policy

Schmidt, C.#; Heidemann, C.; Rommel, A.; Brinks, R.; Claessen, H.; Dreß, J.; Hagen, B.; Hoyer, A.; Laux, G.; Pollmanns, J.; Präger, M.; Böhm, J.; Drösler, S.; Icks, A.; Kümmel, S.; Kurz, C.F.; Kvitkina, T; Laxy, M.; Maier, W.#; Narres, M.; Szecsenyi, J.; Tönnies, T.; Weyermann, M.; Paprott, R.; Reitzle, L.; Baumert, J.; Patelakis, E.; Ziese, T.
Sekundärdaten in der Diabetes-Surveillance – Kooperationsprojekte und Referenzdefinition zur administrativen Diabetesprävalenz.
J. Health Monit., DOI: 10.25646/5982 (2019)
Neben den Gesundheitssurveys des Robert Koch-Instituts ist die zusätzliche Verwendung von Ergebnissen aus Sekundärdatenanalysen für die Zielsetzung einer wiederkehrenden und umfassenden Beschreibung des Diabetesgeschehens im Rahmen der Diabetes-Surveillance am Robert Koch-Institut unerlässlich. Die wesentlichen Gründe hierfür liegen im großen Stichprobenumfang und der routinemäßigen Erfassung der Sekundärdaten, die tief stratifizierte Auswertungen in zeitlich dichter Folge erlauben. Aufgrund der fragmentierten Datenlage sind verschiedene Sekundärdatenquellen notwendig, um die Indikatoren der vier Handlungsfelder der Diabetes-Surveillance mit Ergebnissen zu befüllen. Somit war ein Meilenstein im Projekt, die Eignung verschiedener Datenquellen auf ihre Nutzbarkeit hin zu prüfen und Analysen durchzuführen. Für diese Aufgabe wurden im Rahmen der Diabetes-Surveillance gezielt Kooperationsprojekte gefördert. In diesem Beitrag werden die Ergebnisse der Kooperationsprojekte aus den Jahren 2016 bis 2018 vorgestellt, die thematisch von der Prüfung der Eignung von Sekundärdaten bis hin zur statistischen Modellierung der Entwicklung epidemiologischer Kennzahlen reichen. Daneben wurden auf Grundlage aller rund 70 Millionen gesetzlich Krankenversicherten erste dokumentierte Prävalenzen des Typ-2-Diabetes für die Jahre 2010 und 2011 geschätzt. Um diese Prävalenzen über die Jahre vergleichbar in die Diabetes-Surveillance zu integrieren, wurde zusammen mit externer Expertise eine Referenzdefinition abgestimmt.
Journal of health monitoring

Kurz, C.F.; Rehm, M.; Holle, R.; Teuner, C.M.; Laxy, M.; Schwarzkopf, L.
The effect of bariatric surgery on health care costs: A synthetic control approach using Bayesian structural time series.
Health Econ. 28, 1293-1307 (2019)
Surgical measures to combat obesity are very effective in terms of weight loss, recovery from diabetes, and improvement in cardiovascular risk factors. However, previous studies found both positive and negative results regarding the effect of bariatric surgery on health care utilization. Using claims data from the largest health insurance provider in Germany, we estimated the causal effect of bariatric surgery on health care costs in a time period ranging from 2 years before to 3 years after bariatric intervention. Owing to the absence of a control group, we employed a Bayesian structural forecasting model to construct a synthetic control. We observed a decrease in medication and physician expenditures after bariatric surgery, whereas hospital expenditures increased in the post-intervention period. Overall, we found a slight increase in total costs after bariatric surgery, but our estimates include a high degree of uncertainty.
Health Economics

Szentes, B.L.; Schwarzkopf, L.; Kirsch, F.; Schramm, A.; Leidl, R.
Measuring quality of life in COPD patients: Comparing disease-specific supplements to the EQ-5D-5L.
Expert Rev. Pharmacoecon. Outcomes Res. 20, 523-529 (2019)
Objectives: Patients with chronic obstructive pulmonary disease (COPD) show impairments in health-related quality of life (HRQL). We aimed to find a disease-specific questionnaire for routine application in large cohorts and to assess its additional explanatory power to generic HRQL tool (EQ-5D-5L). Methods: 1,350 participants of the disease management program COPD received the EQ-5D-5L combined with one of the three disease-specific tools: COPD Assessment Test (CAT), Clinical COPD Questionnaire (CCQ) or St. George's Respiratory Disease Questionnaire (SGRQ) (450 participants each). We compared metric properties and evaluated the Germany-specific experience-based values (EBVS) and utilities in comparison to

the Visual Analogue Scale (VAS). We calculated the additional explanatory power of the identified disease-specific tool on VAS through regression analysis. Results: 344 patients returned the questionnaire. CAT, CCQ, and SGRQ group did not differ regarding baseline characteristics. The questionnaire specific response rates were 33.7% for CAT, 30.5% for CCQ, and 34.6% SGRQ, thereof 94.0%, 94.3%, and 65.6% valid answers, respectively. EBVS was better suited to reflect VAS than utilities. CAT increased the explanatory power by 10%. Conclusion: CAT outperformed CCQ and SGRQ, and it increased the explanatory power of VAS. EBV combined with CAT seems superior to only generic or disease-specific approaches.
Expert Review of Pharmacoeconomics and Outcomes Research

Schederecker, F.; Kurz, C.F.; Fairburn, J.; Maier, W.
Do alternative weighting approaches for an Index of Multiple Deprivation change the association with mortality? A sensitivity analysis from Germany.
BMJ Open 9:e028553 (2019)
Objectives This study aimed to assess the impact of using different weighting procedures for the German Index of Multiple Deprivation (GIMD) investigating their link to mortality rates.Design and setting In addition to the original (normative) weighting of the GIMD domains, four alternative weighting approaches were applied: equal weighting, linear regression, maximization algorithm and factor analysis. Correlation analyses to quantify the association between the differently weighted GIMD versions and mortality based on district-level official data from Germany in 2010 were applied (n=412 districts).Outcome measures Total mortality (all age groups) and premature mortality (<65 years).Results All correlations of the GIMD versions with both total and premature mortality were highly significant (p<0.001). The comparison of these associations using Williams's t-test for paired correlations showed significant differences, which proved to be small in respect to absolute values of Spearman's rho (total mortality: between 0.535 and 0.615; premature mortality: between 0.699 and 0.832).Conclusions The association between area deprivation and mortality proved to be stable, regardless of different weighting of the GIMD domains. The theory-based weighting of the GIMD should be maintained, due to the stability of the GIMD scores and the relationship to mortality.
BMJ Open

Lutter, J.; Szentes, B.L.; Wacker, M.; Winter, J.; Wichert, S.; Peters, A.; Holle, R.; Leidl, R.
Are health risk attitude and general risk attitude associated with healthcare utilization, costs and working ability? Results from the German KORA FF4 cohort study.
Health Econ. Rev. 9:26 (2019)
Background: Risk attitudes influence decisions made under uncertainty. This paper investigates the association of risk attitudes with the utilization of preventive and general healthcare services, work absence and resulting costs to explore their contribution to the heterogeneity in utilization. Methods: Data of 1823 individuals (56.5 ± 9.5 years), participating in the German KORA FF4 population-based cohort study (2013/2014) were analyzed. Individuals' general and health risk attitude were measured as willingness to take risk (WTTR) on 11-point scales. Utilization of preventive and medical services and work absence was assessed and annual costs were calculated from a societal perspective. Generalized linear models with log-link function (logistic, negative-binomial and gamma regression) adjusted for age, sex, and height were used to analyze the association of WTTR with the utilizations and costs. Results: Higher WTTR was significantly associated with lower healthcare utilization (physician visits, physical therapy, and medication intake), work absence days and indirect costs. Regarding preventive services, an overall negative correlation between WTTR and utilization was examined but this observation remained non-significant except for the outcome medical check-up. Here, higher WTTR was significantly associated with a lower probability of participation. For all associations mentioned, Odds Ratios ranged between 0.90 and 0.79, with p < 0.05. Comparing the two risk attitudes (general and regarding health) we obtained similar results regarding the directions of associations. Conclusions: We conclude that variations in risk attitudes contribute to the heterogeneity of healthcare utilization. Thus, knowledge of their associations with utilization might help to better understand individual decision-making - especially in case of participation in preventive services.
Health Economics Review

König, U.; Heinzel-Gutenbrunner, M.; Meinlschmidt, G.; Maier, W.; Bachmann, C.J.
Einfluss des sozioökonomischen Status auf Gesundheitskosten für Kinder und Jugendliche mit Störungen des Sozialverhaltens. Eine Analyse von Routinedaten einer gesetzlichen Krankenversicherung
Bundesgesundheitsbl.-Gesund. 62, 1057-1066 (2019)
Hintergrund Für verschiedene somatische und psychiatrische Krankheitsbilder ist bekannt, dass die Inanspruchnahme medizinischer Leistungen und die damit verbundenen Kosten vom sozioökonomischen Status (SES) der Patienten abhängen. Für den Bereich kinder- und jugendpsychiatrischer Störungen liegen zu dieser Thematik bislang keine Untersuchungen vor. Fragestellung Es wurde explorativ untersucht, inwieweit Kosten für Gesundheitsleistungen bei Kindern und Jugendlichen mit Störung des Sozialverhaltens (SSV), einem der häufigsten kinder- und jugendpsychiatrischen Störungsbilder, vom SES abhängen. Material und Methoden Grundlage der Analysen bildeten Routinedaten der AOK Nordost aus dem Jahr 2011 von 6461 Kindern und Jugendlichen (Alter: 5–18 Jahre) mit ICD-10-Diagnose einer SSV. Der SES der Versicherten wurde indirekt über die Sozialstruktur des Wohnortes (PLZ-Bezirk) mithilfe des German Index of Multiple Deprivation (Mecklenburg-Vorpommern, Brandenburg) bzw. des Berliner Sozialindex I (Berlin) bestimmt, die in Quintile aufgeteilt wurden. Auf Basis dieser Quintile wurden die durchschnittlichen Kosten pro Fall für ambulante Behandlungen bei Allgemeinärzten, Pädiatern, Kinder- und Jugendpsychiatern bzw. -psychotherapeuten sowie für stationäre Krankenhausaufenthalte und Arzneimittelverordnungen analysiert. Ergebnisse Für keine der untersuchten Kostenarten fand sich ein funktionaler Zusammenhang zwischen SES und Gesundheitskosten. Diskussion Im Gegensatz zu bisherigen Daten bei Erwachsenen zeigte sich in dieser Studie keine Assoziation zwischen dem SES und den Gesundheitskosten von Kindern und Jugendlichen mit SSV. Es scheint somit bei der medizinischen Versorgung dieser Patientengruppe in Deutschland keine signifikante sozial bedingte Ungleichheit zu bestehen.
Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz

Mehrabian, S.; Schwarzkopf, L.; Auer, S.; Holmerova, I.; Kramberger, M.G.; Boban, M.; Stefanova, E.; Tudose, C.; Bachinskaya, N.; Kovacs, T.; Koranda, P.; Kunchev, T.; Traykov, L.; Diehl-Schmid, J.; Milecka, K.; Kurz, A.
Dementia care in the danube region. A multi-national expert survey.
Neuropsychiatr. Dis. Treat. 15, 2503-2511 (2019)
Background: Dementia is a particularly severe societal challenge in several countries of the Danube Region due to higher-than-average increment in population longevity, disproportionate increase of the old-age dependency ratio, and selective outward migration of health care professionals. A survey was conducted among dementia experts to obtain a deeper understanding of the dementia care structures and services in this geographical area, and to identify the educational needs of health care professionals, and the availability of assistive technology. Subjects and methods: A standardized questionnaire was sent out to 15 leading dementia experts/clinicians in 10 Danube Region countries inquiring about professional groups involved in dementia care, availability and reimbursement of services, inclusion of dementia in professional education and training, acceptability of Internet-based education, and availability of assistive technology. The authors are the survey respondents. Results: The majority of individuals with dementia receive care in the community rather than in institutions. The roles of medical specialties are disparate. General practitioners usually identify dementia symptoms while specialists contribute most to clinical diagnosis and treatment. Health care professionals, particularly those who work closely with patients and carers, have limited access to dementia-specific education and training. The greatest need for dementia-specific education is seen for general practitioners and nurses. An Internet-based education and skill-building program is considered to be equivalent to traditional face-to-face but offer advantages in terms of convenience of access. Assistive technology is available in countries of the Danube Region but is significantly underused. Conclusion: Dementia care in the Danube Region can be improved by an educational and skill-building program for health care professionals who work in the frontline of dementia care. Such a program should also attempt to enhance interdisciplinary and intersectorial collaboration, to intensify the interaction between primary care and specialists, and to promote the implementation of assistive technology.
Neuropsychiatric Disease and Treatment

Kurz, C.F.; Hatfield, L.A.
Identifying and interpreting subgroups in health care utilization data with count mixture regression models.
Stat. Med. 38, 4423-4435 (2019)
Inpatient care is a large share of total health care spending, making analysis of inpatient utilization patterns an important part of understanding what drives health care spending growth. Common features of inpatient utilization measures such as length of stay and spending include zero inflation, overdispersion, and skewness, all of which complicate statistical modeling. Moreover, latent subgroups of patients may have distinct patterns of utilization and relationships between that utilization and observed covariates. In this work, we apply and compare likelihood-based and parametric Bayesian mixtures of negative binomial and zero-inflated negative binomial regression models. In a simulation, we find that the Bayesian approach finds the true number of mixture components more accurately than using information criteria to select among likelihood-based finite mixture models. When we apply the models to data on hospital lengths of stay for patients with lung cancer, we find distinct subgroups of patients with different means and variances of hospital days, health and treatment covariates, and relationships between covariates and length of stay.
Statistics in Medicine

Byng, D.[#]; Lutter, J.[#]; Wacker, M.; Jörres, R.A.; Liu, X.; Karrasch, S.; Schulz, H.; Vogelmeier, C.; Holle, R.
Determinants of healthcare utilization and costs in COPD patients: First longitudinal results from the German COPD cohort COSYCONET.
Int. J. Chron. Obstruct. Pulmon. Dis. 14, 1423-1439 (2019)
Background: In light of overall increasing healthcare expenditures, it is mandatory to study determinants of future costs in chronic diseases. This study reports the first longitudinal results on healthcare utilization and associated costs from the German chronic obstructive pulmonary disease (COPD) cohort COSYCONET. Material and methods: Based on self-reported data of 1904 patients with COPD who attended the baseline and 18-month follow-up visits, direct costs were calculated for the 12 months preceding both examinations. Direct costs at follow-up were regressed on baseline disease severity and other co-variables to identify determinants of future costs. Change score models were developed to identify predictors of cost increases over 18 months. As possible predictors, models included GOLD grade, age, sex, education, smoking status, body mass index, comorbidity, years since COPD diagnosis, presence of symptoms, and exacerbation history. Results: Inflation-adjusted mean annual direct costs increased by 5% (n.s., €6,739 to €7,091) between the two visits. Annual future costs were significantly higher in baseline GOLD grades 2, 3, and 4 (factors 1.24, 95%-confidence interval [1.07-1.43], 1.27 [1.09-1.48], 1.57 [1.27-1.93]). A history of moderate or severe exacerbations within 12 months, a comorbidity count >3, and the presence of dyspnea and underweight were significant predictors of cost increase (estimates ranging between + €887 and + €3,679, all p<0.05). Conclusions: Higher GOLD grade, comorbidity burden, dyspnea and moderate or severe exacerbations were determinants of elevated future costs and cost increases in COPD. In addition we identified underweight as independent risk factor for an increase in direct healthcare costs over time.
International Journal of Chronic Obstructive Pulmonary Disease

Gaertner, W.; Bradley, R.; Xu, Y.; Schwettmann, L.
Against the proportionality principle: Experimental findings on bargaining over losses.
PLoS ONE 14:e0218805 (2019)
© 2019 Gaertner et al. This is an open access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited. But experimental studies of related situations, such as those involving bankruptcies or bequests in which the sum of the legal claims that can be made against a bank or firm or estate are greater than their values, have produced strong support for the proportionality principle. To test whether this principle would find support in other situations involving losses we designed an experimental game in which four players start out with differing initial endowments of real money. They are then informed that a certain amount of this resource has to be given back to the

experimenter. How should the loss be shared among the agents? This game was run at different locations and under different treatments over a period of almost three years. We found that the proportionality principle was rarely proposed and even less frequently accepted as a solution to this problem. One of the main reasons for this result was that the two players with the smallest endowments opposed most of the proposals which asked them to contribute at least some positive amount of their own initial resource.
PLoS ONE

Laxy, M.; Schöning, V.M.; Kurz, C.F.; Holle, R.; Peters, A.; Meisinger, C.; Rathmann, W.; Mühlenbruch, K.; Kähm, K.
Performance of the UKPDS outcomes model 2 for predicting death and cardiovascular events in patients with type 2 diabetes mellitus from a German Population-Based Cohort.
Pharmacoeconomics 37, 1485-1494 (2019)
Background and Objective Accurate prediction of relevant outcomes is important for targeting therapies and to support health economic evaluations of healthcare interventions in patients with diabetes. The United Kingdom Prospective Diabetes Study (UKPDS) risk equations are some of the most frequently used risk equations. This study aims to analyze the calibration and discrimination of the updated UKPDS risk equations as implemented in the UKPDS Outcomes Model 2 (UKPDS-OM2) for predicting cardiovascular (CV) events and death in patients with type 2 diabetes mellitus (T2DM) from population-based German samples. Methods Analyses are based on data of 456 individuals diagnosed with T2DM who participated in two population-based studies in southern Germany (KORA (Cooperative Health Research in the Region of Augsburg)-A: 1997/1998, n = 178; KORA-S4: 1999-2001, n = 278). We compared the participants' 10-year observed incidence of mortality, CV mortality, myocardial infarction (MI), and stroke with the predicted event rate of the UKPDS-OM2. The model's calibration was evaluated by Greenwood-Nam-D'Agostino tests and discrimination was evaluated by C-statistics. Results Of the 456 participants with T2DM (mean age 65 years, mean diabetes duration 8 years, 56% male), over the 10-year follow-up time 129 died (61 due to CV events), 64 experienced an MI, and 46 a stroke. The UKPDS-OM2 significantly over-predicted mortality and CV mortality by 25% and 28%, respectively (Greenwood-Nam-D'Agostino tests: $p < 0.01$), but there was no significant difference between predicted and observed MI and stroke risk. The model poorly discriminated for death (C-statistic [95% confidence interval] = 0.64 [0.60-0.69]), CV death (0.64 [0.58-0.71]), and MI (0.58 [0.52-0.66]), and failed to discriminate for stroke (0.57 [0.47-0.66]). Conclusions The study results demonstrate acceptable calibration and poor discrimination of the UKPDS-OM2 for predicting death and CV events in this population-based German sample. Those limitations should be considered when using the UKPDS-OM2 for economic evaluations of healthcare strategies or using the risk equations for clinical decision-making.
PharmacoEconomics

Phillips, A.; Heier, M.; Strobl, R.; Linkohr, B.; Holle, R.; Peters, A.; Grill, E.
Exposure to anticholinergic and sedative medications using the Drug Burden Index and its association with vertigo, dizziness and balance problems in older people - Results from the KORA-FF4 Study.
Exp. Gerontol. 124:110644 (2019)
Aims: This study examines exposure to anticholinergic and sedative (AS) medications in the general aging population using the Drug Burden Index (DBI) and to analyze the association of AS burden with vertigo, dizziness and balance problems (VDB, primary outcome) and falls (secondary outcome).Methods: We performed a cross-sectional analysis of data from the second follow-up (FF4) in 2013/14 of the Cooperative Health Research in the Region of Augsburg (KORA)-S4 study. AS burden was classified as DBI > 0. Self-reported data of VDB and falls during the previous 12 months were collected. Multivariable logistic regression was used to estimate the association of AS burden with VDB and falls.Results: 883 participants were included in this study (mean age 73.8 years, 48.4% female). AS burden was present in 167 (18.9%) participants, with the highest prevalence in those aged >= 80 years old (26.3%). In the adjusted analysis, AS burden was independently and significantly associated with VDB (Adjusted Odds Ratio (AOR): 1.73 [95% CI: 1.16, 2.56]).Conclusion: This study provides reliable prevalence estimates of AS burden in older people using the DBI in Germany, also indicating a positive and significant association with VDB. As VDB are among the main reasons for falls, we do recommend including the AS burden calculation as routine risk assessment in ambulatory medical care.
Experimental Gerontology

Schildmann, E.; Hodiamont, F.; Leidl, R.; Maier, B.O.; Bausewein, C.
Which reimbursement system fits inpatient palliative care? A qualitative interview study on clinicians' and financing experts' experiences and views.
J. Palliat. Med 22, 1378-1385 (2019)
Context: Internationally, a variety of reimbursement systems exists for palliative care (PC). In Germany, PC units (PCUs) may choose between per-diem rates and diagnosis-related groups (DRGs). Both systems are controversially discussed. Objectives: To explore the experiences and views of German PCU clinicians and experts for PCU financing regarding per-diem rates and DRGs as reimbursement systems with a focus on (1) cost coverage, (2) strengths and weaknesses of both financing systems, and (3) options for further development of funding PCUs. Design: Qualitative semistructured interviews with PCU clinicians and experts for PCU financing, analyzed by thematic analysis using the Framework approach.
Setting/Subjects/Measurements: Ten clinicians and 13 experts for financing were interviewed June-October 2015 on both reimbursement systems for PCU. Results: Interviewees had divergent experiences with both reimbursement systems regarding cost coverage. A described strength of per-diem rates was the perceived possibility of individual care without direct financial pressure. The nationwide variation of per-diem rates and the lack of quality standards were named as weaknesses. DRGs were criticized for incentives perceived as perverse and inadequate representation of PC-specific procedures. However, the quality standards for PCUs required within the German DRG system were described as important strength. Suggestions for improvement of the funding system pointed toward a combination of per-diem rates with a grading according to disease severity/complexity of care. Conclusions: Expert opinions suggest that neither current DRGs nor per-diem rates are ideal for funding of PCUs. Suggested improvements

regarding adequate funding of PCUs resemble and supplement international developments.
Journal of Palliative Medicine

Walter, J.; Tufman, A.; Holle, R.; Schwarzkopf, L.
"Age matters"- German claims data indicate disparities in lung cancer care between elderly and young patients.
PLoS ONE 14:e0217434 (2019)
BackgroundAlthough lung cancer is most commonly diagnosed in elderly patients, evidence about tumor-directed therapy in elderly patients is sparse, and it is unclear to what extent this affects treatment and care. Our study aimed to discover potential disparities in care between elderly patients and those under 65 years of age.MethodsWe studied claims from 13 283 German patients diagnosed with lung cancer in 2009 who survived for at least 90 days after diagnosis. We classified patients as "non-elderly" (<= 65), "young-old" (65-74), "middle-old" (75-84), and "old-old" (>= 85). We compared receipt of tumor-directed therapy (6 months after diagnosis), palliative care, opioids, antidepressants, and pathologic diagnosis confirmation via logistic regression. We used generalized linear regression (gamma distribution) to compare group-specific costs of care for 3 months after diagnosis. We adjusted all models by age, nursing home residency, nursing care need, comorbidity burden, and area of residence (urban, rural). The age group "non-elderly" served as reference group.ResultsCompared with the reference group "non-elderly", the likelihood of receiving any tumor-directed treatment was significantly lower in all age groups with a decreasing gradient with advancing age. Elderly lung cancer patients received significantly fewer resections and radiotherapy than non-elderly patients. In particular, treatment with antineoplastic therapy declined with increasing age ("young-old" (OR = 0.76, CI = [0.70,0.83]), "middle-old" (OR = 0.45, CI = [0.36,0.50]), and "old-old" (OR = 0.13, CI = [0.10,0.17])). Patients in all age groups were less likely to receive structured palliative care than "non-elderly" ("young-old" (OR = 0.84, CI = [0.76,0.92]), "middle-old" (OR = 0.71, CI = [0.63,0.79]), and "old-old" (OR = 0.57, CI = [0.44,0.73])). Moreover, increased age was significantly associated with reduced quotas for outpatient treatment with opioids and antidepressants. Costs of care decreased significantly with increasing age.ConclusionThis study suggests the existence of age-dependent care disparities in lung cancer patients, where elderly patients are at risk of potential undertreatment. To support equal access to care, adjustments to public health policies seem to be urgently required.
PLoS ONE

Präger, M.; Kurz, C.F.; Böhm, J.; Laxy, M.; Maier, W.
Using data from online geocoding services for the assessment of environmental obesogenic factors: A feasibility study.
Int. J. Health Geogr. 18:13 (2019)
BackgroundThe increasing prevalence of obesity is a major public health problem in many countries. Built environment factors are known to be associated with obesity, which is an important risk factor for type 2 diabetes. Online geocoding services could be used to identify regions with a high concentration of obesogenic factors. The aim of our study was to examine the feasibility of integrating information from online geocoding services for the assessment of obesogenic environments.MethodsWe identified environmental factors associated with obesity from the literature and translated these factors into variables from the online geocoding services Google Maps and OpenStreetMap (OSM). We tested whether spatial data points can be downloaded from these services and processed and visualized on maps. True- and false-positive values, false-negative values, sensitivities and positive predictive values of the processed data were determined using search engines and in-field inspections within four pilot areas in Bavaria, Germany.ResultsSeveral environmental factors could be identified from the literature that were either positively or negatively correlated with weight outcomes in previous studies. The diversity of query variables was higher in OSM compared with Google Maps. In each pilot area, query results from Google showed a higher absolute number of true-positive hits and of false-positive hits, but a lower number of false-negative hits during the validation process. The positive predictive value of database hits was higher in OSM and ranged between 81 and 100% compared with a range of 63-89% for Google Maps. In contrast, sensitivities were higher in Google Maps (between 59 and 98%) than in OSM (between 20 and 64%).ConclusionsIt was possible to operationalize obesogenic factors identified from the literature with data and variables available from geocoding services. The validity of Google Maps and OSM was reasonable. The assessment of environmental obesogenic factors via geocoding services could potentially be applied in diabetes surveillance.
International journal of health geographics

Marijic, P.; Walter, J.; Schneider, C.; Schwarzkopf, L.
Cost and survival of video-assisted thoracoscopic lobectomy versus open lobectomy in lung cancer patients: A propensity score-matched study.
Eur. J. Cardio-thorac Surg. 57, 92-99 (2019)
OBJECTIVES: A video-assisted thoracoscopic surgery (VATS) is an accepted alternative to open thoracotomy (OT) in lung cancer patients undergoing lobectomy, but evidence of the benefits of VATS remains inconsistent. The aim of this study was to compare VATS and OT regarding survival, costs and length of hospital stay (LOS).METHODS: We identified lung cancer patients (incident 2013) undergoing VATS or OT from German insurance claims data and performed 1:2 propensity score matching. A 3-year survival was analysed using the Kaplan-Meier curves and a univariable Cox model. Group differences in the 3-year lung cancer-related costs and costs of hospital stay with lobectomy were compared via univariable generalized linear gamma models. LOS was compared using the Mann-Whitney-Wilcoxon test.RESULTS: After propensity score matching, we compared 294 patients undergoing VATS and 588 receiving OT. We found no differences in the 3-year survival (VATS: 73.8%, OT: 69.2%, P = 0.131) or costs for hospital stay with lobectomy (VATS: Euro11 921, OT: Euro12 281, P = 0.573). However, VATS patients had significantly lower lung cancer-related costs (VATS: Euro20 828, OT: Euro23 723, P = 0.028) and median postoperative LOS (VATS: 9 days, OT: 11 days, P < 0.001).CONCLUSIONS: From a payer's perspective, extending the use of VATS is beneficial, as it shows economic benefits without affecting survival. However, for a more comprehensive assessment of the benefits of VATS from a society's point of view, further aspects such as patient-reported outcomes and provider-related standby costs need to be investigated further.
European journal of cardio-thoracic surgery

Marten, O.[#]; Koerber, F.[#]; Bloom, D.; Bullinger, M.; Buysse, C.; Christensen, H.; De Wals, P.; Dohna-Schwake, C.; Henneke, P.;

Kirchner, M.; Knuf, M.; Lawrenz, B.; Monteiro, A.L.; Sevilla, J.P.; Van de Velde, N.; Welte, R.; Wright, C.; Greiner, W.
A DELPHI study on aspects of study design to overcome knowledge gaps on the burden of disease caused by serogroup B invasive meningococcal disease.
Health Qual. Life Outcomes 17:87 (2019)
BACKGROUND: Value assessment of vaccination programs against serogroup B invasive meningococcal disease (IMD) is on the agenda of public health authorities. Current evidence on the burden due to IMD is unfit for pinning down the nature and magnitude of the full social and economic costs of IMD for two reasons. First, the concepts and components that need to be studied are not agreed, and second, measures of the concepts that have been studied are weak and inconsistent. Thus, the economic evaluation of the available serogroup B meningococcal (MenB) vaccines is difficult. The aims of this DELPHI study are to: (1) agree on the concepts and components determining the burden of MenB diseases that need to be studied; and (2) seek consensus on appropriate methods and study designs to measure quality of life (QoL) associated with MenB induced long-term sequelae in future studies. METHODS: We designed a DELPHI questionnaire based on the findings of a recent systematic review on the QoL associated with IMD-induced long-term sequelae, and iteratively interviewed a panel of international experts, including physicians, health economists, and patient representatives. Experts were provided with a controlled feedback based on the results of the previous round. RESULTS: Experts reached consensus on all questions after two DELPHI rounds. Major gaps in the literature relate (i) to the classification of sequelae, which allows differentiation of severity levels, (ii) to the choice of QoL measures, and (iii) to appropriate data sources to examine long-term changes and deficits in patients' QoL. CONCLUSIONS: Better conceptualisation of the structure of IMD-specific sequelae and of how their diverse forms of severity might impact the QoL of survivors of IMD as well as their family network and care-providers is needed to generate relevant, reliable and generalisable data on QoL in the future. The results of this DELPHI panel provide useful guidance on how to choose the study design, target population and appropriate QoL measures for future research and hence, help promote the appropriateness and consistency in study methodology and sample characteristics.
Health and Quality of Life Outcomes

Arnold, M.; Pfeifer, K.; Quante, A.S.
Is risk-stratified breast cancer screening economically efficient in Germany?
PLoS ONE 14:e0217213 (2019)
ObjectivesRisk stratification has so far been evaluated under the assumption that women fully adhere to screening recommendations. However, the participation in German cancer screening programs remains low at 54%. The question arises whether risk-stratified screening is economically efficient under the assumption that adherence is not perfect.MethodWe have adapted a micro-simulation Markov model to the German context. Annual, biennial, and triennial routine screening are compared with five risk-adapted strategies using thresholds of relative risk to stratify screening frequencies. We used three outcome variables (mortality reduction, quality-adjusted life years, and false-positive results) under the assumption of full adherence vs. an adherence rate of 54%. Strategies are evaluated using efficiency frontiers and probabilistic sensitivity analysis (PSA).ResultsThe reduced adherence rate affects both performance and cost; incremental cost-effectiveness ratios remain constant. The results of PSA show that risk-stratified screening strategies are more efficient than biennial routine screening under certain conditions. At any willingness-to-pay (WTP), there is a risk-stratified alternative with a higher likelihood of being the best choice. However, without explicit decision criteria and WTP, risk-stratified screening is not more efficient than biennial routine screening. Potential improvements in the adherence rates have significant health gains and budgetary implications.ConclusionIf the participation rate for mammographic screening is as low as in Germany, stratified screening is not clearly more efficient than routine screening but dependent on the WTP. A more promising design for future stratified strategies is the combination of risk stratification mechanisms with interventions to improve the low adherence in selected high-risk groups.
PLoS ONE

Wang, X.; Strobl, R.; Holle, R.; Seidl, H.; Peters, A.; Grill, E.
Vertigo and dizziness cause considerable more health care resource use and costs: Results from the KORA FF4 study.
J. Neurol. 266, 2120-2128 (2019)
Objectives Vertigo is a common reason for primary care consultations, and its diagnosis and treatment consume considerable medical resources. However, limited information on the specific cost of vertigo is currently available. The aim of this study is to analyse the health care costs of vertigo and examine which individual characteristics would affect these costs. Study design We used cross-sectional data from the German KORA ("Cooperative Health Research in the Augsburg Region") FF4 study in 2013. Methods Impact of personal characteristics and other factors was modelled using a two-part model. Information on health care utilisation was collected by self-report. Results We included 2277 participants with a mean age of 60.8 (SD = 12.4), 48.4% male. Moderate or severe vertigo was reported by 570 (25.0%) participants. People with vertigo spent 818 Euro more than people without vertigo in the last 12 months (2720.9 Euro to 1902.9 Euro, SD = 4873.3 and 5944.1, respectively). Consultation costs at primary care physicians accounted for the largest increase in total health care costs with 177.2 Euro ($p < 0.01$). After adjusting for covariates, the presence of vertigo increased both the probability of having any health care costs (OR = 1.6, 95% CI =[1.2;2.4]) and the amount of costs (exp(beta) = 1.3, 95% CI = [1.1;1.5]). The analysis of determinants of vertigo showed that private insurance and a medium level of education decreased the probability of any costs, while higher income increased it. Conclusions The presence of vertigo and dizziness required considerable health care resources and created significantly more related costs in different health care sectors for both primary and pertinent secondary care.
Journal of Neurology

von Siemens, M.; Joerres, R.A.; Behr, J.; Alter, P.; Lutter, J.; Soehler, S.; Welte, T.; Watz, H.; Trudzinski, F.; Rief, W.; Herbig, B.; Kahnert, K.
Effect of COPD severity and comorbidities on the result of the PHQ-9 tool for the diagnosis of depression: Results from the COSYCONET cohort study.
Internist 60, S49-S49 (2019)
Internist, Der
Meeting abstract

Kahnert, K.; Koenigsdorfer, N.; Soehler, S.; Welte, T.; Behr, J.; Ficker, J.H.; Bals, R.; Watz, H.; Lutter, J.; Lücke, T.; Biertz, F.; Alter, P.; Vogelmeier, C.F.; Joerres, R.A.
Adherence to respiratory and non-respiratory medication in patients with COPD: Results of the German COSYCONET cohort.
Internist 60, S5-S6 (2019)
Internist, Der
Meeting abstract

Zeiser, K.; Hammel, G.; Krabiell, L.; Linkohr, B.; Peters, A.; Schwettmann, L.; Ring, J.; Johar, H.; Ladwig, K.-H.; Traidl-Hoffmann, C.
Different psychosocial factors are associated with seasonal and perennial allergies in adults: Cross-sectional results of the KORA FF4 study.
Int. Arch. Allergy Immunol. 179, 262-272 (2019)
Background: Psychosocial factors are supposed to play a central role in the development of allergic diseases. Associations with seasonal and perennial forms of allergies have not been investigated, yet. Objectives: The aim of the study was to investigate the associations of psychosocial factors (social status, depression, generalized anxiety, psychosocial stress, Type-D personality) with seasonal, perennial, and other forms of allergies in adults. Method: The analysis of self-reported data of the KORA FF4 study was performed with SAS 9.4. The sample consisted of 1,782 study participants in the study region of Augsburg (39-88 years, 61 years, 51.1% female). Descriptive bivariate statistics and multinomial logistic regression models were performed. Age, sex, family predisposition, and smoking status were considered possible confounders. Moreover, several sensitivity analyses were carried out to check whether missing values distorted the results. Results: A positive association between generalized anxiety and seasonal allergies was found in the multivariate model. Depression was positively, and anxiety negatively, associated with perennial allergies. No association between the analyzed psychosocial factors and other forms of allergies could be found. Conclusion: The results support the relevance of psychosocial factors in association with allergies. Looking at the psychosocial factors, a separate consideration of seasonal and perennial allergies seems reasonable. Further longitudinal studies should investigate the direction of the associations, the underlying mechanisms, and other psychosocial factors, such as coping mechanisms, in confirmed allergies.
International Archives of Allergy and Immunology

Frank, A.L.#; Kreuter, M.; Schwarzkopf, L.#
Economic burden of incident interstitial lung disease (ILD) and the impact of comorbidity on costs of care.
Respir. Med. 152, 25-31 (2019)
INTRODUCTION: Evidence about the economic burden related to interstitial lung diseases (ILDs) and the cost-driving factors is sparse. In the knowledge that distinct comorbidities affect the clinical course of ILDs, our study investigates their impact on costs of care within first year after diagnosis. METHODS: Using claims data of individuals diagnosed with Idiopathic Interstitial Pneumonia (IIP) (n = 14 453) or sarcoidosis (n = 9106) between 2010 and 2013, we calculated total and ILD-associated mean annual per capita costs adjusted by age, sex and comorbidity burden via Generalized Linear Gamma models. Then, we assessed the cost impact of chronic obstructive pulmonary disease (COPD), diabetes, coronary artery disease, depression, gastro-esophageal reflux disease, pulmonary hypertension (PH), obstructive sleep apnoea syndrome (OSAS) and lung cancer using the model-based parameter estimates. RESULTS: Total mean annual per capita costs were €11 131 in the pooled cohort, €12 111 in IIP and €8793 in sarcoidosis, each with a 1/3 share of ILD-associated cost. Most comorbidities had a significant cost-driving effect, which was most pronounced for lung cancer in total (1.989 pooled, 2.491 sarcoidosis, 1.696 IIP) and for PH in ILD-associated costs (2.606 pooled, 2.347 IIP, 3.648 sarcoidosis). The lung-associated comorbidities COPD, PH, OSAS more strongly affected ILD-associated than total costs. CONCLUSION: Comorbidities increase the already substantial costs of care in ILDs. To support patient-centred ILD care, not only highly cost-driving conditions that are inherent with high mortality themselves require systematic management. Moreover, conditions that are more rather restricting the patient's activities of daily living should be addressed - despite a low-cost impact.
Respiratory Medicine

Krack, G.
How to make value-based health insurance designs more effective? A systematic review and meta-analysis.
Eur. J. Health Econ. 20, 841-856 (2019)
Value-based health insurance designs (VBIDs) are one approach to increase adherence to highly effective medications and simultaneously contain rising health care costs. The objective of this systematic review was to identify VBID effects on adherence and incentive designs within these programs that were associated with higher effects. Eight economic and medical databases were searched for literature. Random effects meta-analyses and mixed effects meta-regressions were used to synthesize VBID effects on adherence. Thirteen references with evaluation studies, including 12 patient populations with 79 outcomes, were used for primary meta-analyses. For qualitative review and sensitivity analyses, up to 19 references including 20 populations with 119 outcomes were used. Evidence of synthesized effects was good, because references with high risk of bias were excluded. VBIDs significantly increased adherence in all indication areas. Highest effects were found in medications indicated in heart diseases (4.05%-points, $p < 0.0001$). Each additional year increased effects by 0.15%-points ($p < 0.01$). VBIDs with education were more effective than without education, but the difference was not significant. Effects of VBIDs with full coverage were more than twice as high as effects of VBID without that option (4.52 vs 1.81%-points, $p < 0.05$). These findings were robust in most sensitivity analyses. It is concluded that VBID implementation should be encouraged, especially for patients with heart diseases, and that full coverage was associated with higher effects. This review may provide insight for policy-makers into how to make VBIDs more effective.
The European journal of health economics

Fiorito, G.; McCrory, C.; Robinson, O.; Carmeli, C.; Rosales, C.O.; Zhang, Y.; Colicino, E.; Dugué, P.A.; Artaud, F.; Mckay, G.J.; Jeong, A.; Mishra, P.P.; Nøst, T.H.; Krogh, V.; Panico, S.; Sacerdote, C.; Tumino, R.; Palli, D.; Matullo, G.; Guarrera, S.; Gandini, M.; Bochud, M.; Dermitzakis, E.; Muka, T.; Schwartz, J.; Vokonas, P.S.; Just, A.; Hodge, A.M.; Giles, G.G.; Southey, M.C.; Hurme, M.A.; Young, I.; McKnight, A.J.; Kunze, S.; Waldenberger, M.; Peters, A.; Schwettmann, L.; Lund, E.;

Baccarelli, A.; Milne, R.L.; Kenny, R.A.; Elbaz, A.; Brenner, H.; Kee, F.; Voortman, T.; Probst-Hensch, N.; Lehtimäki, T.; Elliot, P.; Stringhini, S.; Vineis, P.; Polidoro, S.
Socioeconomic position, lifestyle habits and biomarkers of epigenetic aging: A multi-cohort analysis.
Aging 11, 2045-2070 (2019)
Differences in health status by socioeconomic position (SEP) tend to be more evident at older ages, suggesting the involvement of a biological mechanism responsive to the accumulation of deleterious exposures across the lifespan. DNA methylation (DNAm) has been proposed as a biomarker of biological aging that conserves memory of endogenous and exogenous stress during life.We examined the association of education level, as an indicator of SEP, and lifestyle-related variables with four biomarkers of age-dependent DNAm dysregulation: the total number of stochastic epigenetic mutations (SEMs) and three epigenetic clocks (Horvath, Hannum and Levine), in 18 cohorts spanning 12 countries.The four biological aging biomarkers were associated with education and different sets of risk factors independently, and the magnitude of the effects differed depending on the biomarker and the predictor. On average, the effect of low education on epigenetic aging was comparable with those of other lifestyle-related risk factors (obesity, alcohol intake), with the exception of smoking, which had a significantly stronger effect.Our study shows that low education is an independent predictor of accelerated biological (epigenetic) aging and that epigenetic clocks appear to be good candidates for disentangling the biological pathways underlying social inequalities in healthy aging and longevity.
Aging

Mühlig, Y.; Remy, M.; Holle, R.; Scherag, A.; Wabitsch, M.; Hebebrand, J.
Psychosoziale Charakterisierung und Integrative Versorgung arbeitsloser Jugendlicher mit extremer Adipositas – ein Modellprojekt.
Psychother. Psychosom. Med. Psychol. 69, 490-498 (2019)
Einleitung Soziale Benachteiligung stellt eine Behandlungsbarriere für Jugendliche mit (extremer) Adipositas dar. Mit der Implementierung einer Spezialambulanz in Kooperation mit fünf Job-Centern sollte geprüft werden, ob arbeitslose Jugendliche mit Adipositas Interesse an einer Behandlung ihrer Adipositas haben und welche Teilnahmeraten sie in einem mehrstufigen Behandlungsprogramm aufweisen. Material und Methoden Jugendliche (15,0–24,9 Jahre) mit einem Body-Mass-Index (BMI) ≥30 kg/m2 erhielten das Angebot zur Beratung bzgl. Behandlungsmöglichkeiten der Adipositas im Job-Center. Interessierte Jugendliche wurden nach einer psychologischen Diagnostik in ein multimodales Behandlungsprogramm (6 Sitzungen) aufgenommen. Bei Interesse und bewiesener Adhärenz (Teilnahme an ≥5 Sitzungen) folgte ein Informationskurs (4 Sitzungen) und eine Indikationsprüfung für eine adipositaschirurgische Maßnahme. Ergebnisse Von 2012–2017 wurden 83 Jugendliche (im Mittel 21,1 Jahre, BMI 48,1 kg/m2, BMI 35,0–39,9 kg/m2: N=7, ≥ 40 kg/m2: N=71) eingeschlossen. 34 bewiesen ihre Adhärenz (≥5/6 Sitzungen in der multimodalen Adipositasintervention), 20 interessierten sich für einen adipositaschirurgischen Eingriff. Bisher wurden 11 Jugendliche operiert mit einer mittleren BMI-Reduktion von 14,3 kg/m2 3–36 Monate nach der Operation („Excess Weight Loss“ 27,3%) im Vergleich zu 3,8 kg/m2 6–48 Monate nach Behandlungsbeginn bei den nicht-operierten Jugendlichen. 13 Teilnehmer wurden auf dem ersten Arbeitsmarkt integriert. Diskussion Einige arbeitslose Jugendliche nahmen das Behandlungsangebot gut an und zeigten eine positive gesundheitliche und berufliche Entwicklung im Verlauf ihrer Teilnahme. Schlussfolgerung Die Implementierung einer Spezialambulanz für arbeitslose Jugendliche mit Adipositas in deutschen Job-Centern erweist sich als eine erfolgreiche Strategie, um diese oft unbehandelte Hochrisikogruppe zu charakterisieren und den individuellen Behandlungsbedarf zu ermitteln. Dieser Befund muss an einer größeren Stichprobe im Langzeitverlauf bestätigt werden.
Psychotherapie, Psychosomatik, Medizinische Psychologie

Stephan, A.-J.; Strobl, R.; Schwettmann, L.; Meisinger, C.; Ladwig, K.-H.; Linkohr, B.; Thorand, B.; Peters, A.; Grill, E.
Being born in the aftermath of World War II increases the risk for health deficit accumulation in older age: Results from the KORA-Age study.
Eur. J. Epidemiol. 34, 675-687 (2019)
Morbidity trends may result from cohort experiences in critical developmental age. Our objective was to compare the health status of 65-71year-olds who were in critical developmental age before (1937-June 1945), during (June 1945-June 1948) and after (June 1948-1950) the early reconstruction and food crisis (ERFC) period in Germany following World War II. Data originate from the KORA (Cooperative Health Research in the Region of Augsburg)-Age study in Southern Germany. We used the 2008 baseline sample born 1937-1943 and the 2015 enrichment sample born 1944-1950. Health status was assessed as the number of accumulated health deficits using a Frailty Index (FI). Cohorts were defined based on co-occurrence of critical developmental age (gestation and the first 2years of life) and the ERFC period. Cohort, age and sex effects on older-age health status were analyzed using generalized linear models. We included 590 (53% male) pre-war and war (PWW), 475 (51% male) ERFC and 171 post-currency reform (PCR) cohort participants (46% male). Adjusted for covariates, FI levels were significantly higher for the ERFC (Ratio 1.14, CL [1.06, 1.23]) but not for the PCR (Ratio 1.06, CL [0.94, 1.20]) as compared to the PWW cohort. Being in critical developmental age during the ERFC period increased FI levels in adults aged 65-71years. Covariates did not explain these effects, suggesting a direct detrimental effect from being in critical developmental age during the ERFC period on older-age health. This expansion of morbidity in Germany was not detected in the PCR cohort.
European Journal of Epidemiology

Hodiamont, F.; Jünger, S.; Leidl, R.; Maier, B.O.; Schildmann, E.; Bausewein, C.
Understanding complexity - the palliative care situation as a complex adaptive system.
BMC Health Serv. Res. 19:157 (2019)
BackgroundThe concept of complexity is used in palliative care (PC) to describe the nature of patients' situations and the extent of resulting needs and care demands. However, the term or concept is not clearly defined and operationalised with respect to its particular application in PC. As a complex problem, a care situation in PC is characterized by reciprocal, nonlinear relations and uncertainties. Dealing with complex problems necessitates problem-solving methods tailored to specific situations. The theory of complex adaptive systems (CAS) provides a framework for locating problems and solutions.This study aims to describe

criteria contributing to complexity of PC situations from the professionals' view and to develop a conceptual framework to improve understanding of the concept of complexity and related elements of a PC situation by locating the complex problem PC situation in a CAS.MethodsQualitative interview study with 42 semi-structured expert (clinical/economical/political) interviews. Data was analysed using the framework method. The thematic framework was developed inductively. Categories were reviewed, subsumed and connected considering CAS theory.ResultsThe CAS of a PC situation consists of three subsystems: patient, social system, and team. Agents in the "system patient" are allocated to further subsystems on patient level: physical, psycho-spiritual, and socio-cultural. The "social system" and the "system team" are composed of social agents, who affect the CAS as carriers of characteristics, roles, and relationships. Environmental factors interact with the care situation from outside the system. Agents within subsystems and subsystems themselves interact on all hierarchical system levels and shape the system behaviour of a PC situation.ConclusionsThis paper provides a conceptual framework and comprehensive understanding of complexity in PC. The systemic view can help to understand and shape situations and dynamics of individual care situations; on higher hierarchical level, it can support an understanding and framework for the development of care structures and concepts. The framework provides a foundation for the development of a model to differentiate PC situations by complexity of patients and care needs. To enable an operationalisation and classification of complexity, relevant outcome measures mirroring the identified system elements should be identified and implemented in clinical practice.
BMC Health Services Research

Witt, S.; Krauss, E.; Barbero, M.A.N.; Müller, V.; Bonniaud, P.; Vancheri, C.; Wells, A.U.; Vasakova, M.; Pesci, A.; Klepetko, W.; Seeger, W.; Crestani, B.; Leidl, R.; Holle, R.; Schwarzkopf, L.; Guenther, A.
Psychometric properties and minimal important differences of SF-36 in Idiopathic Pulmonary Fibrosis.
Respir. Res. 20:47 (2019)
Background: Idiopathic pulmonary fibrosis (IPF) is a rare disease with a median survival of 3-5 years after diagnosis with limited treatment options. The aim of this study is to assess the psychometric characteristics of the Short Form 36 Health Status Questionnaire (SF-36) in IPF and to provide disease specific minimally important differences (MID). Methods: Data source was the European IPF Registry (eurIPFreg). The psychometric properties of the SF-36 version 2 were evaluated based on objective clinical measures as well as subjective perception. We analysed acceptance, feasibility, discrimination ability, construct and criterion validity, responsiveness and test-retest-reliability. MIDs were estimated via distribution and anchor-based approaches. Results: The study population included 258 individuals (73.3% male; mean age 67.3 years, SD 10.7). Of them 75.2% (194 individuals) had no missing item. The distribution of several items was skewed, although floor effect was acceptable. Physical component score (PCS) correlated significantly and moderately with several anchors, whereas the correlations of mental component score (MCS) and anchors were only small. The tests showed mainly significant lower HRQL in individuals with long-term oxygen therapy. Analyses in stable individuals did not show significant changes of HRQL except for one dimension and anchor. Individuals with relevant changes of the health status based on the anchors had significant changes in all SF-36 dimensions and summary scales except for the dimension PAIN. PCS and MCS had mean MIDs of five and six, respectively. Mean MIDs of the dimensions ranged from seven to 21. Conclusion: It seems that the SF-36 is a valid instrument to measure HRQL in IPF and so can be used in RCTs or individual monitoring of disease. Nevertheless, the additional evaluation of longitudinal aspects and MIDs can be recommended to further analyse these factors. Our findings have a great potential impact on the evaluation of IPF patients. Trial registration: The eurIPFreg and eurIPFbank are listed in https://clinicaltrials.gov (NCT02951416).
Respiratory Research

Liu, W.-H.; Schwarzkopf, L.; Herold, T.; Jeremias, I.
Inducible re-expression of KLF4 impairs growth of patient derived acute lymphoma leukemia cells IN VIVO and sensitizes them towards chemotherapy.
Ann. Hematol. 98, S53-S53 (2019)
Annals of Hematology
Meeting abstract

Leidl, R.
Social media, bots and research performance.
Eur. J. Public Health 29:1 (2019)
European Journal of Public Health
Editorial
Editorial
Karl, F.; Holle, R.; Schwettmann, L.; Peters, A.; Laxy, M.
Status quo bias and health behavior: Findings from a cross-sectional study.
Eur. J. Public Health 29, 992-997 (2019)
BACKGROUND: Status quo bias (SQB) has often been referred to as an important tool for improving public health. However, very few studies were able to link SQB with health behavior. METHODS: Analysis were based on data from the population-based KORA S4 study (1999-2001, n = 2309). We operationalized SQB through two questions. The first asked whether participants switched their health insurance for financial benefits since this was enabled in 1996. Those who did were assigned a 'very low SQB' (n = 213). Participants who did not switch were asked a second hypothetical question regarding switching costs. We assigned 'low SQB' to those who indicated low switching costs (n = 1035), 'high SQB' to those who indicated high switching costs (n = 588), and 'very high SQB' to those who indicated infinite switching costs (n = 473). We tested the association between SQB and physical activity, diet, smoking, alcohol consumption, the sum of health behaviors, and body mass index (BMI) using logistic, Poisson and ordinary least square regression models, respectively. Models were adjusted for age, sex, education, income, satisfaction with current health insurance and morbidity. RESULTS: SQB was associated with a higher rate of physical inactivity [OR = 1.22, 95% CI (1.11; 1.35)], a higher sum of unhealthy lifestyle factors [IRR = 1.05, 95% CI (1.01; 1.10)] and a higher BMI [β = 0.30, 95% CI (0.08; 0.51)]. CONCLUSION: A high SQB was associated with unfavorable health behavior and higher BMI. Targeting SQB might be a promising strategy for promoting healthy behavior.
European Journal of Public Health

Rabel, M.; Laxy, M.; Thorand, B.; Peters, A.; Schwettmann, L.; Mess, F.
Clustering of health-related behavior patterns and demographics. Results from the population-based KORA S4/F4 cohort study.
Front. Publ. Health 6:387 (2019)
Health behaviors are of great importance for public health. Previous research shows that health behaviors are clustered and do not occur by chance. The main objective of this study was to investigate and describe the clustering of alcohol consumption, nutrition, physical activity and smoking while also considering the influence of sex, age and education. Using data from the population-based KORA S4/F4 cohort study, latent class regression analysis was undertaken to identify different clusters of health behavior patterns. The clusters were described according to demographics. Furthermore, the clusters were described regarding health-related quality of life at baseline and at a 7 year follow-up. Based on a sample of 4,238 participants, three distinct classes were identified. One overall healthy class and two heterogeneous classes. Classes varied especially according to sex, indicating a healthier behavior pattern for females. No clear association between healthier classes and age, education or physical and mental health-related quality of life was found. This study strengthens the literature on the clustering of health behaviors and additionally describes the identified clusters in association with health-related quality of life. More research on associations between clustering of health behaviors and important clinical outcomes is needed.
Frontiers in Public Health

Huber, M.B.; Kurz, C.F.; Leidl, R.
Predicting patient-reported outcomes following hip and knee replacement surgery using supervised machine learning.
BMC Med. Inform. Decis. Mak. 19:3 (2019)
BackgroundMachine-learning classifiers mostly offer good predictive performance and are increasingly used to support shared decision-making in clinical practice. Focusing on performance and practicability, this study evaluates prediction of patient-reported outcomes (PROs) by eight supervised classifiers including a linear model, following hip and knee replacement surgery.MethodsNHS PRO data (130,945 observations) from April 2015 to April 2017 were used to train and test eight classifiers to predict binary postoperative improvement based on minimal important differences. Area under the receiver operating characteristic, J-statistic and several other metrics were calculated. The dependent outcomes were generic and disease-specific improvement based on the EQ-5D-3L visual analogue scale (VAS) as well as the Oxford Hip and Knee Score (Q score).ResultsThe area under the receiver operating characteristic of the best training models was around 0.87 (VAS) and 0.78 (Q score) for hip replacement, while it was around 0.86 (VAS) and 0.70 (Q score) for knee replacement surgery. Extreme gradient boosting, random forests, multistep elastic net and linear model provided the highest overall J-statistics. Based on variable importance, the most important predictors for post-operative outcomes were preoperative VAS, Q score and single Q score dimensions. Sensitivity analysis for hip replacement VAS evaluated the influence of minimal important difference, patient selection criteria as well as additional data years. Together with a small benchmark of the NHS prediction model, robustness of our results was confirmed.ConclusionsSupervised machine-learning implementations, like extreme gradient boosting, can provide better performance than linear models and should be considered, when high predictive performance is needed. Preoperative VAS, Q score and specific dimensions like limping are the most important predictors for postoperative hip and knee PROMs.
BMC Medical Informatics and Decision Making

Behrndt, E.M.; Straubmeier, M.; Seidl, H.; Vetter, C.; Luttenberger, K.; Graessel, E.
Brief telephone counselling is effective for caregivers who do not experience any major life events - caregiver-related outcomes of the German day-care study.
BMC Health Serv. Res. 19:20 (2019)
BackgroundTo date, there has been a dearth of scientifically tested, established intervention concepts focussed on supporting informal caregivers and embedded in routine health care structures. The aim of this study was to assess effects of a brief telephone intervention for caregivers of persons with cognitive impairment (PCIs) on caregivers' depressiveness and subjective burden.MethodsA two-arm cluster-randomised controlled intervention study was carried out at 32 German day-care centres. During the six-month intervention period, informal caregivers in the intervention group (n=205) received counselling in three phone calls focussed on stress reduction, development of self-management strategies, and how to deal with challenging behaviours. Both the control group (n=154) and the intervention group were free to take part in any support programmes offered by the German Health Care System (TAU). Caregivers' subjective burden and depressiveness were measured with the Burden Scale for Family Caregivers - short version (BSFC-s) and the WHO-5 Well-Being Index (WHO-5). Outcomes were assessed by means of computer-assisted telephone interviews (CATIs) at baseline and at the end of the six-month intervention phase. Multiple regression analyses were used to show the influence of group allocation.ResultsAfter the intervention phase, group allocation was not found to significantly predict caregivers' subjective burden or depressiveness. The baseline scores (p<0.001) were the only significant predictors of change in both outcomes. However, sensitivity analyses for caregivers who did not experience any events that they felt were major (in a negative or positive sense) during the six months (n=271) showed that group allocation (p<0.05) was a significant predictor of positive change in both outcomes (BSFC-s: -1.3, [-2.4, -0.3], Cohen's d=0.27; WHO-5: 1.5, [0.4, 2.7], Cohen's d=0.26). Effect sizes were highest in the subgroup of caregivers of people with mild dementia (BSFC-s: Cohen's d=0.43; WHO-5: Cohen's d=0.42).ConclusionsA low-dose psychoeducative telephone intervention designed to empower caregivers is effective, especially in an early stage, if the overlap between the effect of the intervention and the effect of events that are experienced as major events in the caregiver's life is considered.Trial registrationIdentifier: ISRCTN16412551 (Registration date: 30 July 2014, registered retrospectively).
BMC Health Services Research

Scholz, S.; Koerber, F.; Meszaros, K.; Fassbender, R.M.; Ultsch, B.; Welte, R.R.; Greiner, W.
The cost-of-illness for invasive meningococcal disease caused by serogroup B Neisseria meningitidis (MenB) in Germany.
Vaccine 37, 1692-1701 (2019)
Introduction: Invasive meningococcal disease (IMD) is a severe disease mainly affecting infants and young children. The most

common serogroup causing IMD in Germany is the serogroup type B Neisseria meningitidis (MenB). The aim of the present study is to estimate the economic burden of MenB-related IMD in Germany.Method: A bottom-up, model-based costing approach has been used to calculate the diagnose- and age-specific yearly lifetime costs of a hypothetical cohort of MenB-related IMD cases. Direct costs contain the treatment cost for the acute phase of the disease, long-term sequelae, costs for rehabilitation, and public health response. Indirect costs are calculated for the human-capital approach and the friction-cost approach considering productivity losses of patients or parents for the acute phase and long-term sequelae. Publicly available databases from the Federal Statistical Office, the SOEP panel data set, literature, and expert opinion were used as data sources. All future costs beyond the reference year of 2015 were discounted at 3%.Results: The total costs for the hypothetical cohort (343 patients) from a societal perspective are (sic)19.6 million ((sic)57,100/IMD case) using the friction-cost approach and (sic)58.8 million ((sic)171,000/IMD case) using the human-capital approach. Direct costs amount to (sic)18.6 million or (sic)54,300 (sic)/case. Sequelae are responsible for 81% of the direct costs/case.Discussion: The elevated costs/MenB-related IMD case reflect the severity of the disease. The total costs are sensitive to the productivity-loss estimation approach applied. MenB is an uncommon but severe disease; The costs/case reflect the severity of the disease and is within the same magnitude as for human papilloma virus infections. The available literature on sequelae is due to the uncommonness limited and heterogeneous. (C) 2019 GlaxoSmithKline Biologicals SA. Published by Elsevier Ltd.
Vaccine

Pedron, S.; Emmert-Fees, K.; Laxy, M.; Schwettmann, L.
The impact of diabetes on labour market participation: A systematic review of results and methods.
BMC Public Health 19:25 (2019)
BackgroundDiabetes mellitus is a major chronic disease, which is connected to direct and indirect costs and productivity losses. However, its effects on labour market participation are not straightforward to identify, nor are they consistently included in cost-of-illness studies. First, this study aims to synthesise existing evidence regarding the impact of diabetes on labour market outcomes that imply a complete absence of work. Second, the analysis takes a particular look at relevant methodological choices and the resulting quality of the studies included.MethodsWe conducted a systematic literature research (PubMed, Embase, PsychINFO), by applying a standard screening, selection and results extraction process, which considered all types of studies including cross-sectional and longitudinal approaches. Risk-of-bias and quality within the studies were assessed and results were compared. We dedicated special attention to the modelling of potential reverse causality between diabetes and labour market outcomes and the consideration of comorbidities and complications.ResultsOverall, 30 studies satisfied our inclusion criteria. We identified four main labour participation outcomes: absence of employment, unemployment, early retirement, and disability pension. The studies reviewed show a negative impact of diabetes on the labour market participation outcomes considered. However, only a few studies controlled for endogeneity, differentiated between type 1 and type 2 diabetes or modelled the impact of comorbidities. We report how modelling choices affect the directions and interpretations of the effects.ConclusionsThe available evidence mainly suggests a negative impact of diabetes on several outcomes indicating labour market participation. The methodological limitations identified can guide future research with respect to both outcomes and methods. This study provides therefore an empirical contribution to the discussion on how to model the economic impact of diabetes.
BMC Public Health

von Siemens, S.M.; Jörres, R.A.; Behr, J.; Alter, P.; Lutter, J.; Lucke, T.; Söhler, S.; Welte, T.; Watz, H.; Vogelmeier, C.F.; Trudzinski, F.; Rief, W.; Herbig, B.; Kahnert, K.
Effect of COPD severity and comorbidities on the result of the PHQ-9 tool for the diagnosis of depression: Results from the COSYCONET cohort study.
Respir. Res. 20:30 (2019)
The diagnosis of depression, a frequent comorbidity of chronic obstructive pulmonary disease (COPD), is often supported by questionnaires, such as the Patient Health Questionnaire 9 (PHQ-9). It is unknown to which extent its single questions are affected by the clinical characteristics of COPD patients.We addressed this question in 2255 GOLD grade 1-4 patients from the COSYCONET (COPD and Systemic Consequences - Comorbidities Network) COPD cohort. The dependence on COPD severity was assessed using symptoms, exacerbation risk (GOLD A-D; modified Medical Research Council dyspnoea scale (mMRC)), and frequent comorbidities as predictors of PHQ-9 results, while including age, gender, body mass index (BMI) and smoking habits as covariates.Symptoms and exacerbation risk were associated with depression in an additive manner, with mean elevations in the PHQ-9 sum score by 2.75 and 1.44 points, respectively. Asthma, sleep apnoea, gastrointestinal disorders, osteoporosis and arthritis were linked to increases by 0.8 to 1.3 points. Overall, the COPD characteristics contributed to the mean PHQ-9 score by increases from 4.5 or 5.2 to 6.3 points, respectively, when either taking GOLD A as reference or the absence of comorbidities. This finding was independent of the diagnosis of mental disorder or the intake of antidepressants. The presence of COPD led to an increase in the proportion of scores indicating depression from 12 to 22%. Single item analysis revealed homogenous effects regarding GOLD groups, but heterogeneous effects regarding GOLD grades.These findings indicate specific effects of COPD severity on the PHQ-9 depression score, especially symptoms and exacerbation risk, explaining the high prevalence of depression in COPD. Alternative explanations like an overlap of COPD severity and PHQ-9 items are discussed. Of note, we also found COPD treatment effects on depression scores.
Respiratory Research

Kueffner, R.; Zach, N.; Bronfeld, M.; Norel, R.; Atassi, N.; Balagurusamy, V.; di Camillo, B.; Chio, A.; Cudkowicz, M.; Dillenberger, D.; Garcia-Garcia, J.; Hardiman, O.; Hoff, B.; Knight, J.; Leitner, M.L.; Li, G.; Mangravite, L.; Norman, T.; Wang, L.; Alkallas, R.; Anghel, C.; Avril, J.; Bacardit, J.; Balser, B.; Balser, J.; Bar-Sinai, Y.; Ben-David, N.; Ben-Zion, E.; Bliss, R.; Cai, J.; Chernyshev, A.; Chiang, J.; Chicco, D.; Corriveau, B.A.N.; Dai, J.; Deshpande, Y.; Desplats, E.; Durgin, J.S.; Espiritu, S.M.G.; Fan, F.; Fevrier, P.; Fridley, B.L.; Godzik, A.; Golinska, A.; Gordon, J.; Graw, S.; Guo, Y.; Herpelinck, T.; Hopkins, J.; Huang, B.; Jacobsen, J.; Jahandideh, S.; Jeon, J.; Ji, W.; Jung, K.; Karanevich, A.; Koestler, D.C.; Kozak, M.; Kurz,

C.F.; Lalansingh, C.; Larrieu, T.; Lazzarini, N.; Lerner, B.; Lesinski, W.; Liang, X.; Lin, X.; Lowe, J.; Mackey, L.; Meier, R.; Min, W.; Mnich, K.; Nahmias, V.; Noel-MacDonnell, J.; O'Donnell, A.; Paadre, S.; Park, J.; Polewko-Klim, A.; Raghavan, R.; Rudnicki, W.; Saghapour, E.; Salomond, J.; Sankaran, K.; Sendorek, D.; Sharan, V.; Shiah, Y.; Sirois, J.; Sumanaweera, D.N.; Usset, J.; Vang, Y.S.; Vens, C.; Wadden, D.; Wang, D.; Wong, W.C.; Xie, X.; Xu, Z.; Yang, H.; Yu, X.; Zhang, H.; Zhang, L.; Zhang, S.; Zhu, S.; Xiao, J.; Fang, W.; Peng, J.; Yang, C.; Chang, H.; Stolovitzky, G.
Stratification of amyotrophic lateral sclerosis patients: A crowdsourcing approach.
Sci. Rep. 9:690 (2019)
Amyotrophic lateral sclerosis (ALS) is a fatal neurodegenerative disease where substantial heterogeneity in clinical presentation urgently requires a better stratification of patients for the development of drug trials and clinical care. In this study we explored stratification through a crowdsourcing approach, the DREAM Prize4Life ALS Stratification Challenge. Using data from > 10,000 patients from ALS clinical trials and 1479 patients from community-based patient registers, more than 30 teams developed new approaches for machine learning and clustering, outperforming the best current predictions of disease outcome. We propose a new method to integrate and analyze patient clusters across methods, showing a clear pattern of consistent and clinically relevant sub-groups of patients that also enabled the reliable classification of new patients. Our analyses reveal novel insights in ALS and describe for the first time the potential of a crowdsourcing to uncover hidden patient sub-populations, and to accelerate disease understanding and therapeutic development.
Scientific Reports

Hübner, J.; Lewin, P.; Pritzkuleit, R.; Eisemann, N.; Maier, W.; Katalinic, A.
Colorectal cancer screening by colonoscopy and trends in disease-specific mortality: A population-based ecological study of 358 German districts.
Int. J. Colorectal Dis. 34, 599-605 (2019)
Purpose Screening for colorectal cancer (CRC) by colonoscopy was implemented in Germany in 2002. Although the procedure has proven to be effective in reducing disease-specific mortality in numerous clinical studies, its effect at the population level is unclear. We performed an ecological study at the level of 358 German districts, testing the hypothesis that a higher participation rate in screening colonoscopy is associated with a stronger decline in CRC mortality from 2001 to 2012.Methods Information on the use of colonoscopy in each district was extracted from settlement data, used for the remuneration of physicians of the ambulant sector from 2008 to 2011. Yearly mortality rates for each district from 2001 to 2012 were derived from the official mortality statistics. A spatial model was fitted, considering other factors which might influence early detection of CRC (fecal occult blood test (FOBT), diagnostic colonoscopy, material and social area deprivation, and rural-urban disparities).Results The population-weighted mean annual participation rate during 2008-2011 in screening colonoscopy was 2.0% (range 0.6 to 3.9%). The weighted mean annual percentage change (APC) of CRC mortality was -2.9% (range -7.8 to 1.2%). According to the fully adjusted model, a 1% higher annual participation rate in colonoscopy screening was associated with an additional annual change in CRC mortality rate of -0.34% (p = 0.015). Given an annual 2.0% participation rate, colonoscopy screening attributed 23% to the observed decline.Conclusions Our real-world data from Germany provide first evidence that colonoscopy screening for CRC is effective in reducing disease-specific mortality at the population level.
International Journal of Colorectal Disease

Ulrich, L.R.; Petersen, J.J.; Mergenthal, K.; Berghold, A.; Pregartner, G.; Holle, R.; Siebenhofer, A.
Cost-effectiveness analysis of case management for optimized antithrombotic treatment in German general practices compared to usual care - Results from the PICANT trial.
Health Econ. Rev. 9:4 (2019)
Background: By performing case management, general practitioners and health care assistants can provide additional benefits to their chronically ill patients. However, the economic effects of such case management interventions often remain unclear although how to manage the burden of chronic disease is a key question for policy-makers. This analysis aimed to compare the cost-effectiveness of 24 months of primary care case management for patients with a long-term indication for oral anticoagulation therapy with usual care. Methods: This analysis is part of the cluster-randomized controlled Primary Care Management for Optimized Antithrombotic Treatment (PICANT) trial. A sample of 680 patients with German statutory health insurance was initially considered for the cost analysis (92% of all participants at baseline). Costs included all disease-related direct health care costs from the payer's perspective (German statutory health insurers) plus case management costs for the intervention group. A-Quality Adjusted Life Year (QALY) measurement (EQ-5D-3 L instrument) was used to evaluate utility, and incremental cost-effectiveness ratio (ICER) to assess cost-effectiveness. Mean differences were calculated and displayed with 95%-confidence intervals (CI) from non-parametric bootstrapping (1000 replicates). Results: N = 505 patients (505/680, 74%) were included in the cost analysis (complete case analysis with a follow-up after 12 and 24 months as well as information on cost and QALY). After two years, the mean difference of direct health care costs per patient (€115, 95% CI [- 201; 406]) and QALYs (0.03, 95% CI [- 0.04; 0.11]) in the two groups was small and not significant. The costs of case management in the intervention group caused mean total costs per patient in this group to rise significantly (mean difference €503, 95% CI [188; 794]). The ICER was €16,767 per QALY. Regardless of the willingness of insurers to pay per QALY, the probability of the intervention being cost-effective never rose above 70%. Conclusions: A primary care case management for patients with a long-term indication for oral anticoagulation therapy improved QALYs compared to usual care, but was more costly. However, the results may help professionals and policy-makers allocate scarce health care resources in such a way that the overall quality of care is improved at moderate costs, particularly for chronically ill patients. Trial registration: Current Controlled Trials ISRCTN41847489.
Health Economics Review

Müller, D.; Danner, M.; Schmutzler, R.; Engel, C.; Wassermann, K.; Stollenwerk, B.; Stock, S.; Rhiem, K.
Economic modeling of risk-adapted screen-and-treat strategies in women at high risk for breast or ovarian cancer.
Eur. J. Health Econ. 20, 739-750 (2019)

BACKGROUND: The 'German Consortium for Hereditary Breast and Ovarian Cancer' (GC-HBOC) offers women with a family history of breast and ovarian cancer genetic counseling. The aim of this modeling study was to evaluate the cost-effectiveness of genetic testing for BRCA 1/2 in women with a high familial risk followed by different preventive interventions (intensified surveillance, risk-reducing bilateral mastectomy, risk-reducing bilateral salpingo-oophorectomy, or both mastectomy and salpingo-oophorectomy) compared to no genetic test. METHODS: A Markov model with a lifelong time horizon was developed for a cohort of 35-year-old women with a BRCA 1/2 mutation probability of ≥ 10%. The perspective of the German statutory health insurance (SHI) was adopted. The model included the health states 'well' (women with increased risk), 'breast cancer without metastases', 'breast cancer with metastases', 'ovarian cancer', 'death', and two post (non-metastatic) breast or ovarian cancer states. Outcomes were costs, quality of life years gained (QALYs) and life years gained (LYG). Important data used for the model were obtained from 4380 women enrolled in the GC-HBOC. RESULTS: Compared with the no test strategy, genetic testing with subsequent surgical and non-surgical treatment options provided to women with deleterious BRCA 1 or 2 mutations resulted in additional costs of €7256 and additional QALYs of 0,43 (incremental cost-effectiveness ratio of €17,027 per QALY; cost per LYG: €22,318). The results were robust in deterministic and probabilistic sensitivity analyses. CONCLUSION: The provision of genetic testing to high-risk women with a BRCA1 and two mutation probability of ≥ 10% based on the individual family cancer history appears to be a cost-effective option for the SHI.
The European journal of health economics

Pedron, S.; Becker, J.; Greiner, G.; Murawski, M.
Der dggö-Ausschuss Allokation und Verteilung – IX. Workshop dggö.
Gesundheitsökon. Qualitätsmanag. 24, 14-16 (2019)
Management im Gesundheitswesen (IGM) am Helmholtz Zentrum München statt. Die präsentierten Forschungsprojekte reichten von empirischen und experimentellen Ansätzen bis hin zu theoretischen Modellen und beschäftigten sich mit zahlreichen aktuellen Fragen der Verteilung und Allokation im Gesundheitswesen. Die Keynote Talks wurden von Robert Nuscheler (Universität Augsburg) und Rüdiger von Kries (STIKO, LMU München) gehalten.
Gesundheitsökonomie & Qualitätsmanagement
Sonstiges: Nachrichtenmeldung
Other: News Item
Kowall, B.; Rathmann, W.; Bongaerts, B.; Kuss, O.; Stang, A.; Roden, M.; Herder, C.; Koenig, W.; Huth, C.; Heier, M.; Thorand, B.; Ladwig, K.-H.; Holle, R.; Meisinger, C.; Peters, A.
Incidence rates of type 2 diabetes in people with impaired fasting glucose (ADA vs. WHO Criteria) and impaired glucose tolerance: Results from an older population (KORA S4/F4/FF4 Study).
Diabetes Care 42, E18-E20:DC181473 (2019)
Diabetes Care

Rospleszcz, S.; Thorand, B.; de Las Heras Gala, T.; Meisinger, C.; Holle, R.; Koenig, W.; Mansmann, U.; Peters, A.
Temporal trends in cardiovascular risk factors and performance of the Framingham Risk Score and the Pooled Cohort Equations.
J. Epidemiol. Community Health 73, 19-25 (2019)
Background The Framingham Risk Score (FRS) and the Pooled Cohort Equations (PCE) are established tools for the prediction of cardiovascular disease (CVD) risk. In the Western world, decreases in incidence rates of CVD were observed over the last 30 years. Thus, we hypothesise that there are also temporal trends in the risk prediction performance of the FRS and PCE from 1990 to 2000. Methods We used data from n=7789 men and women aged 40-74 years from three prospective population-based cohort studies enrolled in Southern Germany in 1989/1990, 1994/1995 and 1999/2000. 10-year CVD risk was calculated by recalibrated equations of the FRS or PCE. Calibration was evaluated by percentage of overestimation and Hosmer-Lemeshow tests. Discrimination performance was assessed by receiver operating characteristic (ROC) curves and corresponding area under the curve (AUC). Results Across the three studies, we found significant temporal trends in risk factor distributions and predicted risks by both risk scores (men: 18.0%, 15.4%, 14.9%; women: 8.7%, 11.2%, 10.8%). Furthermore, also the discrimination performance evolved differently for men (AUC PCE: 76.4, 76.1, 72.8) and women (AUC PCE: 75.9, 79.5, 80.5). Both risk scores overestimated actual CVD risk. Conclusion There are temporal trends in the performance of the FRS and PCE. Although the overall performance remains adequate, sex-specific trends have to be taken into account for further refinement of risk prediction models.
Journal of Epidemiology and Community Health

Icks, A.; Haastert, B.; Arend, W.; Konein, J.; Thorand, B.; Holle, R.; Laxy, M.; Schunk, M.; Neumann, A.; Wasem, J.; Chernyak, N.
Time spent on self-management by people with diabetes: Results from the population-based KORA survey in Germany.
Diabetic Med. 36, 970-981 (2019)
Aims Time needed for health-related activities in people with diabetes is assumed to be substantial, yet available data are limited. Time spent on self-management and associated factors was analysed using cross-sectional data from people with diagnosed diabetes enrolled in a population-based study. Methods Mean total time spent on self-management activities was estimated using a questionnaire for all participants with diagnosed diabetes in the KORA FF4 study (n = 227, 57% men, mean age 69.7, sd 9.9 years). Multiple two-part regression models were fitted to evaluate associated factors. Multiple imputation was performed to adjust for bias due to missing values. Results Some 86% of participants reported spending time on self-management activities during the past week. Over the entire sample, a mean of 149 (sd 241) min/week were spent on self-management-activities. People with insulin or oral anti-hyperglycaemic drug treatment, better diabetes education, HbA(1c) 48 to < 58 mmol/mol (6.5% to < 7.5%) or lower quality of life, spent more time on self-management activities. For example, people without anti-hyperglycaemic medication invested 66 min/week in self-management, whereas those taking insulin and oral anti-hyperglycaemic drugs invested 269 min/week (adjusted ratio 4.34, 95% confidence interval 1.85-10.18). Conclusions Time spent on self-management activities by people with diabetes was substantial and varied with an individual's characteristics. Because of the small sample size and missing values, the results should be interpreted in an explorative manner. Nevertheless, time needed for self-

management activities should be routinely considered because it may affect diabetes self-care and quality of life.
Diabetic Medicine

Kähm, K.; Laxy, M.; Schneider, U.; Holle, R.
Exploring different strategies of assessing the economic impact of multiple diabetes-associated complications and their interactions: A large claims-based in Germany.
Pharmacoeconomics 37, 63-74 (2019)
In the context of an aging population with increasing diabetes prevalence, people are living longer with diabetes, which leads to increased multimorbidity and economic burden.The primary aim was to explore different strategies that address the economic impact of multiple type 2 diabetes-related complications and their interactions.We used a generalized estimating equations approach based on nationwide statutory health insurance data from 316,220 patients with type 2 diabetes (baseline year 2012, 3 years of follow-up). We estimated annual total costs (in 2015 euros) for type 2 diabetes-related complications and, in addition, explored different strategies to assess diabetes-related multimorbidity: number of prevalent complications, co-occurrence of micro- and macrovascular complications, disease-disease interactions of prevalent complications, and interactions between prevalent/incident complications.The increased number of complications was significantly associated with higher total costs. Further assessment of interactions showed that macrovascular complications (e.g., chronic heart failure) and high-cost complications (e.g., end-stage renal disease, amputation) led to significant positive effects of interactions on costs, whereas early microvascular complications (e.g., retinopathy) caused negative interactions. The chronology of the onset of these complications turned out to have an additional impact on the interactions and their effect on total costs.Health economic diabetes models and evaluations of interventions in patients with diabetes-related complications should pay more attention to the economic effect of specific disease interactions. Politically, our findings support the development of more integrated diabetes care programs that take better account of multimorbidity. Further observational studies are needed to elucidate the shared pathogenic mechanisms of diabetes complications.
PharmacoEconomics

2018
Portas, L.; Calciano, L.; Corsico, A.G.; Cazzoletti, L.; Cerveri, I.; Gerbase, M.W.; Gislason, D.; Gronseth, R.; Heinrich, J.; Jõgi, R.; Johannessen, A.; Marcon, A.; Pin, I.; Wacker, M.; Jarvis, D.; Janson, C.; Accordini, S.
Cost variations of asthma over 10 years in adults.
Thorax 73, A249-A250 (2018)
Thorax
Meeting abstract

Szentes, B.L.; Kirsch, F.; Schramm, A.; Schwarzkopf, L.; Leidl, R.
Association between severe, moderate and mild exacerbations with generic health-related quality of life in COPD patients.
Value Health 21, S419-S419 (2018)
Value in Health
Meeting abstract

Walter, J.; Schwarzkopf, L.
First insights into comparing expenditures for targeted therapy and survival in NSCLC.
Value Health 21, S35-S35 (2018)
Value in Health
Meeting abstract

Byng, D.; Lutter, J.; Holle, R.; Joerres, R.A.; Karch, A.; Karrasch, S.; Schulz, H.; Vogelmeier, C.F.; Wacker, M.
Identifying predictors of healthcare utilization and costs in COPD patients over 18 months: First longitudinal results of the COSYCONET cohort.
Eur. Respir. J. 52 (2018)
European Respiratory Journal
Meeting abstract

Witt, S.; Waelscher, J.; Schwarzkopf, L.; Kreuter, M.
Hospitalisation pattern in Interstitial Lung Diseases: A claims data study.
Eur. Respir. J. 52 (2018)
European Respiratory Journal
Meeting abstract

Szentes, B.L.; Schwarzkopf, L.; Lehbert, N.; Wittmann, M.; Wagner, R.; Nowak, D.; Faller, H.; Schüler, M.; Schultz, K.
Suitable questionnaires to measure quality of life in patients with asthma bronchial undergoing pulmonary rehabilitation.
Eur. Respir. J. 52 (2018)
European Respiratory Journal
Meeting abstract

Walter, J.; Holle, R.; Tufman, A.; Schwarzkopf, L.
Changes in targeted therapy and costs in NSCLC between 2009 and 2013.
Eur. Respir. J. 52 (2018)
European Respiratory Journal
Meeting abstract

Lingner, H.; Klett-Tammen, C.J.; Kuhlmann, A.; Schmidt, T.; Lutter, J.; Von Der Schulenburg, J.M.; Kreuter, M.; Welte, T.
Describing "real world" COPD patients in primary care in Germany - Findings of the BeoNet-Registry.
Eur. Respir. J. 52 (2018)
European Respiratory Journal
Meeting abstract

Witt, S.; Szentes, B.L.; Bush, A.; Cunningham, S.; Kiper, N.; Lange, J.; Leidl, R.; Terheggen-Lagro, S.; Schwerk, N.; Snijders, D.; Griese, M.; Schwarzkopf, L.
Medication for childhood interstitial lung diseases differs internationally.
Eur. Respir. J. 52 (2018)
European Respiratory Journal
Meeting abstract

Kreuter, M.; Kabitz, H.; Hagmeyer, L.; Hammerl, P.; Esselmann, A.; Wiederhold, C.; Skowasch, D.; Stolpe, C.; Joest, M.; Veitshans, S.; Witt, S.; Leidl, R.; Hellmann, A.; Pfeifer, M.; Behr, J.; Guenther, A.; Kauschka, D.; Herth, F.J.F.; Markart, P.
Outcome differences between idiopathic pulmonary fibrosis (IPF) and other interstitial lung diseases (ILD) - data from the EXCITING registry.
Eur. Respir. J. 52 (2018)

European Respiratory Journal
Meeting abstract

Schultz, K.; Wittmann, M.; Wagner, R.; Lehbert, N.; Schwarzkopf, L.; Szentes, B.L.; Nowak, D.; Faller, H.; Schüler, M.
Effectiveness of pulmonary Rrhabilitation for patients with asthma: EPRA-RCT.
Eur. Respir. J. 52 (2018)
European Respiratory Journal
Meeting abstract

Schwarzkopf, L.; Witt, S.; Waelscher, J.; Polke, M.; Kreuter, M.
Associations between comorbidities, their treatment and survival in patients with interstitial lung diseases - a claims data analysis.
Eur. Respir. J. 52 (2018)
European Respiratory Journal
Meeting abstract

Schwarzkopf, L.; Murawski, M.
Survival impact of comorbidity in German Lung Cancer patients - a claims data-based 'Comorbidome'.
Eur. Respir. J. 52 (2018)
European Respiratory Journal
Meeting abstract

Liu, W.-H.#; Schwarzkopf, L.; Jeremias, I.#
Inducible re-expression of KLF4 impairs growth of patient-derived ALL in mice and sensitizes towards chemotherapy.
Poster: XXII. Wilsede Meeting 2018, 30 June - 03 July 2018, Wilsede, Germany. (2018)
Jeremias, I.; Schwarzkopf, L.; Liu, W.-H.
Re-expression of KLF4 impairs growth of patient-derived acute lymphoma leukemia cells in vivo and sensitizes towards chemotherapy.
Poster: SFB 1243 Internation Symposium Cancer Evolution 2018, 01-03 March 2018 (2018)
Grill, E.; Heuberger, M.; Strobl, R.; Saglam, M.; Holle, R.; Linkohr, B.; Ladwig, K.-H.; Peters, A.; Schneider, E.; Jahn, K.; Lehnen, N.
Prevalence, determinants, and consequences of vestibular hypofunction. Results from the KORA-FF4 survey.
Front. Neurol. 9, 1076:1076 (2018)
Uni- or bilateral vestibular hypofunction (VH) impairs balance and mobility, and may specifically lead to injury from falls and to disability. The extent of this problem in the general population is still unknown and most likely to be underestimated. Objective of this study was to determine the prevalence, determinants, and consequences of VH in the general population. Data originates from the cross-sectional second follow-up (FF4) in 2013/14 of the KORA (Cooperative Health Research in the Region of Augsburg)-S4 study (1999-2001) from Southern Germany. This was a random sample of the target population consisting of all residents of the region aged 25-74 years in 1999. We included all participants who reported moderate or severe vertigo or dizziness during the last 12 months and a random sub-sample of participants representative for the general population without vertigo or dizziness during the last 12 months were tested. VH was assessed with the Video-Head Impulse Test (vHIT). Trained examiners applied high-acceleration, small-amplitude passive head rotations ("head impulses") to the left and right in the plane of the horizontal semicircular canals while participants fixated a target straight ahead. During head impulses, head movements were measured with inertial sensors, eye movements with video-oculography (EyeSeeCam vHIT). A total of 2,279 participants were included (mean age 60.8 years, 51.6% female), 570 (25.0%) with moderate or severe vertigo or dizziness during the last 12 months. Of these, 450 were assessed with vHIT where 26 (5.8%) had unilateral VH, and 16 (3.6%) had bilateral VH. Likewise, 190 asymptomatic participants were tested. Of these 5 (2.6%) had unilateral VH, and 2 (1.1%) had bilateral VH. Prevalence of uni- or bilateral VH among tested symptomatic participants was 2.4% in those < 48 years, and 32.1% in individuals aged 79 and over. Age-adjusted prevalence was 6.7% (95% CI 4.8%; 8.6%). VH was associated with worse health, falls, hearing loss, hearing impairment, and ear pressure. VH may affect between 53 and 95 million adults in Europe and the US. While not all affected persons will experience the full spectrum of symptoms and consequences, adequate diagnostic and therapeutic measures should become standard of care to decrease the burden of disease.
Frontiers in neurology

Kähm, K.; Holle, R.; Laxy, M.
Diabetes mellitus: Kosten von Komplikationen erstmals detailliert berechnet.
Dtsch. Ärztebl. 115:14 (2018)
Deutsches Ärzteblatt
Sonstiges: Meinungsartikel
Other: Opinion
Walter, J.; Schwarzkopf, L.
Lungenkrebspatienten frühzeitig palliativmedizinisch betreuen.
Im Focus Onko. 9, accepted (2018)
Im Focus Onkologie
Editorial
Editorial
Ptushkina, V.; Jacobs, E.; Schipf, S.; Völzke, H.; Markus, M.R.P.; Nauck, M.; Meisinger, C.; Peters, A.; Maier, W.; Herder, C.; Roden, M.; Rathmann, W.
Regional differences of macrovascular disease in Northeast and South Germany: The population-based SHIP-TREND and KORA-F4 studies.
BMC Public Health 18:1331 (2018)
BackgroundPrevious studies found regional differences in the prevalence and incidence of type 2 diabetes between Northeast and South of Germany. The aim of this study was to investigate if regional variations are also present for macrovascular disease in people with type 2 diabetes and in the general population. A further aim was to investigate if traditional risk factors of macrovascular complications can explain these regional variations.MethodsData of persons aged 30-79 from two regional population-based studies, SHIP-TREND (Northeast Germany, 2008-2012, n=2539) and KORA-F4 (South Germany, 2006-2008, n=2932), were analysed. Macrovascular disease was defined by self-reported previous myocardial infarction, stroke or coronary angiography. Multivariable logistic regression was performed to estimate odds ratios (OR) and 95% confidence intervals (CI) for prevalence of macrovascular disease in persons with type 2 diabetes and in the general population.ResultsThe prevalence of macrovascular disease in persons with type 2 diabetes and in the general population was considerably higher in the Northeast (SHIP-TREND: 32.8 and 12.0%) than in the South of Germany (KORA-F4: 24.9 and 8.8%), respectively. The odds of macrovascular disease in persons with type 2 diabetes

was 1.66 (95% CI: 1.11-2.49) in the Northeast in comparison to the South after adjustment for sex, age, body mass index, hypertension, hyperlipidemia and smoking. In the general population, SHIP-TREND participants also had a significantly increased odds of macrovascular disease compared to KORA-F4 participants (OR=1.63, 95% CI: 1.33-2.00). After excluding coronary angiography (myocardial infarction or stroke only), the ORs for region decreased in all models, but the difference between SHIP-TREND and KORA-F4 participants was still significant in the age- and sex-adjusted model for the general population (OR=1.34, 95% CI: 1.01-1.78).ConclusionsThis study provides an indication for regional differences in macrovascular disease, which is not explained by traditional risk factors. Further examinations of other risk factors, such as regional deprivation or geographical variations in medical care services are needed.
BMC Public Health

Kreuter, M.; Witt, S.; Polke, M.; Waelscher, J.; Schwarzkopf, L.
Financial burden of interstitial lung disease -a claims data based study.
Am. J. Respir. Crit. Care Med. 197 (2018)
American Journal of Respiratory and Critical Care Medicine
Meeting abstract

Kreuter, M.; Herth, F.J.F.; Witt, S.; Kabitz, H.; Hagmeyer, L.; Hammerl, P.; Esselmann, A.; Wiederhold, C.; Skowasch, D.; Stolpe, C.; Joest, M.; Veitshans, S.; Leidl, R.; Hellmann, A.; Pfeifer, M.; Behr, J.; Guenther, A.; Markart, P.
Diagnosis and management of patients with interstitial lung disease (ILD) in clinical practice in Germany: Exciting-ILD registry.
Am. J. Respir. Crit. Care Med. 197 (2018)
American Journal of Respiratory and Critical Care Medicine
Meeting abstract

Maier, W.; Schwettmann, L.
Area deprivation in Germany: The 'German Index of Multiple Deprivation (GIMD)'.
Public Health Forum 26, 376-379 (2018)
© 2018 Walter de Gruyter GmbH, Berlin/Boston. Numerous international studies show that Indices of Multiple Deprivation are a suitable instrument to determine socio-spatial effects on the health of the population and, thereby, to display social inequalities. For Germany, the German Index of Multiple Deprivation is such an established instrument. In the future, corresponding well-founded results should receive more attention when it comes to the allocation of resources or the planning of medical requirements.
Public Health Forum

Murawski, M.; Walter, J.; Schwarzkopf, L.
Assessing the lung cancer comorbidome: An analysis of German claims data.
Lung Cancer 127, 122-129 (2018)
Objectives: In presence of lung cancer, the additional impact of comorbidity on survival is often neglected, although comorbidities are likely to be prevalent. Our study examines the comorbidity profile and the impact of distinct conditions on survival in German lung cancer patients.Material and methods: We investigated claims data from a large nationwide statutory health insurance fund of 16,202 patients initially diagnosed with lung cancer in 2009. We calculated the prevalence of comorbidities grouped according to an extension of the Elixhauser Comorbidity Index (EI). Effects of distinct comorbidities on 5-year survival were examined using multivariate Cox proportional hazards models, adjusted for sex, age and metastases at baseline. All analyses were stratified by initial lung cancer-related treatment regimen (Surgery, Chemotherapy/Radiotherapy, No treatment). Findings were visualized in the form of a comorbidome.Results: Our study population was predominantly male (70.6%) with a mean age of 68.6 years, and a mean EI score of 3.94. Patients without treatment were older (74.4 years), and their comorbidity burden was higher (mean EI = 4.59). Median survival varied by subgroup (Surgery: 24.4 months, Chemotherapy/Radiotherapy: 8.8 months, No treatment: 2.0 months), and so did the comorbidity profile and the impact of distinct conditions on survival. Generally, the effect of comorbidities on survival was detrimental and the negative association was most pronounced for 'Weight Loss' and' Paralysis'. In contrast, 'Lipid Metabolism Disorders' and 'Obesity' were positively associated with survival. Noteworthily, highly prevalent conditions tended not to show any significant association.Conclusion: We found specific comorbidity profiles within the distinct treatment regimens. Moreover, there were negative but also some positive associations with survival, and the strength of these effects varied by stratum. Particularly the positive effects of 'Obesity" and 'Lipid Metabolism Disorders' which were robust across strata need to be further investigated to elucidate potential biomedical explanations.
Lung Cancer

von Philipsborn, P.#; Effertz, T.; Laxy, M.; Schwettmann, L.#; Stratil, J.M.
Prävention von Adipositas und Diabetes mellitus als gesundheitspolitische Herausforderung.
Adipositas, DOI: 10.1055/s-0038-1675252 (2018)
Die Prävention von Adipositas und Diabetes mellitus ist eine der zentralen gesundheitspolitischen Herausforderungen der Gegenwart. Bezüglich beider Krankheiten ist in Deutschland noch keine Trendwende in der Prävalenzentwicklung gelungen. Zu diversen Präventionsmaßnahmen liegt mittlerweile hinreichende Evidenz vor, so dass die entscheidenden Hemmnisse für bessere Prävention im Bereich der Durch- und Umsetzung zu sehen sind. Erforderlich ist insbesondere eine stärkere Nutzung verhältnispräventiver Ansätze, die ein besonders großes Potenzial bieten, auf Bevölkerungsebene wirksam und wirtschaftlich zu sein. In Deutschland hat das Thema zuletzt vermehrt politische Aufmerksamkeit erfahren, was sich auch in den Inhalten des im März 2018 beschlossenen Koalitionsvertrags zwischen CDU, CSU und SPD zeigt. Insgesamt besteht in Deutschland jedoch auch im internationalen Vergleich weiterhin großer Nachholbedarf. Fortgesetztes Engagement auf kommunaler, Landes- und Bundesebene ist nötig, um evidenzbasierten Ansätzen zur Umsetzung zu verhelfen.
Adipositas: Ursachen, Klinik, Folgeerkrankungen

Lennerz, B.S.; Moss, A.; von Schnurbein, J.; Bickenbach, A.; Bollow, E.; Brandt, S.; Luetke-Brintrup, D.; Mühlig, Y.; Neef, M.; Ose, C.; Remy, M.; Stark, R.G.; Teuner, C.M.; Wolters, B.; Kiess, W.; Scherag, A.; Reinehr, T.; Holl, R.W.; Holle, R.; Wiegand, S.; Hebebrand, J.; Wabitsch, M.

Do adolescents with extreme obesity differ according to previous treatment seeking behavior? The Youth with Extreme obesity Study (YES) cohort.
Int. J. Obes., DOI: 10.1038/s41366-018-0237-4 (2018)
© 2018, Springer Nature Limited. Objectives: Adolescent extreme obesity is associated with somatic and psychiatric comorbidity, low quality of life, and social dysfunction. Nevertheless, few adolescents seek obesity treatment, thus many may elope appropriate care. We examine whether previous treatment seeking relates to disease burden, and whether previously non-treatment seeking adolescents accept diagnostic and therapeutic offers. This information is important to inform intervention strategies. Methods: The Youth with Extreme obesity Study (YES) is a prospective, multicenter cohort study. We developed a novel recruitment strategy to span medical and vocational ascertainment settings and directly compare previously treatment seeking and non-treatment seeking youth. Participants aged 14–24 years; BMI ≥ 30 kg/m2 were enrolled at four medical- and one job centers. We present comorbidity and psycho-social baseline data by sex, obesity WHO grade I-III, and treatment-seeking status, defined as self-reported previous participation in a weight-loss program. Results: Of 431 participants, 47% were male; mean age 16.6 (standard deviation 2.3) years, BMI 39.2 (7.5) kg/m2. Somatic comorbidity increased with obesity grade, $p < 0.05$: hypertension (42, 55, 64%), dyslipidemia (28, 24, 37%,), dysglycemia (9, 19, 20%,), elevated transaminases (15, 26, 30%). Quality of life (EQ5 D) decreased (74, 71, 70). Rates of psychiatric disorders were stable: depression 11%, attention deficit disorder 6%, substance use disorder 2%, self-injurious behavior 5%, suicide attempt 3%. Only 63% (56, 64, 69%) reported previous treatment seeking. Acceptance of the diagnostic (89%) or therapeutic (28%) program, medical or psychosocial situation did not differ by treatment seeking status. Acceptance of the therapeutic program was generally low, but high at the job center (92%). Conclusion: Irrespective of previous treatment seeking, adolescent extreme obesity was associated with high comorbidity and psychosocial burden. Acceptance of the diagnostic program overall and the therapeutic program at the job center were high. This underscores the need of innovative, accessible programs beyond the currently offered care.
International Journal of Obesity

Deckert, K.[#°]; Walter, J.[#]; Schwarzkopf, L.[°]
Factors related to and economic implications of inhospital death in German lung cancer patients - results of a Nationwide health insurance claims data based study.
BMC Health Serv. Res. 18, 793 (2018)
Background: When patients die in a hospital their quality of life is lower than when they die at home or in a hospice. Despite efforts to improve palliative care supply structures, still about 60% of lung cancer patients die in a hospital. Studies have examined factors related to inhospital death in lung cancer patients, yet none used data of a representative German population, additionally including economic aspects. This study aimed to identify factors related to inhospital death in German lung cancer patients and analysed resulting costs.Methods: We analysed a dataset of health insurance claims of 17,478 lung cancer patients (incident 2009) with 3 year individual follow-up. We grouped patients into inhospital death and death elsewhere. Studied factors were indicators of healthcare utilization, palliative care, comorbidities and disease spread. We used logistic regression models with LASSO selection method to identify relevant factors. We compared all-cause healthcare expenditures for the last 30 days of life between both groups using generalized linear models with gamma distribution.Results: Twelve thousand four hundred fifty-seven patients died in the observation period, thereof 6965 (55.9%) in a hospital. The key factors for increased likelihood of inhospital death were receipt of inpatient palliative care (OR = 1.85), chemotherapeutic treatments in the last 30 days of life (OR = 1.61) and comorbid Congestive Heart Failure (OR = 1.21), and Renal Disease (OR = 1.19). In contrast, higher care level (OR = 0.16), nursing home residency (OR = 0. 25) and receipt of outpatient palliative care (OR = 0.25) were associated with a reduced likelihood. All OR were significant (p-values< 0.05). Expenditures in the last 30 days of life were significantly higher for patients with inhospital death ((sic) 6852 vs. (sic) 33,254, p-value< 0.0001).Conclusion: Findings suggest that factors associated with inhospital death often relate to previous contact with hospitals like prior hospitalizations, and treatment of the tumour or comorbidities. Additionally, factors associated with dying elsewhere relate to access to care settings which are more focused on palliation than hospitals. From these results, we can derive that implementing tools like palliative care into tumour-directed therapy might help patients make self-determined decisions about their place of death. This can possibly be achieved at reduced economic burden for SHIs.
BMC Health Services Research

Greiner, G.; Schwettmann, L.; Goebel, J.; Maier, W.
Primary care in Germany: Access and utilisation - a cross-sectional study with data from the German Socio-Economic Panel (SOEP).
BMJ Open 8:e021036 (2018)
Objectives (1) To describe the accessibility of general practitioners (GPs) by the German population; (2) to determine factors on individual and area level, such as settlement structure and area deprivation, which are associated with the walking distance to a GP; and (3) to identify factors that may cause differences in the utilisation of any doctors.Design Cross-sectional study using individual survey data from the representative German Socio-Economic Panel (SOEP) linked with area deprivation data from the German Index of Multiple Deprivation for 2010 (GIMD 2010) and official data for settlement structure (urban/rural areas) at district level. Logistic regression models were estimated to determine the relationship of individual and area factors with the distance to a GP. Negative binomial regressions were used to analyse the association with utilisation.Setting Germany.Population n=20 601 respondents from the SOEP survey data 2009.Primary outcome measure Walking distance to a GP.Secondary outcome measure Doctor visits.Results Nearly 70% of the sample lives within a 20 min walk to a GP. People living in the most deprived areas have a 1.4-fold (95% CI 1.3 to 1.6) increased probability of a greater walking distance compared with the least deprived quintile, even after controlling for settlement structure and individual factors. In rural districts, people have a 3.1-fold (95% CI 2.8 to 3.4) higher probability of a greater walking distance compared with those in cities. Both area deprivation and rurality have a negative relationship with the utilisation of physicians, whereas the distance to a GP is not associated with the utilisation of physicians.Conclusion Walking distance to a GP depends on individual and area factors. In Germany, area deprivation is negatively correlated with the accessibility of GPs while

controlling for settlement structure and individual factors. Both area factors are negatively associated with the utilisation of doctors. This knowledge could be used for future GP requirement plans.
BMJ Open

Schwarzkopf, L.; Walter, J.; Murawski, M.
Survival impact of comorbidity in German Lung Cancer patients: A claims data-based 'Comorbidome'
Poster: ERS International Congress 2018, 15-19 September 2018, Paris, France. (2018)
Becker, C.; Leidl, R.; Schildmann,, E.; Hodiamont,, F.; Bausewein,, C.
A pilot study on patient-related costs and factors associated with the cost of specialist palliative care in the hospital: First steps towards a patient classification system in Germany.
Cost Eff. Resour. Alloc. 16:35 (2018)
Background: Specialist palliative care in the hospital addresses a heterogeneous patient population with complex care needs. In Germany, palliative care patients are classified based on their primary diagnosis to determine reimbursement despite findings that other factors describe patient needs better. To facilitate adequate resource allocation in this setting, in Australia and in the UK important steps have been undertaken towards identifying drivers of palliative care resource use and classifying patients accordingly. We aimed to pioneer patient classification based on determinants of resource use relevant to specialist palliative care in Germany first, by calculating the patient-level cost of specialist palliative care from the hospital's perspective, based on the recorded resource use and, subsequently, by analysing influencing factors. Methods: Cross-sectional study of consecutive patients who had an episode of specialist palliative care in Munich University Hospital between 20 June and 4 August, 2016. To accurately reflect personnel intensity of specialist palliative care, aside from administrative data, we recorded actual use of all involved health professionals' labour time at patient level. Factors influencing episode costs were assessed using generalized linear regression and LASSO variable selection. Results: The study included 144 patients. Mean costs of specialist palliative care per palliative care unit episode were 6542€ (median: 5789€, SE: 715€) and 823€ (median: 702€, SE: 31€) per consultation episode. Based on multivariate models that considered both variables recorded at beginning and at the end of episode, we identified factors explaining episode cost including phase of illness, Karnofsky performance score, and type of discharge. Conclusions: This study is an important step towards patient classification in specialist palliative care in Germany as it provides a feasible patient-level costing method and identifies possible starting points for classification. Application to a larger sample will allow for meaningful classification of palliative patients.
Cost effectiveness and resource allocation

Karl, F.; Holle, R.; Schwettmann, L.; Peters, A.; Laxy, M.
Time preference, outcome expectancy, and self-management in patients with type 2 diabetes.
Patient pre. adh. 12, 1937-1945 (2018)
Background: Patient self-management is crucial to prevent complications and mortality in type 2 diabetes. From an economic perspective, time preference predicts short-sighted decision making and thus might help to explain non-adherence to self-anagement recommendations. However, recent studies on this association have shown mixed results. Purpose: In this study, we tested whether the combination of time preference and outcome expectancy can improve the predictions of self-management behavior. Patients and methods: Data from 665 patients with type 2 diabetes were obtained from the cross-sectional KORA (Cooperative Health Research in the Region of Augsburg) GEFU 4 study. Time preference and outcome expectancy were measured by one question each, which were answered on a 4-point Likert scale. Their association with six self-managing behaviors was tested in logistic and linear regression analyses. Likewise, we examined the association between self-management and the interaction of outcome expectancy and time preference. Results: A high time preference was associated with a significantly lower sum of self-management behaviors (β=-0.29, 95% CI [-0.54,-0.04]). Higher outcome expectancy was associated with a higher self-management score (β=0.21, 95% CI [-0.03, 0.45]). The interaction model showed that low time preference was only associated with better self-management when combined with a high outcome expectancy (β=0.05, 95% CI [-0.28, 0.39] vs β=0.27, 95% CI [-0.09, 0.63]). Conclusion: Time preference and outcome expectancy are interrelated predictors of patient self-management and could be used to identify and to intervene on patients with a potentially poor self-management.
Patient preference and adherence

Auzanneau, M.; Lanzinger, S.; Bohn, B.; Kroschwald, P.; Kuhnle-Krahl, U.; Holterhus, P.M.; Placzek, K.; Hamann, J.; Bachran, R.; Rosenbauer, J.; Maier, W.
Area deprivation and regional disparities in treatment and outcome quality of 29,284 pediatric patients with type 1 diabetes in Germany: A cross-sectional multicenter DPV analysis.
Diabetes Care 41, 2517-2525 (2018)
OBJECTIVEThis study analyzed whether area deprivation is associated with disparities in health care of pediatric type 1 diabetes in Germany.RESEARCH DESIGN AND METHODSWe selected patients <20 years of age with type 1 diabetes and German residence documented in the "diabetes patient follow-up" (Diabetes-Patienten-Verlaufsdokumentation [DPV]) registry for 2015/2016. Area deprivation was assessed by quintiles of the German Index of Multiple Deprivation (GIMD 2010) at the district level and was assigned to patients. To investigate associations between GIMD 2010 and indicators of diabetes care, we used multivariable regression models (linear, logistic, and Poisson) adjusting for sex, age, migration background, diabetes duration, and German federal state.RESULTSWe analyzed data from 29,284 patients. From the least to the most deprived quintile, use of continuous glucose monitoring systems (CGMS) decreased from 6.3 to 3.4% and use of long-acting insulin analogs from 80.8 to 64.3%, whereas use of rapid-acting insulin analogs increased from 74.7 to 79.0%; average HbA(1c) increased from 7.84 to 8.07% (62 to 65 mmol/mol), and the prevalence of overweight from 11.8 to 15.5%, but the rate of severe hypoglycemia decreased from 12.1 to 6.9 events/100 patient-years. Associations with other parameters showed a more complex pattern (use of continuous subcutaneous insulin infusion [CSII]) or were not significant.CONCLUSIONSArea deprivation was associated not only with key outcomes in pediatric type 1 diabetes but also with treatment modalities. Our results show, in particular, that the access to CGMS and CSII could be improved in the most deprived regions in Germany.
Diabetes Care

Ali, M.K.; Siegel, K.R.; Laxy, M.; Gregg, E.W.
Advancing measurement of diabetes at the population level.
Curr. Diab. Rep. 18:108 (2018)
PurposeThe measurement and estimation of diabetes in populations guides resource allocation, health priorities, and can influence practice and future research. To provide a critical reflection on current diabetes surveillance, we provide in-depth discussion about how upstream determinants, prevalence, incidence, and downstream impacts of diabetes are measured in the USA, and the challenges in obtaining valid, accurate, and precise estimates.FindingsCurrent estimates of the burden of diabetes risk are obtained through national surveys, health systems data, registries, and administrative data. Several methodological nuances influence accurate estimates of the population-level burden of diabetes, including biases in selection and response rates, representation of population subgroups, accuracy of reporting of diabetes status, variation in biochemical testing, and definitions of diabetes used by investigators. Technological innovations and analytical approaches (e.g., data linkage to outcomes data like the National Death Index) may help address some, but not all, of these concerns, and additional methodological advances and validation are still needed.SummaryCurrent surveillance efforts are imperfect, but measures consistently collected and analyzed over several decades enable useful comparisons over time. In addition, we proposed that focused subsampling, use of technology, data linkages, and innovative sensitivity analyses can substantially advance population-level estimation.
Current Diabetes Reports

Stephan, A.J.; Strobl, R.; Holle, R.; Grill, E.
Wealth and occupation determine health deficit accumulation onset in Europe - Results from the SHARE study.
Exp. Gerontol. 113, 74-79 (2018)
While socio-economic characteristics have been shown to be associated with health deficit accumulation (DA) trajectories, their effect on the age at DA onset remains unclear. The objective of this study was to compare the median age at DA onset across nine European countries and to investigate the effects of income, occupation and wealth on DA onset after age 50. We used population samples aged 50 years and older from the SHARE (Survey of Health, Aging and Retirement in Europe) study. Participants from nine European countries with longitudinal data from at least three of the 2004/05, 2006/07, 2010/11, 2012/13 and 2014/15 waves were included in the analysis. A Frailty Index (FI, range 0-1) was constructed from 50 health deficits. DA onset was defined as having FI values > 0.08 in at least two consecutive measurements following an initial FI value <= 0.08. We investigated the effect of income, occupation and wealth on DA onset using a random effects model for time-to-event data. Potential confounding variables were identified using directed acyclic graphs. Out of 8616 (mean age 62 years, 49.0% female) participants initially at risk, 2640 (30.6%) experienced a subsequent DA onset. Median age at onset was 71 years overall, ranging from 66 years (Germany) to 76 years (Switzerland). Wealth and occupation were found to have significant effects on DA onset which decreased with age. In sum, the median age at DA onset differs between European countries. On an individual-level, wealth and occupation, but not income influence the age at DA onset.
Experimental Gerontology

Bächle, C.; Peneva, A.; Maier, W.; Castillo, K.; Stahl-Pehe, A.; Kuß, O.; Holle, R.; Hermann, J.M.; Holl, R.W.; Rosenbauer, J.
Association of individual and area-level socioeconomic conditions with quality of life and glycaemic control in 11-to 21-year-old adolescents with early-onset type 1 diabetes: A cross-sectional study.
Qual. Life Res. 27, 3131-3136 (2018)
PurposeTo analyse the association of area-level deprivation (German Index of Multiple Deprivation, GIMD 2010) with health- and disease-related quality of life (QoL) and glycaemic control (HbA1c) jointly with individual-level socioeconomic status (SES) in young patients with preschool-onset type 1 diabetes.MethodsA total of 425 male and 414 female patients aged 11-21years from a Germany-wide population-based survey completed the generic KINDL-R, the DISABKIDS chronic-generic module (DCGM-12), and the DISABKIDS diabetes-specific module with impact and treatment scales (QoL indicators; range 0-100 with higher scores representing better QoL). To analyse the association of area-level deprivation and SES with QoL and HbA1c, multiple linear regression models were applied adjusting for sociodemographic and health-related variables.ResultsMean QoL scores (SD) were 73.2 (12.2) for the KINDL-R, 76.1 (16.1) for the DCGM-12, 66.2 (19.9) for diabetes impact, and 56.4 (27.3) for diabetes treatment (DISABKIDS). Mean HbA1c was 8.3 (1.4)%. While both QoL outcomes and HbA1c level improved with increasing individual SES, no association was observed between area-level deprivation (GIMD 2010) and either outcome.ConclusionsCompared with individual SES, area-level deprivation seems to be of minor importance for QoL and glycaemic control in young people with early-onset type 1 diabetes.
Quality of Life Research

Heuberger, M.; Grill, E.; Saglam, M.; Ramaioli, C.; Müller, M.; Strobl, R.; Holle, R.; Peters, A.; Schneider, E.; Lehnen, N.
Usability of the video head impulse test: Lessons from the population-based prospective KORA study.
Front. Neurol. 9:659 (2018)
The video head impulse test (vHIT) has become a common examination in the work-up for dizziness and vertigo. However, recent studies suggest a number of pitfalls, which seem to reduce vHIT usability. Within the framework of a population-based prospective study with naïve examiners, we investigated the relevance of previously described technical mistakes in vHIT testing, and the effect of experience and training. Data originates from the KORA (Cooperative Health Research in the Region of Augsburg) FF4 study, the second follow-up of the KORA S4 population-based health survey. 681 participants were selected in a case-control design. Three examiners without any prior experience were trained in video head impulse testing. VHIT quality was assessed weekly by an experienced neuro-otologist. Restrictive mistakes (insufficient technical quality restricting interpretation) were noted. Based on these results, examiners received further individual training. Twenty-two of the 681 vHITs (3.2%) were not interpretable due to restrictive mistakes. Restrictive mistakes could be grouped into four categories: slippage, i.e., goggle movement relative to the head (63.6%), calibration problems (18.2%), noise (13.6%), and low velocity of the head impulse (4.6%). The overall rate of restrictive mistakes decreased significantly during the study (12% / examiner within the first 25 tested participants and 2.1% during the rest of the

examinations, < 0.0001). Few categories suffice to explain restrictive mistakes in vHIT testing. With slippage being most important, trainers should emphasize the importance of tight goggles. Experience and training seem to be effective in improving vHIT quality, leading to high usability.
Frontiers in neurology

Karl, F.; Tremmel, M.; Luzak, A.; Schulz, H.; Peters, A.; Meisinger, C.; Holle, R.; Laxy, M.
Direct healthcare costs associated with device assessed and self-reported physical activity: Results from a cross-sectional population-based study.
BMC Public Health 18:966 (2018)
Background: Physical inactivity (PIA) is an important risk factor for many chronic conditions and therefore might increase healthcare utilization and costs. This study aimed to analyze the association of PIA using device assessed and self-reported physical activity (PA) data with direct healthcare costs.Methods: Cross-sectional data was retrieved from the population based KORA FF4 study (Cooperative Health Research in the Region of Augsburg) that was conducted in southern Germany from 2013 to 2014 (n = 2279). Self-reported PA was assessed with two questions regarding sports related PA in summer and winter and categorized into "high activity", "moderate activity", "low activity" and "no activity". In a subsample (n = 477), PA was assessed with accelerometers and participants were categorized into activity quartiles ("very high", "high", "low" and "very low") according to their mean minutes per day spent in light intensity, or in moderate-vigorous PA (MVPA). Self-reported healthcare utilization was used to estimate direct healthcare costs. We regressed direct healthcare costs on PA using a two-part gamma regression, adjusted for age, sex and socio-demographic variables. Additional models, including and excluding potential additional confounders and effect mediators were used to check the robustness of the results.Results: Annual direct healthcare costs of individuals who reported no sports PA did not differ from those who reported high sports PA [+(sic)189, 95% CI: -188, 598]. In the subsample with accelerometer data, participants with very low MVPA had significantly higher annual costs than participants with very high MVPA [+(sic)986, 95% CI: 15, 1982].Conclusion: Device assessed but not self-reported PIA was associated with higher direct healthcare costs. The magnitude and significance of the association depended on the choice of covariates in the regression models. Larger studies with device assessed PA and longitudinal design are needed to be able to better quantify the impact of PIA on direct healthcare costs.
BMC Public Health

Thiele, I.; Linseisen, J.; Heier, M.; Holle, R.; Kirchberger, I.; Peters, A.; Thorand, B.; Meisinger, C.
Time trends in stroke incidence and in prevalence of risk factors in Southern Germany, 1989 to 2008/09.
Sci. Rep. 8:11981 (2018)
In prior studies, stroke incidence has mainly shown either declining time trends or stable rates in high-income countries. Changes could partially be linked to trends in classic cardiovascular disease (CVD) risk factors. In the present study, we analyzed the incidence of stroke in parallel with the prevalence of CVD risk factors over time in a German population. Data from three independent population-based MONICA/KORA Augsburg surveys conducted in 1989/90 (S2), 1994/95 (S3), and 1999/2001 (S4) were used to calculate age-standardized incidence rates (IR) of first-ever stroke over eight years from each baseline survey. Furthermore, the age-standardized prevalence rates of CVD risk factors were analyzed for these surveys. Changes in IR or prevalence were considered significantly different if their 95% confidence intervals (CI) did not overlap. The age-standardized IR of stroke showed no significant time trend (S2: IR = 203.4 per 100,000 person-years; CI 176.4-233.4, S3: IR = 225.6; 197.1-257.0, S4: IR = 209.9; CI 182.4-240.3). In agreement, the prevalence of the CVD risk factors was quite stable over time, showing divergent, but mostly non-significant changes. However, due to the aging Western societies and the longer survival time of stroke patients, the total number of stroke patients in the population will increase even with a stable IR.
Scientific Reports

Bauer, H.; Maier, W.
GIMD 2010 – Ein Update des ‚German Index of Multiple Deprivation‘.
Berichte des Helmholtz Zentrums München (2018)
Hintergrund und Zielsetzung: Mit dem „German Index of Multiple Deprivation“ (GIMD) steht mittlerweile auch in Deutschland ein Deprivationsindex zur Verfügung, der es ermöglicht, auf statistisch effiziente und prägnante Weise regionale soziale Disparitäten abzubilden und kleinräumige Unterschiede bei gesundheitlichen Risiken zu erfassen. Ziel ist es, eine aktualisierte Version, den GIMD 2010, zu erstellen.
Berichte des Helmholtz Zentrums München

Huber, M.B.; Vogelmann, M.; Leidl, R.
Valuing health-related quality of life: Systematic variation in health perception.
Health Qual. Life Outcomes 16:156 (2018)
Background: Population-based value sets are widely used to transform health states into utilities, but may deviate from actual patient experience. Whether this occurs in a systematic way can be analyzed, in a first step, for respondents who do not report problems on the five domains of the EQ-5D-5L instrument in population studies.Methods: EQ-5D-5L results from three annual cross-sectional surveys (2012, 2013, and 2014) were filtered for participants who reported being problem-free. Continuous visual analog scale (VAS) scores, ranging from 0 (worst imaginable health) to 100 (best imaginable health) were then used to measure their actual health perception and to compare results with the proposed EQ-5D-5L value. A multiple linear regression model was used to identify possible risk factors for low VAS scores.Results: Some 3739 (615%) participants reported being problem-free. Their mean age was 41.1 years and mean VAS score was 91.9. Age and BMI were significantly associated with lower VAS scores. Age groups from 50 years onwards reported VAS means of 90.0 and below. Female gender and low education also had small but significant negative effects on patient experience. The presence of BMI class III as well as diabetes had the greatest negative effect on VAS results (- 9.0 and - 8.4) and reached the range of minimally important differences. Heart disease (- 6.2) and musculoskeletal disease (- 3.4) also had strong negative effects. The 25th percentile of VAS scores in our sample was 90.0, and the 50th percentile was 95.0.Conclusions: For some groups in population studies, especially older people with high BMI and those affected by specific diseases, no problems on all five domains of the EQ-5D-

5L fails to reflect the respondents' health perception as measured by the VAS.
Health and Quality of Life Outcomes

Steinbeisser, K.; Grill, E.; Holle, R.; Peters, A.; Seidl, H.
Determinants for utilization and transitions of long-term care in adults 65+in Germany: Results from the longitudinal KORA-Age study.
BMC Geriatr. 18:172 (2018)
Background: Societies around the world face the burden of an aging population with a high prevalence of chronic conditions. Thus, the demand for different types of long-term care will increase and change over time. The purpose of this exploratory study was to identify determinants for utilization and transitions of long-term care in adults older than 65 years by using Andersen's Behavioral Model of Health Services Use.Methods: The study examined individuals older than 65 years between 2011/2012 (t(1)) and 2016 (t(2)) from the population-based Cooperative Health Research in the Region of Augsburg (KORA)-Age study from Southern Germany. Analyzed determinants consisted of predisposing (age, sex, education), enabling (living arrangement, income) and need (multimorbidity, disability) factors. Generalized estimating equation logistic models were used to identify determinants for utilization and types of long-term care. A logistic regression model examined determinants for transitions to long-term care over four years through a longitudinal analysis.Results: We analyzed 810 individuals with a mean age of 78.4 years and 24.4% receiving long-term care at t(1). The predisposing factors higher age and female sex, as well as the need factors higher multimorbidity and higher disability score, were determinants for both utilization and transitions of long-term care. Living alone, higher income and a higher disability score had a significant influence on the utilization of formal versus informal long-term care.Conclusion: Our results emphasize that both utilization and transitions of long-term care are influenced by a complex construct of predisposing, enabling and need factors. This knowledge is important to identify at-risk populations and helps policy-makers to anticipate future needs for long-term care.
BMC Geriatrics

Qosaj, F.A.; Froeschl, G.; Berisha, M.; Bellaq, B.; Holle, R.
Catastrophic expenditures and impoverishment due to out-of-pocket health payments in Kosovo.
Cost Eff. Resour. Alloc. 16:26 (2018)
Background: The current health system reforms in Kosovo aim to improve health status through universal health coverage. Risk pooling and ensuring access to necessary care without financial hardship are envisaged through compulsory health insurance. We measure the level of financial risk protection through two commonly applied concepts: catastrophic health expenditures and impoverishment. Methods: Data from the 2014 Kosovo Household Budget Survey were used to estimate catastrophic health expenditures as a percentage of household consumption expenditures at different thresholds. Poverty head counts and gaps were estimated before and after out-of-pocket (OOP) health payments. Results: Approximately 80% of the households in Kosovo incurred OOP health payments. Most of these expenditures were for medicine, pharmaceutical products and medical devices, followed by diagnostic and outpatient services. Hospital services and treatment abroad were less frequent but highly costly. Although households from the upper consumption groups spent more, households from the lower consumption groups spent a greater share of their consumption expenditures on healthcare. The catastrophic health expenditure head count showed an increase, while the impoverishment and poverty gap remained stable compared to 2011. Regression analysis showed that age of the household head, insurance coverage, household size, belonging to the lowest consumption expenditure quintiles, and having disabled and aged household members were significant predictors of the probability of experiencing catastrophic health expenditures. Conclusions: Ongoing financing reforms should target the lower income quintiles and vulnerable groups, pharmaceutical policies should be revisited, and the internal referral system should be strengthened to overcome excessive spending for treatment abroad.
Cost effectiveness and resource allocation

Laxy, M.; Wilson, E.C.F.; Boothby, C.E.; Griffin, S.J.
How good are GPS at adhering to a pragmatic trial protocol in primary care? Results from the ADDITION-Cambridge cluster-randomised pragmatic trial.
BMJ Open 8:e015295 (2018)
Objective To assess the fidelity of general practitioners' (GPS) adherence to a long-term pragmatic trial protocol. Design Retrospective analyses of electronic primary care records of participants in the pragmatic cluster-randomised ADDITION (Anglo-Danish-Dutch Study of Intensive Treatment In People with Screen Detected Diabetes in Primary Care)-Cambridge trial, comparing intensive multifactorial treatment (IT) versus routine care (RC). Data were collected from the date of diagnosis until December 2010. Setting Primary care surgeries in the East of England. Study sample/participants A subsample (n=189, RC arm: n=99, IT arm: n=90) of patients from the ADDITION-Cambridge cohort (867 patients), consisting of patients 40-69 years old with screen-detected diabetes mellitus. Interventions In the RC arm treatment was delivered according to concurrent treatment guidelines. Surgeries in the IT arm received funding for additional contacts between GPS/nurses and patients, and GPS were advised to follow more intensive treatment algorithms for the management of glucose, lipids and blood pressure and aspirin therapy than in the RC arm. Outcome measures The number of annual contacts between patients and GPS/nurses, the proportion of patients receiving prescriptions for cardiometabolic medication in years 1-5 after diabetes diagnosis and the adherence to prescription algorithms. Results The difference in the number of annual GP contacts (β=0.65) and nurse contacts (β=0.15) between the study arms was small and insignificant. Patients in the IT arm were more likely to receive glucose-lowering (OR=3.27), ACE-inhibiting (OR=2.03) and lipid-lowering drugs (OR=2.42, all p values <0.01) than patients in the RC arm. The prescription adherence varied between medication classes, but improved in both trial arms over the 5-year follow-up. Conclusions The adherence of GPS to different aspects of the trial protocol was mixed. Background changes in healthcare policy need to be considered as they have the potential to dilute differences in treatment intensity and hence incremental effects.
BMJ Open

Rogowski, W.H.
Evaluation as institution: A contractarian argument for needs-based economic evaluation.
BMC Med. Ethics 19:59 (2018)

Skin affections after sulfur mustard (SM) exposure include erythema, blister formation and severe inflammation. An antidote or specific therapy does not exist. Anti-inflammatory compounds as well as substances counteracting SM-induced cell death are under investigation. In this study, we investigated the benzylisoquinoline alkaloide berberine (BER), a metabolite in plants like berberis vulgaris, which is used as herbal pharmaceutical in Asian countries, against SM toxicity using a well-established in vitro approach. Keratinocyte (HaCaT) mono-cultures (MoC) or HaCaT/THP-1 co-cultures (CoC) were challenged with 100, 200 or 300 mM SM for 1 h. Post-exposure, both MoC and CoC were treated with 10, 30 or 50 mu M BER for 24 h. At that time, supernatants were collected and analyzed both for interleukine (IL) 6 and 8 levels and for content of adenylate-kinase (AK) as surrogate marker for cell necrosis. Cells were lysed and nucleosome formation as marker for late apoptosis was assessed. In parallel, AK in cells was determined for normalization purposes. BER treatment did not influence necrosis, but significantly decreased apoptosis. Anti-inflammatory effects were moderate, but also significant, primarily in CoC. Overall, BER has protective effects against SM toxicity in vitro. Whether this holds true should be evaluated in future in vivo studies.
BMC Medical Ethics

Leidl, R.
On the contribution of health economic research to medical care.
Gesundheitsökon. Qualitätsmanag. 23, 159-165 (2018)
Health economics can take many approaches to support optimal use of resources in medical care. Following a view upon developments in the process-oriented, morbidity-based regulation of inpatient care, the paper focuses on outcomes, especially on the patient perspective and on patient-reported outcomes. The paper introduces measurement approaches and impacts of valuing health related quality of life, either based on preferences, or on experience. Therefore, it analyzes population samples and routinely collected patient samples. For the outcome-related approach of value-based health care, the paper critically discusses the meaning of value. A new approach to integrate medical and economic aims in health care is outcome-oriented management. Trends in development, a management cycle, and a study example outline the approach. Outcomes make up a promising future topic, by which health economic research may further contribute to medical care.
Gesundheitsökonomie & Qualitätsmanagement

Präger, M.; Kiechle, M.; Stollenwerk, B.; Hinzen, C.; Glatz, J.; Vogl, M.; Leidl, R.
Costs and effects of intra-operative fluorescence molecular imaging - A model-based, early assessment.
PLoS ONE 13:e0198137 (2018)
Successful breast conserving cancer surgeries come along with tumor free resection margins and account for cosmetic outcome. Positive margins increase the likelihood of tumor recurrence. Intra-operative fluorescence molecular imaging (IFMI) aims to focus surgery on malignant tissue thus substantially lowering the presence of positive margins as compared with standard techniques of breast conservation (ST). A goal of this paper is to assess the incremental number of surgeries and costs of IFMI vs. ST. METHODS: We developed a decision analytical model and applied it for an early evaluation approach. Given uncertainty we considered that IFMI might reduce the proportion of positive margins found by ST from all to none and this proportion is assumed to be reduced to 10% for the base case. Inputs included data from the literature and a range of effect estimates. For the costs of IFMI, respective cost components were added to those of ST. RESULTS: The base case reduction lowered number of surgeries (mean [95% confidence interval]) by 0.22 [0.15; 0.30] and changed costs (mean [95% confidence interval]) by €-663 [€-1,584; €50]. A tornado diagram identified the Diagnosis Related Group (DRG) costs, the proportion of positive margins of ST, the staff time saving factor and the duration of frozen section analysis (FSA) as important determinants of this cost. CONCLUSIONS: These early results indicate that IFMI may be more effective than ST and through the reduction of positive margins it is possible to save follow-up surgeries-indicating further health risk-and to save costs through this margin reduction and the avoidance of FSA.
PLoS ONE

Szentes, B.L.; Kreuter, M.; Bahmer, T.; Birring, S.S.; Claussen, M.; Waelscher, J.; Leidl, R.; Schwarzkopf, L.
Quality of life assessment in interstitial lung diseases: A comparison of the disease-specific K-BILD with the generic EQ-5D-5L.
Respir. Res. 19:101 (2018)
Background: Patients with interstitial lung diseases (ILD) have impaired health-related quality of life (HRQL). Little is known about the applicability of the disease-specific King's Brief Interstitial Lung Disease questionnaire (K-BILD) and the generic EQ-5D-5L in a German setting. Methods: We assessed disease-specific (K-BILD) and generic HRQL (EQ-5D experience based value set (EBVS) and Visual Analog Scale (VAS)) in 229 patients with different ILD subtypes in a longitudinal observational study (HILDA). Additionally, we assessed the correlation of the HRQL measures with lung function and comorbidities. In a linear regression model, we investigated predictors (including age, sex, ILD subtype, FVC percentage of predicted value (FVC%pred), DLCO percentage of predicted value, and comorbidities). Results: Among the 229 patients mean age was 63.2 (Standard deviation (SD): 12.9), 67.3% male, 24.0% had idiopathic pulmonary fibrosis, and 22.3% sarcoidosis. Means scores were as follows for EQ-5D EBVS 0.66(SD 0.17), VAS 61.4 (SD 19.1) and K-BILD Total 53.6 (SD 13.8). K-BILD had good construct validity (high correlation with EQ-5D EBVS (0.71)) and good internal consistency (Cronbach's alpha 0.89). Moreover, all HRQL measures were highly accepted by patients including low missing items and there were no ceiling or floor effects. A higher FVC % pred was associated with higher HRQL in all measures meanwhile comorbidities had a negative influence on HRQL. Conclusions: K-BILD and EQ-5D had similar HRQL trends and were associated similarly to the same disease-related factors in Germany. Our data supports the use of K-BILD in clinical practice in Germany, since it captures disease specific effects of ILD. Additionally, the use of the EQ-5D-5L could provide comparison to different disease areas and give an overview about the position of ILD patients in comparison to general population.
Respiratory Research

Krack, G.; Holle, R.; Kirchberger, I.; Kuch, B.; Amann, U.; Seidl, H.
Determinants of adherence and effects on health-related quality of life after myocardial infarction: A prospective cohort study.

BMC Geriatr. 18:136 (2018)
Human adenovirus (HAdV) E1B-55K is a multifunctional regulator of productive viral replication and oncogenic transformation in nonpermissive mammalian cells. These functions depend on E1B-55K's posttranslational modification with the SUMO protein and its binding to HAdV E4orf6. Both early viral proteins recruit specific host factors to form an E3 ubiquitin ligase complex that targets antiviral host substrates for proteasomal degradation. Recently, we reported that the PML-NB associated factor Daxx represses efficient HAdV productive infection and is proteasomally degraded via a SUMO-E1B-55K-dependent, E4orf6-independent pathway, the details of which remained to be established. RNF4, a cellular SUMO-targeted ubiquitin ligase (STUbL), induces ubiquitinylation of specific SUMOy lated proteins and plays an essential role during DNA repair. Here, we show that E1B-55K recruits RNF4 to the insoluble nuclear matrix fraction of the infected cell to support RNF4/Daxx association, promoting Daxx PTM and thus inhibiting this antiviral factor. Removing RNF4 from infected cells using RNA interference resulted in blocking the proper establishment of viral replication centers and significantly diminished viral gene expression. These results provide a model for how HAdV antagonize the antiviral host responses by exploiting the functional capacity of cellular STUbLs. Thus, RNF4 and its STUbL function represent a positive factor during lytic infection and a novel candidate for future therapeutic antiviral intervention strategies.IMPORTANCE Daxx is a PML-NB-associated transcription factor that was recently shown to repress efficient HAdV productive infection. To counteract this antiviral measurement during infection, Daxx is degraded via a novel pathway including viral E1B-55K and host proteasomes. This virus-mediated degradation is independent of the classical HAdV E3 ubiquitin ligase complex, which is essential during viral infection to target other host antiviral substrates. To maintain a productive viral life cycle, HAdV E1B-55K early viral protein inhibits the chromatin-remodeling factor Daxx in a SUMO-dependent manner. In addition, viral E1B-55K protein recruits the STUbL RNF4 and sequesters it into the insoluble fraction of the infected cell. E1B-55K promotes complex formation between RNF4-and E1B-55K-targeted Daxx protein, supporting Daxx posttranslational modification prior to functional inhibition. Hence, RNF4 represents a novel host factor that is beneficial for HAdV gene expression by supporting Daxx counteraction. In this regard, RNF4 and other STUbL proteins might represent novel targets for therapeutic intervention.
BMC Geriatrics

Arnold, M.; Quante, A.S.
Personalized mammography screening and screening adherence-A simulation and economic evaluation.
Value Health 21, 799-808 (2018)
Objective: Personalized breast cancer screening has so far been economically evaluated under the assumption of full screening adherence. This is the first study to evaluate the effects of nonadherence on the evaluation and selection of personalized screening strategies. Methods: Different adherence scenarios were established on the basis of findings from the literature. A Markov microsimulation model was adapted to evaluate the effects of these adherence scenarios on three different personalized strategies. Results: First, three adherence scenarios describing the relationship between risk and adherence were identified: 1) a positive association between risk and screening adherence, 2) a negative association, or 3) a curvilinear relationship. Second, these three adherence scenarios were evaluated in three personalized strategies. Our results show that it is more the absolute adherence rate than the nature of the risk-adherence relationship that is important to determine which strategy is the most cost-effective. Furthermore, probabilistic sensitivity analyses showed that there are risk-stratified screening strategies that are more cost-effective than routine screening if the willingness-to-pay threshold for screening is below US $60,000. Conclusions: Our results show that "nonadherence" affects the relative performance of screening strategies. Thus, it is necessary to include the true adherence level to evaluate personalized screening strategies and to select the best strategy.
Value in Health

Graf, J.; Lucke, T.; Herrera, R.E.; Watz, H.; Holle, R.; Vogelmeier, C.; Ficker, J.H.; Jörres, R.A.
Compatibility of medication with PRISCUS criteria and identification of drug interactions in a large cohort of patients with COPD.
Pulm. Pharmacol. Ther. 49, 123-129 (2018)
Purpose of Review Advances in technology have expanded telemedicine opportunities covering medical practice, research, and education. This is of particular importance in movement disorders (MDs), where the combination of disease progression, mobility limitations, and the sparse distribution of MD specialists increase the difficulty to access. In this review, we discuss the prospects, challenges, and strategies for telemedicine in MDs.Recent Findings Telemedicine for MDs has been mainly evaluated in Parkinson's disease (PD) and compared to in-office care is cost-effective with similar clinical care, despite the barriers to engagement. However, particular groups including pediatric patients, rare MDs, and the use of telemedicine in underserved areas need further research.Summary Interdisciplinary telemedicine and tele-education for MDs are feasible, provide similar care, and reduce travel costs and travel time compared to in-person visits. These benefits have been mainly demonstrated for PD but serve as a model for further validation in other movement disorders.
Pulmonary Pharmacology and Therapeutics

Schopohl, D.; Bidlingmaier, C.; Herzig, D.; Klamroth, R.; Kurnik, K.; Rublee, D.; Schramm, W.; Schwarzkopf, L.; Berger, K.
Prospects for research in haemophilia with real-world dataAn analysis of German registry and secondary data.
Haemophilia 24, 584-594 (2018)
Introduction and aimOpen questions in haemophilia, such as effectiveness of innovative therapies, clinical and patient-reported outcomes (PROs), epidemiology and cost, await answers. The aim was to identify data attributes required and investigate the availability, appropriateness and accessibility of real-world data (RWD) from German registries and secondary databases to answer the aforementioned questions.MethodsSystematic searches were conducted in BIOSIS, EMBASE and MEDLINE to identify non-commercial secondary healthcare databases and registries of patients with haemophilia (PWH). Inclusion of German patients, type of patients, data elementsstratified by use in epidemiology, safety, outcomes and health economics researchand accessibility were investigated by desk research.ResultsScreening of 676 hits, identification of four registries [national PWH (DHR),

national/international paediatric (GEPARD, PEDNET), international safety monitoring (EUHASS)] and seven national secondary databases. Access was limited to participants in three registries and to employees in one secondary database. One registry asks for PROs. Limitations of secondary databases originate from the ICD-coding system (missing: severity of haemophilia, presence of inhibitory antibodies), data protection laws and need to monitor reliability.ConclusionRigorous observational analysis of German haemophilia RWD shows that there is potential to supplement current knowledge and begin to address selected policy goals. To improve the value of existing RWD, the following efforts are proposed: ethical, legal and methodological discussions on data linkage across different sources, formulation of transparent governance rules for data access, redefinition of the ICD-coding, standardized collection of outcome data and implementation of incentives for treatment centres to improve data collection.
Haemophilia

Cheung, K.L.; Hiligsmann, M.; Präger, M.; Jones, T.; Józwiak-Hagymásy, J.; Muñoz, C.; Lester-George, A.; Pokhrel, S.; López-Nicolás,; Trapero-Bertran, M.; Evers, S.M.A.A.; de Vries, H.
Optimizing usability of an economic decision tool: Prototype of the EQUIPT tool.
Int. J. Technol. Assess. Health Care 34, 68-77 (2018)
OBJECTIVES: Economic decision-support tools can provide valuable information for tobacco control stakeholders, but their usability may impact the adoption of such tools. This study aims to illustrate a mixed-method usability evaluation of an economic decision-support tool for tobacco control, using the EQUIPT ROI tool prototype as a case study. METHODS: A cross-sectional mixed methods design was used, including a heuristic evaluation, a thinking aloud approach, and a questionnaire testing and exploring the usability of the Return of Investment tool. RESULTS: A total of sixty-six users evaluated the tool (thinking aloud) and completed the questionnaire. For the heuristic evaluation, four experts evaluated the interface. In total twenty-one percent of the respondents perceived good usability. A total of 118 usability problems were identified, from which twenty-six problems were categorized as most severe, indicating high priority to fix them before implementation. CONCLUSIONS: Combining user-based and expert-based evaluation methods is recommended as these were shown to identify unique usability problems. The evaluation provides input to optimize usability of a decision-support tool, and may serve as a vantage point for other developers to conduct usability evaluations to refine similar tools before wide-scale implementation. Such studies could reduce implementation gaps by optimizing usability, enhancing in turn the research impact of such interventions.
International Journal of Technology Assessment in Health Care

Kisch, R.; Bergmann, A.; Koller, D.; Leidl, R.; Mansmann, U.; Mueller, M.; Sanftenberg, L.; Schelling, J.; Sundmacher, L.; Voigt, K.; Grill, E.
Patient trajectories and their impact on mobility, social participation and quality of life in patients with vertigo/dizziness/balance disorders and osteoarthritis (MobilE-TRA): Study protocol of an observational, practice-based cohort study.
BMJ Open 8:e022970 (2018)
Introduction Mobility limitations have a multitude of different negative consequences on elderly patients including decreasing opportunities for social participation, increasing the risk for morbidity and mortality. However, current healthcare has several shortcomings regarding mobility sustainment of older adults, namely a narrow focus on the underlying pathology, fragmentation of care across services and health professions and deficiencies in personalising care based on patients' needs and experiences. A tailored healthcare strategy targeted at mobility of older adults is still missing. Objective The objective is to develop multiprofessional care pathways targeted at mobility sustainment and social participation in patients with vertigo/dizziness/balance disorders (VDB) and osteoarthritis (OA). Methods Data regarding quality of life, mobility limitation, pain, stiffness and physical function is collected in a longitudinal observational study between 2017 and 2019. General practitioners (GPs) recruit their patients with VDB or OA. Patients who visited their GP in the last quarter will be identified in the practice software based on VDB and OA-related International Classification of Diseases 10th Revision. Study material will be sent from the practice to patients by mail. Six months and 12 months after baseline, all patients will receive a mail directly from the study team containing the follow-up questionnaire. GPs fill out questionnaires regarding patient diagnostics, therapy and referrals. Ethics and dissemination The study was approved by the ethical committee of the Ludwig-Maximilians-Universität München and of the Technische Universität Dresden. Results will be published in scientific, peer-reviewed journals and at national and international conferences. Results will be disseminated via newsletters, the project website and a regional conference for representatives of local and national authorities.
BMJ Open

Mena, E.; Kroll, L.E.; Maier, W.; Bolte, G.
Gender inequalities in the association between area deprivation and perceived social support: A cross-sectional multilevel analysis at the municipality level in Germany.
BMJ Open 8:e019973 (2018)
© 2018 Article author(s) (or their employer(s) unless otherwise stated in the text of the article). All rights reserved. Objectives To investigate the association between area deprivation at municipality level with low perceived social support, independent of individual socioeconomic position and demographic characteristics. To assess whether there are gender inequalities in this association. Design Cross-sectional multilevel analysis of survey data. Setting Germany. Participants 3350 men and 3665 women living in 167 municipalities throughout Germany participating in the German Health Interview and Examination Survey for Adults' (DEGS1 2008-2011) as part of the national health monitoring. Outcome Perceived social support as measured by Oslo-3 Social Support Scale. Results Prevalence of low perceived social support was 11.4% in men and 11.1% in women. Low social support was associated in men and women with sociodemographic characteristics that indicate more disadvantaged living situations. Taking these individual-level characteristics into account, municipal-level deprivation was independently associated with low perceived social support in men (OR for the most deprived quintile: 1.80 (95% CI 1.14 to 2.84)), but not in women (OR 1.22 (95% CI 0.78 to 1.90)). Conclusion The results of our multilevel analysis suggest that there are gender inequalities in the association of municipal-level deprivation with the prevalence of low perceived social support in Germany independent of individual socioeconomic position.

Community health interventions aiming at promotion of social support among residents might profit from a further understanding of the observed gender differences.
BMJ Open

Schwarzkopf, L.; Witt, S.; Waelscher, J.; Polke, M.; Kreuter, M.
Associations between comorbidities, their treatment and survival in patients with interstitial lung diseases - a claims data analysis.
Respir. Res. 19:73 (2018)
BACKGROUND: Interstitial lung diseases (ILDs) are associated with a high burden of disease. However, data on the prognostic impact of comorbidities and comorbidity-related pharmaceutical treatments in patients with various ILDs remain sparse. METHODS: Using longitudinal claims data from a German Statutory Health Insurance Fund, we assessed comorbidity in ILD subtypes and associated drug treatments. Baseline comorbidity was assessed via the Elixhauser Comorbidity Index that was amended by ILD-relevant conditions. Drug treatment was assessed on the substance level using the ATC-codes of drugs prescribed at the time of ILD diagnosis. Subsequently, the comorbid conditions (main analysis) and pharmaceutical substances (secondary analysis) with a meaningful association to survival were identified for the complete ILD cohort and within the subtype strata. For this, we applied multivariate Cox models using a LASSO selection process and visualized the findings within comorbidomes. RESULTS: In the 36,821 patients with ILDs, chronic obstructive pulmonary disease (COPD), arterial hypertension, and ischaemic heart disease (IHD) were the most prevalent comorbidities. The majority of patients with cardiovascular diseases received pharmaceutical treatment, while, in other relevant comorbidities, treatment quotas were low (COPD 46%, gastro-oesophageal reflux disease 65%). Comorbidities had a clinically meaningful detrimental effect on survival that tended to be more pronounced in the case of untreated conditions (e.g. hazard ratios for treated IHD 0.97 vs. 1.33 for untreated IHD). Moreover, comorbidity impact varied substantially between distinct subtypes. CONCLUSIONS: Our analyses suggest that comorbid conditions and their treatment profile significantly affect mortality in various ILDs. Therefore, comprehensive comorbidity assessment and management remains important in any ILD.
Respiratory Research

Arvandi, M.; Strasser, B.; Volaklis, K.A.; Ladwig, K.-H.; Grill, E.; Matteucci Gothe, R.; Horsch, A.; Laxy, M.; Siebert, U.; Peters, A.; Thorand, B.; Meisinger, C.
Mediator effect of balance problems on association between grip strength and falls in older adults: Results from the KORA-age study.
Gerontol. Geriatr. Med. 4:2333721418760122 (2018)
To examine the association between grip strength and history of falls among older individuals, and to assess the possible mediating effect of balance problems on this relationship.Data originate from KORA (Cooperative Health Research in the Region of Augsburg)-Age Study of 808 individuals (65 years and above). Follow-up assessment occurred 3 years later.The risk of falls within the last 12 months was reduced on average by 3% (odds ratio [OR] 95% confidence interval [95% CI] = 0.97 [0.94, 0.99];value = .026) per 1-kg increase in maximum grip strength after adjusting for age and gender. There was a trend toward an indirect effect of grip strength through the mediator variable balance problems (value = .043).Increased muscular strength is associated with a reduced risk of falls in older age after adjustment for age and gender. The association is partially mediated by balance problems. Thus, in older adults, muscle-strengthening exercises may decrease the risk of falling.
Gerontology and geriatric medicine

Rost, S.; Freuer, D.; Peters, A.; Thorand, B.; Holle, R.; Linseisen, J.; Meisinger, C.
New indexes of body fat distribution and sex-specific risk of total and cause-specific mortality: A prospective cohort study.
BMC Public Health 18:427 (2018)
Background: A number of prior studies have examined the association between anthropometric measures and mortality, but studies investigating the sex-specific predictive value of novel anthropometric measures on mortality are scarce so far. Therefore, we investigated the sex-specific relevance of the new anthropometric measures body adiposity index (BAI) and waist to height ratio (WHtR) as well as the common measures body mass index (BMI), waist circumference (WC), and waist to hip ratio (WHR) for cause-specific mortality risk. Methods: The analysis was based on data from the German population based KORA (Cooperative Health Research in the Region of Augsburg) Augsburg cohort study. A total of 6670 men and 6637 women aged 25 to 74 years at baseline examination were included. During a mean follow-up period of 15.4 years, 2409 persons died. Via Cox proportional hazard regression, the associations between the different anthropometric measures and all cause-, cardiovascular disease (CVD)- and cancer mortality were assessed. Results: BMI, WC, and WHR were significantly associated with all-cause and CVD-mortality in both sexes. WC and WHR were particularly associated with higher all-cause and CVD-mortality risk in women, while in men especially WHtR and BAI were strongly related to these outcomes. Females with WC, WHtR, and WHR measures in the 4th quartile compared with women in the 2nd quartile had a higher risk of death from cancer. Contrary, men in the lowest quartile of WC and WHtR in comparison to men in the 2nd quartile had a significantly elevated cancer mortality risk. BAI was no risk predictor for all-cause and cause-specific mortality in women. Conclusions: Central obesity reflects higher all-cause and CVD-mortality risk particularly in women. BAI and WHtR seem to be valid as risk predictors for all-cause and especially CVD mortality in men but not women. There are marked sex-differences regarding cancer mortality risk for the different anthropometric measures.
BMC Public Health

Vogl, M.; Schildmann, E.; Leidl, R.; Hodiamont, F.; Kalies, H.; Maier, B.O.; Schlemmer, M.; Roller, S.; Bausewein, C.
Redefining diagnosis-related groups (DRGs) for palliative care - A cross-sectional study in two German centres.
BMC Palliat. Care 17:58 (2018)
Background: Hospital costs and cost drivers in palliative care are poorly analysed. It remains unknown whether current German Diagnosis-Related Groups, mainly relying on main diagnosis or procedure, reproduce costs adequately. The aim of this study was therefore to analyse costs and reimbursement for inpatient palliative care and to identify relevant cost drivers. Methods: Two-center, standardised micro-costing approach with patient-level cost calculations and analysis of the reimbursement situation for patients receiving palliative care at two German hospitals (7/2012-12/2013). Data were analysed for the total group receiving hospital care covering, but not exclusively,

palliative care (group A) and the subgroup receiving palliative care only (group B). Patient and care characteristics predictive of inpatient costs of palliative care were derived by generalised linear models and investigated by classification and regression tree analysis. Results: Between 7/2012 and 12/2013, 2151 patients received care in the two hospitals including, but not exclusively, on the PCUs (group A). In 2013, 784 patients received care on the two PCUs only (group B). Mean total costs per case were € 7392 (SD 7897) (group A) and € 5763 (SD 3664) (group B), mean total reimbursement per case € 5155 (SD 6347) (group A) and € 4278 (SD 2194) (group B). For group A/B on the ward, 58%/67% of the overall costs and 48%/53%, 65%/82% and 64%/72% of costs for nursing, physicians and infrastructure were reimbursed, respectively. Main diagnosis did not significantly influence costs. However, duration of palliative care and total length of stay were (related to the cost calculation method) identified as significant cost drivers. Conclusions: Related to the cost calculation method, total length of stay and duration of palliative care were identified as significant cost drivers. In contrast, main diagnosis did not reflect costs. In addition, results show that reimbursement within the German Diagnosis-Related Groups system does not reproduce the costs adequately, but causes a financing gap for inpatient palliative care.
BMC palliative care

Trapero-Bertran, M.; Leidl, R.; Muñoz, C.; Kulchaitanaroaj, P.; Coyle, K.; Präger, M.; Józwiak-Hagymásy, J.; Cheung, K.L.; Hiligsmann, M.; Pokhrel, S.
Estimates of costs for modelling return on investment from smoking cessation interventions.
Addiction 113, 1, 32-41 (2018)
BACKGROUND AND AIMS: Modelling return on investment (ROI) from smoking cessation interventions requires estimates of their costs and benefits. This paper describes a standardized method developed to source both economic costs of tobacco smoking and costs of implementing cessation interventions for a Europe-wide ROI model [European study on Quantifying Utility of Investment in Protection from Tobacco model (EQUIPTMOD)]. DESIGN: Focused search of administrative and published data. A standardized checklist was developed in order to ensure consistency in methods of data collection. SETTING AND PARTICIPANTS: Adult population (15+ years) in Hungary, Netherlands, Germany, Spain and England. For passive smoking-related costs, child population (0-15 years) was also included. MEASUREMENTS: Costs of treating smoking-attributable diseases; productivity losses due to smoking-attributable absenteeism; and costs of implementing smoking cessation interventions. FINDINGS: Annual costs (per case) of treating smoking attributable lung cancer were between €5074 (Hungary) and €52 106 (Germany); coronary heart disease between €1521 (Spain) and €3955 (Netherlands); chronic obstructive pulmonary disease between €1280 (England) and €4199 (Spain); stroke between €1829 (Hungary) and €14 880 (Netherlands). Costs (per recipient) of smoking cessation medications were estimated to be: for standard duration of varenicline between €225 (England) and €465 (Hungary); for bupropion between €25 (Hungary) and €220 (Germany). Costs (per recipient) of providing behavioural support were also wide-ranging: one-to-one behavioural support between €34 (Hungary) and €474 (Netherlands); and group-based behavioural support between €12 (Hungary) and €257 (Germany). The costs (per recipient) of delivering brief physician advice were: €24 (England); €9 (Germany); €4 (Hungary); €33 (Netherlands); and €27 (Spain). CONCLUSIONS: Costs of treating smoking-attributable diseases as well as the costs of implementing smoking cessation interventions vary substantially across Hungary, Netherlands, Germany, Spain and England. Estimates for the costs of these diseases and interventions can contribute to return on investment estimates in support of national or regional policy decisions.
Addiction

Trapero-Bertran, M.; Muñoz, C.; Coyle, K.; Coyle, D.; Lester-George, A.; Leidl, R.; Németh, B.; Cheung, K.L.; Pokhrel, S.; Lopez-Nicolás,
Cost-effectiveness of alternative smoking cessation scenarios in Spain: Results from the EQUIPTMOD.
Addiction 113, 1, 65-75 (2018)
Ambient inhalable particulate matter (PM) is a serious health concern worldwide, but especially so in China where high PM concentrations affect huge populations. Atmospheric processes and emission sources cause spatial and temporal variations in PM concentration and chemical composition, but their influence on the toxicological characteristics of PM are still inadequately understood.In this study, we report an extensive chemical and toxicological characterization of size-segregated urban air inhalable PM collected in August and October 2013 from Nanjing, and assess the effects of atmospheric processes and likely emission sources. A549 human alveolar epithelial cells were exposed to day- and nighttime PM samples (25, 75, 150, 200, 300 mu g/ml) followed by analyses of cytotoxicity, genotoxicity, cell cycle, and inflammatory response.PM10-2.5 and PM0.2 caused the greatest toxicological responses for different endpoints, illustrating that particles with differing size and chemical composition activate distinct toxicological pathways in A549 cells. PM10-2.5 displayed the greatest oxidative stress and genotoxic responses; both were higher for the August samples compared with October. In contrast, PM0.2 and PM2.5-1.0 samples displayed high cytotoxicity and substantially disrupted cell cycle; August samples were more cytotoxic whereas October samples displayed higher cell cycle disruption. Several components associated with combustion, traffic, and industrial emissions displayed strong correlations with these toxicological responses. The lower responses for PM1.0-0.2 compared to PM0.2 and PM2.5-1.0 indicate diminished toxicological effects likely due to aerosol aging and lower proportion of fresh emission particles rich in highly reactive chemical components in the PM1.0-0.2 fraction.Different emission sources and atmospheric processes caused variations in the chemical composition and toxicological responses between PM fractions, sampling campaigns, and day and night. The results indicate different toxicological pathways for coarse-mode particles compared to the smaller particle fractions with typically higher content of combustion-derived components. The variable responses inside PM fractions demonstrate that differences in chemical composition influence the induced toxicological responses.
Addiction

Kurz, C.F.
Statistical methods for healthcare performance monitoring
In:. 2018. 381-382 (Biometrics; 74)
Biometrics

Luzak, A.; Karrasch, S.; Wacker, M.; Thorand, B.; Nowak, D.; Peters, A.; Schulz, H.
Association of generic health-related quality of life (EQ-5D dimensions) and inactivity with lung function in lung-healthy German adults: Results from the KORA studies F4L and Age.
Qual. Life Res. 27, 735-745 (2018)
Among patients with lung disease, decreased lung function is associated with lower health-related quality of life. However, whether this association is detectable within the physiological variability of respiratory function in lung-healthy populations is unknown. We analyzed the association of each EQ-5D-3L dimension (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) and self-reported physical inactivity with spirometric indices in lung-healthy adults. Modulating effects between inactivity and EQ-5D dimensions were considered. 1132 non-smoking, apparently lung-healthy participants (48% male, aged 64 +/- 12 years) from the population-based KORA F4L and Age surveys in Southern Germany were analyzed. Associations of each EQ-5D dimension and inactivity with spirometric indices serving as outcomes (forced expiratory volume in 1 s (FEV1), forced vital capacity (FVC), FEV1/FVC, and mid-expiratory flow) were examined by linear regression, considering possible confounders. Interactions between EQ-5D dimensions (no problems/any problems) and inactivity (four categories of time spent engaging in exercise: inactive to most active) were assessed. Among all participants 42% reported no problems in any EQ-5D dimension, 24% were inactive and 32% exercised > 2 h/week. After adjustment, FEV1 was - 99 ml (95% CI - 166; - 32) and FVC was - 109 ml (95% CI - 195; - 24) lower among subjects with mobility problems. Comparable estimates were observed for usual activities. Inactivity was negatively associated with FVC (beta-coefficient: - 83 ml, 95% CI - 166; 0), but showed no interactions with EQ-5D. Problems with mobility or usual activities, and inactivity were associated with slightly lower spirometric parameters in lung-healthy adults, suggesting a relationship between perceived physical functioning and volumetric lung function.
Quality of Life Research

Kulchaitanaroaj, P.; Kaló, Z.; West, R.; Cheung, K.L.; Evers, S.; Vokó, Z.; Hiligsmann, M.; de Vries, H.; Owen, L.; Trapero-Bertran, M.; Leidl, R.; Pokhrel, S.
Understanding perceived availability and importance of tobacco control interventions to inform European adoption of a UK economic model: A cross-sectional study.
BMC Health Serv. Res. 18:115 (2018)
Background: The evidence on the extent to which stakeholders in different European countries agree with availability and importance of tobacco-control interventions is limited. This study assessed and compared stakeholders' views from five European countries and compared the perceived ranking of interventions with evidence-based ranking using cost-effectiveness data. Methods: An interview survey (face-to-face, by phone or Skype) was conducted between April and July 2014 with five categories of stakeholders - decision makers, service purchasers, service providers, evidence generators and health promotion advocates - from Germany, Hungary, the Netherlands, Spain, and the United Kingdom. A list of potential stakeholders drawn from the research team's contacts and snowballing served as the sampling frame. An email invitation was sent to all stakeholders in this list and recruitment was based on positive replies. Respondents were asked to rate availability and importance of 30 tobacco control interventions. Kappa coefficients assessed agreement of stakeholders' views. A mean importance score for each intervention was used to rank the interventions. This ranking was compared with the ranking based on cost-effectiveness data from a published review. Results: Ninety-three stakeholders (55.7% response rate) completed the survey: 18.3% were from Germany, 17.2% from Hungary, 30.1% from the Netherlands, 19.4% from Spain, and 15.1% from the UK. Of those, 31.2% were decision makers, 26.9% evidence generators, 19.4% service providers, 15.1% health-promotion advocates, and 7.5% purchasers of services/pharmaceutical products. Smoking restrictions in public areas were rated as the most important intervention (mean score = 1.89). The agreement on availability of interventions between the stakeholders was very low (kappa = 0.098; 95% CI = [0.085, 0.111] but the agreement on the importance of the interventions was fair (kappa = 0.239; 95% CI = [0.208, 0.253]). A correlation was found between availability and importance rankings for stage-based interventions. The importance ranking was not statistically concordant with the ranking based on published cost-effectiveness data (Kendall rank correlation coefficient = 0.40; p-value = 0.11; 95% CI = [-0.09, 0.89]). Conclusions: The intrinsic differences in stakeholder views must be addressed while transferring economic evidence Europe-wide. Strong engagement with stakeholders, focussing on better communication, has a potential to mitigate this challenge.
BMC Health Services Research

Wagner, C.J.; Dintsios, C.M.; Metzger, F.G.; L'hoest, H.; Marschall, U.; Stollenwerk, B.; Stock, S.
Longterm persistence and nonrecurrence of depression treatment in Germany: A four-year retrospective follow-up using linked claims data.
Int. J. Methods Psychiatr. Res. 27:e1607 (2018)
Objectives: To measure persistence and nonrecurrence of depression treatment and investigate potential risk factors. Methods: We retrospectively observed a closed cohort of insurees with new-onset depression treatment in 2007 and without most psychiatric comorbidity for 16 quarters (plus one to ascertain discontinuation). We linked inpatient/outpatient/drug-data per person and quarter. Person-quarters containing specified depression services were classified as depression-treatment-person-quarters (DTPQ). We defined longterm-DTPQ-persistence as 16 + 1 continuous DTPQ and longterm-DTPQ-nonrecurrence as 12 continuous quarters without DTPQ and used multivariate logistic regression to explore associations with these outcomes. Results: Within first 16 quarters, 28,348 patients' first period (total time) persisted for a mean/median 5.4/3 (8.7/8) quarters. Fourteen percent had longterm-DTPQ-persistence, associated (p <.05) with baseline hospital (odds ratio, OR = 1.80), psychotherapy/specialist-interview and antidepressants (OR = 1.81), age (years, OR = 1.03), unemployment (OR = 1.21), retirement (OR = 1.31), and insured as a dependent (OR = 1.32). Thirty-four percent had longterm-DTPQ-nonrecurrence, associated with psychotherapy/specialist-interview (OR = 1.40), antidepressants (OR = 0.54), female sex (OR = 0.84), age (years, OR = 0.99), retirement (OR = 1.18), and insured as a dependent (OR = 0.88). Women differed for episodic and not chronic treatment. Conclusion: Treatment measures compared to survey's symptoms measures. We suggest further research on “treatment-free-time.” Antidepressants(−) and psychotherapy/specialist-interview(+)

were significantly associated with longterm-DTPQ-nonrecurrence. This was presumably moderated by possible short-time/low-dosage antidepressants use(−) and selective therapy assignment(+). Sample selectivity limited data misclassification.
International Journal of Methods in Psychiatric Research

Bamberger, C.; Rossmeier, A.; Lechner, K.; Wu, L.; Waldmann, E.; Fischer, S.; Stark, R.G.; Altenhofer, J.; Henze, K.; Parhofer, K.G.
A walnut-enriched diet affects gut microbiome in healthy caucasian subjects: A randomized, controlled trial.
Nutrients 10:244 (2018)
Regular walnut consumption is associated with better health. We have previously shown that eight weeks of walnut consumption (43 g/day) significantly improves lipids in healthy subjects. In the same study, gut microbiome was evaluated. We included 194 healthy subjects (134 females, 63 +/- 7 years, BMI 25.1 +/- 4.0 kg/m(2)) in a randomized, controlled, prospective, cross-over study. Following a nut-free run-in period, subjects were randomized to two diet phases (eight weeks each); 96 subjects first followed a walnut-enriched diet (43 g/day) and then switched to a nut-free diet, while 98 subjects followed the diets in reverse order. While consuming the walnut-enriched diet, subjects were advised to either reduce fat or carbohydrates or both to account for the additional calories. Fecal samples were collected from 135 subjects at the end of the walnut-diet and the control-diet period for microbiome analyses. The 16S rRNA gene sequencing data was clustered with a 97% similarity into Operational Taxonomic Units (OTUs). UniFrac distances were used to determine diversity between groups. Differential abundance was evaluated using the Kruskal-Wallis rank sum test. All analyses were performed using Rhea. Generalized UniFrac distance shows that walnut consumption significantly affects microbiome composition and diversity. Multidimensional scaling (metric and non-metric) indicates dissimilarities of approximately 5% between walnut and control ($p = 0.02$). The abundance of Ruminococcaceae and Bifidobacteria increased significantly ($p < 0.02$) while Clostridium sp. cluster XIVa species (Blautia; Anaerostipes) decreased significantly ($p < 0.05$) during walnut consumption. The effect of walnut consumption on the microbiome only marginally depended on whether subjects replaced fat, carbohydrates or both while on walnuts. Daily intake of 43 g walnuts over eight weeks significantly affects the gut microbiome by enhancing probiotic and butyric acid-producing species in healthy individuals. Further evaluation is required to establish whether these changes are preserved during longer walnut consumption and how these are linked to the observed changes in lipid metabolism.
Nutrients

Stollenwerk, B.; Iannazzo, S.; Akehurst, R.; Adena, M.; Briggs, A.; Dehmel, B.; Parfrey, P.; Belozeroff, V.
A decision-analytic model to assess the cost-effectiveness of etelcalcetide vs. cinacalcet.
Pharmacoeconomics 36, 603-612 (2018)
Introduction: Etelcalcetide is a novel intravenous calcimimetic for the treatment of secondary hyperparathyroidism (SHPT) in haemodialysis patients. The clinical efficacy and safety of etelcalcetide (in addition to phosphate binders and vitamin D and/or analogues [PB/VD]) was evaluated in three phase III studies, including two placebo-controlled trials and a head-to-head study versus the oral calcimimetic cinacalcet. Objective: The objective of this study was to develop a decision-analytic model for economic evaluation of etelcalcetide compared with cinacalcet. Methods: We developed a life-time Markov model including potential treatment effects on mortality, cardiovascular events, fractures, and subjects' persistence. Long-term efficacy of etelcalcetide was extrapolated from the reduction in parathyroid hormone (PTH) in the phase III trials and the available data from the outcomes study in cinacalcet (EVOLVE trial). Etelcalcetide was compared with cinacalcet, both in addition to PB/VD. We applied unit costs averaged from five European countries and a range of potential etelcalcetide pricing options assuming parity price to weekly use of cinacalcet and varying it by a 15 or 30% increase. Results: Compared with cinacalcet, the incremental cost-effectiveness ratio of etelcalcetide was €1,355 per QALY, €24,521 per QALY, and €47,687 per QALY for the three prices explored. The results were robust across the probabilistic and deterministic sensitivity analyses. Conclusions: Our modelling approach enabled cost-utility assessment of the novel therapy for SHPT based on the observed and extrapolated data. This model can be used for local adaptations in the context of reimbursement assessment.
PharmacoEconomics

Kurz, C.F.; Holle, R.
Demand for medical care by the elderly: A nonparametric variational Bayesian mixture approach.
OASIcs 4, 4:1-4:7 (2018)
Outpatient care is a large share of total health care spending, making analysis of data on outpatient utilization an important part of understanding patterns and drivers of health care spending growth. Common features of outpatient utilization measures include zero-inflation, overdispersion, and skewness, all of which complicate statistical modeling. Mixture modeling is a popular approach because it can accommodate these features of health care utilization data. In this work, we add a nonparametric clustering component to such models. Our fully Bayesian model framework allows for an unknown number of mixing components, so that the data, rather than the researcher, determine the number of mixture components. We apply the modeling framework to data on visits to physicians by elderly individuals and show that each subgroup has different characteristics that allow easy interpretation and new insights.
Open access series in informatics

Bächle, C.; Claessen, H.; Maier, W.; Tamayo, T.; Schunk, M.; Rückert-Eheberg, I.-M.; Holle, R.; Meisinger, C.; Moebus, S.; Jöckel, K.H.; Schipf, S.; Völzke, H.; Hartwig, S.; Kluttig, A.; Kroll, L.E.; Linnenkamp, U.; Icks, A.
Regional differences in antihyperglycemic medication are not explained by individual socioeconomic status, regional deprivation, and regional health care services. Observational results from the German DIAB-CORE consortium.
PLoS ONE 13:e0191559 (2018)
Aims This population-based study sought to extend knowledge on factors explaining regional differences in type 2 diabetes mellitus medication patterns in Germany. Methods Individual baseline and follow-up data from four regional population-based German cohort studies (SHIP [northeast], CARLA [east], HNR [west], KORA [south]) conducted between 1997 and 2010 were pooled and merged with both data on regional deprivation and regional health care services. To analyze regional differences in

any or newer anti-hyperglycemic medication, medication prevalence ratios (PRs) were estimated using multivariable Poisson regression models with a robust error variance adjusted gradually for individual and regional variables. Results The study population consisted of 1,437 people aged 45 to 74 years at baseline, (corresponding to 49 to 83 years at follow-up) with self-reported type 2 diabetes. The prevalence of receiving any anti-hyperglycemic medication was 16% higher in KORA (PR 1.16 [1.08 +/- 1.25]), 10% higher in CARLA (1.10 [1.01 +/- 1.18]), and 7% higher in SHIP (PR 1.07 [1.00 +/- 1.15]) than in HNR. The prevalence of receiving newer anti-hyperglycemic medication was 49% higher in KORA (1.49 [1.09 +/- 2.05]), 41% higher in CARLA (1.41 [1.02 +/- 1.96]) and 1% higher in SHIP (1.01 [0.72 +/- 1.41]) than in HNR, respectively. After gradual adjustment for individual variables, regional deprivation and health care services, the effects only changed slightly. Conclusions Neither comprehensive individual factors including socioeconomic status nor regional deprivation or indicators of regional health care services were able to sufficiently explain regional differences in anti-hyperglycemic treatment in Germany. To understand the underlying causes, further research is needed.
PLoS ONE

Kahnert, K.; Alter, P.; Young, D.M.; Lucke, T.; Heinrich, J.; Huber, R.M.; Behr, J.; Wacker, M.; Biertz, F.; Watz, H.; Bals, R.; Welte, T.; Wirtz, H.; Herth, F.; Vestbo, J.; Wouters, E.F.; Vogelmeier, C.F.; Jörres, R.A.
The revised GOLD 2017 COPD categorization in relation to comorbidities.
Respir. Med. 134, 79-85 (2018)
Introduction: The COPD classification proposed by the Global Initiative for Obstructive Lung Disease was recently revised, and the A to D grouping is now based on symptoms and exacerbations only. Potential associations with comorbidities have not been assessed so far. Thus the aim of the present study was to determine the relationship between the revised (2017) GOLD groups A-D and major comorbidities. Methods: We used baseline data from the COPD cohort COSYCONET. Comorbidities were identified from patient self-reports and disease-specific medication: gastrointestinal disorders, asthma, sleep apnea, hyperuricemia, hyperlipidemia, diabetes, osteoporosis, mental disorders, heart failure, hypertension, coronary artery disease. The A-D groups were based on either the COPD Assessment Test or the modified Medical Research Council scale. Exacerbations were also categorized as per GOLD recommendations. Results: Data from 2228 patients were analyzed. Using GOLD group A as a reference, group D was associated with nearly all comorbidities, followed by group B and C. When groups A-D were dichotomized as AC vs. BD (symptoms) and AB vs. CD (exacerbations), all comorbidities correlated with symptoms and/or exacerbations. This was true for both mMRC- and CAT-based categorizations. Conclusions: These findings suggest that the recently modified GOLD categorization is clinically relevant beyond being purely an assessment of symptoms and exacerbations. As the A-D groups correlated with the risk of important comorbidities, with some differences in terms of the correlation with symptoms and exacerbations, the findings underline the importance of identifying comorbidities in COPD, particularly in non-responders to therapy who have high symptoms and/or exacerbation rates.
Respiratory Medicine

Walter, J.; Tufman, A.; Leidl, R.; Holle, R.; Schwarzkopf, L.
Rural versus urban differences in end-of-life care for lung cancer patients in Germany.
Support Care Cancer 26, 2275-2283 (2018)
PURPOSE: To assess rural-urban differences in healthcare utilization and supportive care at the end-of-life in German lung cancer patients. METHODS: We identified 12,929 patients with incident lung cancer in 2009 from claims data and categorized them to four district types (major city, urban, rural, remote rural). We compared site of death, unplanned hospitalizations, hospital days, outpatient doctor, general practitioner (GP) and home visits, structured palliative care, therapy with antidepressants, pain relief medication and chemotherapy, and therapeutic puncturing in the last 30 and 14 days of life using mixed models with logistic link function for binary outcomes and log link function for count data. We adjusted all models by age, sex, comorbidities, metastases location and presence of multiple tumors at diagnosis, survival in months, and type of tumor-directed treatment. RESULTS: We found significant differences in two of the outcomes measured. The likelihood of > 14 hospital days in the last 30 days was significantly higher in rural districts than in remote rural districts (1.27 [1.05, 1.52], p = 0.0003). The number of visits to the GP in the last 30 days of life was significantly lower in urban districts than in remote rural districts (β = - 0.19 [- 0.32, - 0.06], p = <0.0001). No other endpoints were associated with regional differences. Triggering factors for high and low utilization of healthcare were mostly age, comorbidities, and prior anticancer treatment. CONCLUSION: Healthcare utilization and supportive care did not differ significantly between different district types. Results reject the hypothesis of regional inequity in end-of-life care of lung cancer patients in Germany.
Supportive care in cancer

Kauhl, B.; Maier, W.; Schweikart, J.; Keste, A.; Moskwyn, M.
Who is where at risk for Chronic Obstructive Pulmonary Disease? A spatial epidemiological analysis of health insurance claims for COPD in Northeastern Germany.
PLoS ONE 13:e0190865 (2018)
Background Chronic obstructive pulmonary disease (COPD) has a high prevalence rate in Germany and a further increase is expected within the next years. Although risk factors on an individual level are widely understood, only little is known about the spatial heterogeneity and population-based risk factors of COPD. Background knowledge about broader, population-based processes could help to plan the future provision of healthcare and prevention strategies more aligned to the expected demand. The aim of this study is to analyze how the prevalence of COPD varies across northeastern Germany on the smallest spatial-scale possible and to identify the location-specific population-based risk factors using health insurance claims of the AOK Nordost. Methods To visualize the spatial distribution of COPD prevalence at the level of municipalities and urban districts, we used the conditional autoregressive Besag-York-Mollie A (BYM) model. Geographically weighted regression modelling (GWR) was applied to analyze the location-specific ecological risk factors for COPD. Results The sex-and age-adjusted prevalence of COPD was 6.5% in 2012 and varied widely across northeastern Germany. Population-based risk factors consist of the proportions of insurants aged 65 and older, insurants with migration background, household size and area deprivation. The results of the GWR model revealed that the population at risk for COPD varies considerably across northeastern Germany.

Conclusion Area deprivation has a direct and an indirect influence on the prevalence of COPD. Persons ageing in socially disadvantaged areas have a higher chance of developing COPD, even when they are not necessarily directly affected by deprivation on an individual level. This underlines the importance of considering the impact of area deprivation on health for planning of healthcare. Additionally, our results reveal that in some parts of the study area, insurants with migration background and persons living in multi-persons households are at elevated risk of COPD.
PLoS ONE

Kähm, K.; Laxy, M.; Schneider, U.; Rogowski, W.H.; Lhachimi, S.K.; Holle, R.
Health care costs associated with incident complications in patients with type 2 diabetes in Germany.
Diabetes Care 41, 971-978 (2018)
OBJECTIVE: The aim of this study is to provide reliable regression-based estimates of costs associated with different type 2 diabetes complications. RESEARCH DESIGN AND METHODS: We used nationwide statutory health insurance (SHI) data from 316,220 patients with type 2 diabetes. Costs for inpatient and outpatient care, pharmaceuticals, rehabilitation, and nonmedical aids and appliances were assessed in the years 2013-2015. Quarterly observations are available for each year. We estimated costs (in 2015 euro) for complications using a generalized estimating equations model with a normal distribution adjusted for age, sex, occurrence of different complications, and history of complications at baseline, 2012. Two- and threefold interactions were included in an extended model. RESULTS: The base case model estimated total costs in the quarter of event for the example of a 60-69-year-old man as follows: diabetic foot €1,293, amputation €14,284, retinopathy €671, blindness €2,933, nephropathy €3,353, end-stage renal disease (ESRD) €22,691, nonfatal stroke €9,769, fatal stroke €11,176, nonfatal myocardial infarction (MI)/cardiac arrest (CA) €8,035, fatal MI/CA €8,700, nonfatal ischemic heart disease (IHD) €6,548, fatal IHD €20,942, chronic heart failure €3,912, and angina pectoris €2,695. In the subsequent quarters, costs ranged from €681 for retinopathy to €6,130 for ESRD. CONCLUSIONS: Type 2 diabetes complications have a significant impact on total health care costs in the SHI system, not only in the quarter of event but also in subsequent years. Men and women from different age-groups differ in their costs for complications. Our comprehensive estimates may support the parametrization of diabetes models and help clinicians and policymakers to quantify the economic burden of diabetic complications in the context of new prevention and treatment programs.
Diabetes Care

Németh, B.; Józwiak-Hagymásy, J.; Kovács, G.; Kovács, A.L.; Demjén, T.; Huber, M.B.; Cheung, K.L.; Coyle, K.; Lester-George, A.; Pokhrel, S.; Vokó, Z.
Cost-effectiveness of possible future smoking cessation strategies in Hungary: Results from the EQUIPTMOD.
Addiction 113, 1, 76-86 (2018)
AIMS: To evaluate potential health and economic returns from implementing smoking cessation interventions in Hungary. METHODS: The EQUIPTMOD, a Markov-based economic model, was used to assess the cost-effectiveness of three implementation scenarios: (a) introducing a social marketing campaign; (b) doubling the reach of existing group-based behavioural support therapies and proactive telephone support; and (c) a combination of the two scenarios. All three scenarios were compared with current practice. The scenarios were chosen as feasible options available for Hungary based on the outcome of interviews with local stakeholders. Life-time costs and quality-adjusted life years (QALYs) were calculated from a health-care perspective. The analyses used various return on investment (ROI) estimates, including incremental cost-effectiveness ratios (ICERs), to compare the scenarios. Probabilistic sensitivity analyses assessed the extent to which the estimated mean ICERs were sensitive to the model input values. RESULTS: Introducing a social marketing campaign resulted in an increase of 0.3014 additional quitters per 1 000 smokers, translating to health-care cost-savings of €0.6495 per smoker compared with current practice. When the value of QALY gains was considered, cost-savings increased to €14.1598 per smoker. Doubling the reach of existing group-based behavioural support therapies and proactive telephone support resulted in health-care savings of €0.2539 per smoker (€3.9620 with the value of QALY gains), compared with current practice. The respective figures for the combined scenario were €0.8960 and €18.0062. Results were sensitive to model input values. CONCLUSIONS: According to the EQUIPTMOD modelling tool, it would be cost-effective for the Hungarian authorities introduce a social marketing campaign and double the reach of existing group-based behavioural support therapies and proactive telephone support. Such policies would more than pay for themselves in the long term.
Addiction

Dalke, C.; Neff, F.; Bains, S.K.; Bright, S.; Lord, D.J.; Reitmeir, P.; Rößler, U.; Samaga, D.; Unger, K.; Braselmann, H.; Wagner, F.; Greiter, M.; Gomolka, M.; Hornhardt, S.; Kunze, S.; Kempf, S.J.; Garrett, L.; Hölter, S.M.; Wurst, W.; Rosemann, M.; Azimzadeh, O.; Tapio, S.; Aubele, M.; Theis, F.J.; Hoeschen, C.; Slijepcevic, P.; Kadhim, M.; Atkinson, M.J.; Zitzelsberger, H.; Kulka, U.; Graw, J.
Lifetime study in mice after acute low-dose ionizing radiation: A multifactorial study with special focus on cataract risk.
Radiat. Environ. Biophys. 57, 99-113 (2018)
Because of the increasing application of ionizing radiation in medicine, quantitative data on effects of low-dose radiation are needed to optimize radiation protection, particularly with respect to cataract development. Using mice as mammalian animal model, we applied a single dose of 0, 0.063, 0.125 and 0.5 Gy at 10 weeks of age, determined lens opacities for up to 2 years and compared it with overall survival, cytogenetic alterations and cancer development. The highest dose was significantly associated with increased body weight and reduced survival rate. Chromosomal aberrations in bone marrow cells showed a dose-dependent increase 12 months after irradiation. Pathological screening indicated a dose-dependent risk for several types of tumors. Scheimpflug imaging of the lens revealed a significant dose-dependent effect of 1% of lens opacity. Comparison of different biological end points demonstrated long-term effects of low-dose irradiation for several biological end points.
Radiation and Environmental Biophysics

Kauhl, B.; Maier, W.; Schweikart, J.; Keste, A.; Moskwyn, M.

Exploring the small-scale spatial distribution of hypertension and its association to area deprivation based on health insurance claims in Northeastern Germany.
BMC Public Health 18:121 (2018)
Background: Hypertension is one of the most frequently diagnosed chronic conditions in Germany. Targeted prevention strategies and allocation of general practitioners where they are needed most are necessary to prevent severe complications arising from high blood pressure. However, data on chronic diseases in Germany are mostly available through survey data, which do not only underestimate the actual prevalence but are also only available on coarse spatial scales. The discussion of including area deprivation for planning of healthcare is still relatively young in Germany, although previous studies have shown that area deprivation is associated with adverse health outcomes, irrespective of individual characteristics. The aim of this study is therefore to analyze the spatial distribution of hypertension at very fine geographic scales and to assess location-specific associations between hypertension, socio-demographic population characteristics and area deprivation based on health insurance claims of the AOK Nordost. Methods: To visualize the spatial distribution of hypertension prevalence at very fine geographic scales, we used the conditional autoregressive Besag-York-Mollie (BYM) model. Geographically weighted regression modelling (GWR) was applied to analyze the location-specific association of hypertension to area deprivation and further socio-demographic population characteristics. Results: The sex-and age-adjusted prevalence of hypertension was 33.1% in 2012 and varied widely across northeastern Germany. The main risk factors for hypertension were proportions of insurants aged 45-64, 65 and older, area deprivation and proportion of persons commuting to work outside their residential municipality. The GWR model revealed important regional variations in the strength of the examined associations. Conclusion: Area deprivation has only a significant and therefore direct influence in large parts of Mecklenburg-West Pomerania. However, the spatially varying strength of the association between demographic variables and hypertension indicates that there also exists an indirect effect of area deprivation on the prevalence of hypertension. It can therefore be expected that persons ageing in deprived areas will be at greater risk of hypertension, irrespective of their individual characteristics. The future planning and allocation of primary healthcare in northeastern Germany would therefore greatly benefit from considering the effect of area deprivation.
BMC Public Health

Cheung, K.L.; Wijnen, B.F.M.; Hiligsmann, M.; Coyle, K.; Coyle, D.; Pokhrel, S.; de Vries, H.; Präger, M.; Evers, S.M.A.A.
Is it cost-effective to provide internet-based interventions to complement the current provision of smoking cessation services in the Netherlands? An analysis based on the EQUIPTMOD.
Addiction 113, 1, 97-95 (2018)
BACKGROUND AND AIM: The cost-effectiveness of internet-based smoking cessation interventions is difficult to determine when they are provided as a complement to current smoking cessation services. The aim of this study was to evaluate the cost-effectiveness of such an alternate package compared with existing smoking cessation services alone (current package). METHODS: A literature search was conducted to identify internet-based smoking cessation interventions in the Netherlands. A meta-analysis was then performed to determine the pooled effectiveness of a (web-based) computer-tailored intervention. The mean cost of implementing internet based interventions was calculated using available information, while intervention reach was sourced from an English study. We used EQUIPTMOD, a Markov-based state-transition model, to calculate the incremental cost-effectiveness ratios [expressed as cost per quality-adjusted life years (QALYs) gained] for different time horizons to assess the value of providing internet-based interventions to complement the current package.). Deterministic sensitivity analyses tested the uncertainty around intervention costs per smoker, relative risks, and the intervention reach. RESULTS: Internet-based interventions had an estimated pooled relative risk of 1.40; average costs per smoker of €2.71; and a reach of 0.41% of all smokers. The alternate package (i.e. provision of internet-based intervention to the current package) was dominant (cost-saving) compared with the current package alone (0.14 QALY gained per 1000 smokers; reduced health-care costs of €602.91 per 1000 smokers for the life-time horizon). The alternate package remained dominant in all sensitivity analyses. CONCLUSION: Providing internet-based smoking cessation interventions to complement the current provision of smoking cessation services could be a cost-saving policy option in the Netherlands.
Addiction

Huber, M.B.; Präger, M.; Coyle, K.; Coyle, D.; Lester-George, A.; Trapero-Bertran, M.; Nemeth, B.; Cheung, K.L.; Stark, R.G.; Vogl, M.; Pokhrel, S.; Leidl, R.
Cost-effectiveness of increasing the reach of smoking cessation interventions in Germany: Results from the EQUIPTMOD.
Addiction 113, 1, 52-64 (2018)
Aims To evaluate costs, effects and cost-effectiveness of increased reach of specific smoking cessation interventions in Germany. Design A Markov-based state transition return on investment model (EQUIPTMOD) was used to evaluate current smoking cessation interventions as well as two prospective investment scenarios. A health-care perspective (extended to include out-of-pocket payments) with life-time horizon was considered. A probabilistic analysis was used to assess uncertainty concerning predicted estimates. Setting Germany. Participants Cohort of current smoking population (18+ years) in Germany. Interventions Interventions included group-based behavioural support, financial incentive programmes and varenicline. For prospective scenario 1 the reach of group-based behavioral support, financial incentive programme and varenicline was increased by 1% of yearly quit attempts (= 57 915 quit attempts), while prospective scenario 2 represented a higher reach, mirroring the levels observed in England. Measurements EQUIPTMOD considered reach, intervention cost, number of quitters, quality-of-life years (QALYs) gained, cost-effectiveness and return on investment. Findings The highest returns through reduction in smoking-related health-care costs were seen for the financial incentive programme (€2.71 per €1 invested), followed by that of group-based behavioural support (€1.63 per €1 invested), compared with no interventions. Varenicline had lower returns (€1.02 per €1 invested) than the other two interventions. At the population level, prospective scenario 1 led to 15 034 QALYs gained and €27 million cost-savings, compared with current investment. Intervention effects and reach contributed most to the uncertainty around the return-on-investment estimates. At a hypothetical willingness-to-pay threshold of only €5000, the probability of being cost-effective is

approximately 75% for prospective scenario 1. Conclusions Increasing the reach of group-based behavioural support, financial incentives and varenicline for smoking cessation by just 1% of current annual quit attempts provides a strategy to German policymakers that improves the population's health outcomes and that may be considered cost-effective.
Addiction

Griese, M.; Seidl, E.; Hengst, M.; Reu, S.; Rock, H.; Anthony, G.; Kiper, N.; Emiralioğlu, N.; Snijders, D.; Goldbeck, L.; Leidl, R.; Ley-Zaporozhan, J.; Krüger-Stollfuss, I.; Kammer, B.; Wesselak, T.; Eismann, C.; Schams, A.; Neuner, D.; MacLean, M.; Nicholson, A.G.; Lauren, M.; Clement, A.B.; Epaud, R.; de Blic, J.; Ashworth, M.; Aurora, P.; Calder, A.A.; Wetzke, M.; Kappler, M.; Cunningham, S.; Schwerk, N.; Bush, A.
International management platform for children's interstitial lung disease (chILD-EU).
Thorax 73, 231-239 (2018)
It is undeniably one of the greatest findings in biology that (with some very minor exceptions) every cell in the body possesses the whole genetic information needed to generate a complete individual. Today, this concept has been so thoroughly assimilated that we struggle to still see how surprising this finding actually was: all cellular phenotypes naturally occurring in one person are generated from genetic uniformity, and thus are per definition epigenetic. Transcriptional mechanisms are clearly critical for developing and protecting cell identities, because a mis-expression of few or even single genes can efficiently induce inappropriate cellular programmes. However, how transcriptional activities are molecularly controlled and which of the many known epigenomic features have causal roles remains unclear. Today, clarification of this issue is more pressing than ever because profiling efforts and epigenome-wide association studies (EWAS) continuously provide comprehensive datasets depicting epigenomic differences between tissues and disease states. In this commentary, we propagate the idea of a widespread follow-up use of epigenome editing technology in EWAS studies. This would enable them to address the questions of which features, where in the genome, and which circumstances are essential to shape development and trigger disease states.
Thorax

Laxy, M.; Teuner, C.M.; Holle, R.; Kurz, C.F.
The association between BMI and health-related quality of life in the US population: Sex, age and ethnicity matters.
Int. J. Obes. 42, 318-326 (2018)
Background:Obesity is a major public health problem. Detailed knowledge about the relationship between body mass index (BMI) and health-related quality of life (HRQL) is important for deriving effective and cost-effective prevention and weight management strategies. This study aims to describe the sex-, age- and ethnicity-specific association between BMI and HRQL in the US adult population.Methods:Analyses are based on pooled cross-sectional data from 41 459 participants of the Medical Expenditure Panel Survey (MEPS) Household Component (HC) for the years 2000-2003. BMI was calculated using self-reported height and weight, and HRQL was assessed with the EuroQol five-dimensional questionnaire. Generalized additive models were fitted with a smooth function for BMI and a smooth-factor interaction for BMI with sex adjusted for age, ethnicity, poverty, smoking and physical activity. Models were further stratified by age and ethnicity.Results:The association between BMI and HRQL is inverse U-shaped with a HRQL high point at a BMI of 22 kg m '2 in women and a HRQL high plateau at BMI values of 22-30 kg m '2 in men. Men aged 50 years and older with a BMI of 29 kg m '2 reported on average five-point higher visual analog scale (VAS) scores than peers with a BMI of 20 kg m '2. The inverse U-shaped association is more pronounced in older people, and the BMI-HRQL relationship differs between ethnicities. In Hispanics, the BMI associated with the highest HRQL is higher than in white people and, in black women, the BMI-HRQL association has an almost linear negative slope.Conclusions:The results show that a more differentiated use of BMI cutoffs in scientific discussions and daily practice is indicated. The findings should be considered in the design of future weight loss and weight management programs.
International Journal of Obesity

Bauer, J.; Maier, W.; Müller, R.; Groneberg, D.A.
Hausärztliche Versorgung in Deutschland – Gleicher Zugang für alle?
Dtsch. Med. Wochenschr. 142, E9-E17 (2018)
Hintergrund Ein gleichmäßiger Zugang zu hausärztlicher Versorgung spielt eine wesentliche Rolle bei der medizinischen Versorgung in Deutschland und ist daher Ziel der ambulanten Bedarfsplanung. Ziel der Arbeit Mit der vorliegenden Arbeit sollen räumliche Aspekte des Zugangs zur hausärztlichen Versorgung untersucht und mit den Zielen der aktuellen Bedarfsplanung verglichen werden. Material und Methoden Der räumliche Zugang zur hausärztlichen Versorgung wurde auf Basis der „integrated Floating Catchment Area“-Methodik unter Einsatz eines geografischen Informationssystems auf Ebene von Quadratkilometer-Zellen (Hektarzellen für Großstädte) gemessen („Zugangsindex“). Ergebnisse Die Analyse von 649 Millionen generierten Datensätzen zeigte erhebliche geografische Variationen des Zugangs: 4,7 % der Gesamtbevölkerung leben in Gebieten mit signifikant niedrigerem hausärztlichen Zugang (z-Wert = –3,4) während 48,0 % in einem Gebiet mit signifikant höherem hausärztlichen Zugang leben (z-Wert = 9,7). Der durchschnittliche Zugangsindex lag bei 0,14 (SD = 0,15) und war umso höher, je urbaner das Gebiet (r = 0,64; p < 0,001) und je geringer der Grad der regionalen Deprivation war (r = –0,37; p < 0,001). Innerhalb der Bedarfsplanungsregionen variierte der Zugangsindex um durchschnittlich Δ = 0,23 (SD = 0,19) und korrelierte nicht mit dem hausärztlichen Versorgungsgrad (r = –0,04; p = 0,28). Diskussion Bezüglich des Zugangs zu hausärztlicher Versorgung bestehen in Deutschland Stadt-Land-Disparitäten sowie soziale Ungleichheit im Sinne regionaler Deprivation. Aus diesem Grund sollte die Bedarfsplanung zukünftig räumliche Aspekte des Zugangs wie Erreichbarkeit und Verfügbarkeit stärker berücksichtigen.
Deutsche Medizinische Wochenschrift - DMW

Coyle, K.; Coyle, D.; Lester-George, A.; West, R.; Nemeth, B.; Hiligsmann, M.; Trapero-Bertran, M.; Leidl, R.; Pokhrel, S.
Development and application of an economic model (EQUIPTMOD) to assess the impact of smoking cessation.
Addiction 113, 1, 7-18 (2018)
BACKGROUND AND AIMS: Although clear benefits are associated with reducing smoking, there is increasing pressure on public health providers to justify investment in tobacco control

measures. Decision-makers need tools to assess the Return on Investment (ROI)/cost-effectiveness of programmes. The EQUIPT project adapted an ROI tool for England to four European countries (Germany, the Netherlands, Spain and Hungary). EQUIPTMOD, the economic model at the core of the ROI tool, is designed to assess the efficiency of packages of smoking cessation interventions. The objective of this paper is to describe the methods for EQUIPTMOD and identify key outcomes associated with continued and cessation of smoking. METHODS: EQUIPTMOD uses a Markov model to estimate life-time costs, quality-adjusted life years (QALYs) and life years associated with a current and former smoker. It uses population data on smoking prevalence, disease prevalence, mortality and the impact of smoking combined with associated costs and utility effects of disease. To illustrate the tool's potential, costs, QALYs and life expectancy were estimated for the average current smoker for five countries based on the assumptions that they continue and that they cease smoking over the next 12 months. Costs and effects were discounted at country-specific rates. RESULTS: For illustration, over a life-time horizon, not quitting smoking within the next 12 months in England will reduce life expectancy by 0.66, reduce QALYs by 1.09 and result in £4961 higher disease-related health care costs than if the smoker ceased smoking in the next 12 months. For all age-sex categories, costs were lower and QALYs higher for those who quit smoking in the 12 months than those who continued. CONCLUSIONS: EQUIPTMOD facilitates assessment of the cost effectiveness of smoking cessation strategies. The demonstrated results indicate large potential benefits from smoking cessation at both an individual and population level.
Addiction

Karrasch, S.; Behr, J.; Huber, R.M.; Nowak, D.; EUMODIC Consortium (Peters, A.; Holle, R.; Schulz, H.; Leidl, R.; Meisinger, C.; Strauch, K.); Peters, S.; Jörres, R.A.
Heterogeneous pattern of differences in respiratory parameters between elderly with either good or poor FEV_1.
BMC Pulm. Med. 18:27 (2018)
Spirometric indices as well as other respiratory and functional parameters decline with age, but the link between the changes is not well studied. We assessed their relationship in elderly subjects with either good or poor spirometric parameters to reveal whether different domains of lung function show comparable differences between the two groups. Among subjects of the population-based KORA-Age cohort (n=935, 65-90y; 51% male) two groups were selected from either the lower (LED; n=51) or the upper (UED; n=72) end of the FEV1 distribution. All subjects did not have a history of lung disease and were non-smokers at the time of the study. Measurements included spirometry, body plethysmography, diffusing capacity for NO and CO, respiratory pump function and exhaled NO (FeNO). In addition, 6-minute walking distance as a functional overall measure, as well as telomere length of blood leukocytes and serum 8-hydroxydeoxyguanosine (8-OHdG) as potential markers of overall biological ageing and stress were determined. In the majority of parameters, LED subjects showed significantly impaired values compared to UED subjects. Differences in spirometric parameters, airway resistance and respiratory pump function ranged between 10% and more than 90% in terms of predicted values. In contrast, volume-related CO and NO diffusing capacity showed differences between groups of lower than 5%, while telomere length, 8-OHdG and FeNO were similar. This was reflected in the differences in functional age as derived from prediction equations. In elderly subjects without a history of lung disease the differences in lung-mechanical parameters of spirometry and body plethysmography were higher than those of gas exchange. Thus, the concept of a general functional “lung age” might be inadequate and specific terms such as “spirometric age” should be preferred.
BMC Pulmonary Medicine

Kopetsch, T.; Maier, W.
Analyse des Zusammenhangs zwischen regionaler Deprivation und Inanspruchnahme: Ein Diskussionsbeitrag zur Ermittlung des Arztbedarfes in Deutschland.
Gesundheitswesen 80, 27-33 (2018)
Hintergrund: Bei der anstehenden Neukonzeption der Bedarfsplanung soll die Sozial- und Morbiditätsstruktur der Bevölkerung bei der Ermittlung einer bedarfsgerechten Versorgung Berücksichtigung finden. Das Ziel des Beitrages besteht darin, zu untersuchen, inwiefern der Grad der regionalen Deprivation bei der Berechnung des regionalen fachgruppenspezifischen Ärztebedarfes in Deutschland berücksichtigt werden sollte. Methoden: Zur Messung des regionalen Deprivationsstatus auf Kreisebene verwendeten wir den im Helmholtz Zentrum München entwickelten „German Index of Multiple Deprivation“ (GIMD). Für die Landkreise und kreisfreien Städte Deutschlands wurden Scores für deren jeweiligen Deprivationsstatus berechnet. Die Berechnung des deprivationsadjustierten Ärztebedarfes erfolgte mittels linearer Regressionsanalysen. Dabei wurden regionalisierte ambulante Abrechnungsdaten und Arztzahldaten zugrunde gelegt. Die Analysen wurden mit dem Software-Paket SPSS, Version 20, durchgeführt. Ergebnisse: Die Analysen zeigten einen deutlichen positiven Zusammenhang zwischen regionaler Deprivation und der Inanspruchnahme medizinischer Leistungen in Form von ambulanten und stationären Fällen einerseits, sowie Sterblichkeit und Morbidität, gemessen durch den RSA-Risikofaktor, andererseits. Es zeigten sich darüber hinaus Zusammenhänge unterschiedlicher Intensität zwischen dem Grad der Deprivation und der Inanspruchnahme von 12 Arztgruppen der Bedarfsplanung auf Kreisebene. Darauf aufbauend wurde ein Algorithmus entwickelt, mit dessen Hilfe die kreisbezogene Deprivation in eine Erhöhung oder Verringerung der facharztbezogenen Verhältniszahl umgerechnet werden kann. Diskussion und Schlussfolgerung: Mithilfe des GIMD und diverser Determinanten medizinischer Inanspruchnahme konnte im Modell der gesteigerte medizinische Bedarf bei erhöhter regionaler Deprivation gezeigt werden. Allerdings reicht in dieser Analyse das statistische Niveau (R2) der Zusammenhänge im vertragsärztlichen Bereich für die einzelnen Facharztgruppen nicht aus, um allein darauf ein Planungssystem zu implementieren, das mit Einschränkungen der Berufsfreiheit einhergeht. Im Einzelfall, sprich: Sonderbedarfszulassungen, kann das entwickelte Instrumentarium aufgrund seines geringen Aufwandes und der damit verbundenen Praktikabilität geeignet sein, Mehr- oder Minderbedarfe an Ärzten auf regionaler Ebene auszuweisen.
Gesundheitswesen, Das

2017
Kurz, C.F.; Holle, R.
Demand for medical care by the elderly: A nonparametric variational bayesian mixture approach.

In: (2017 Imperial College Computing Student Workshop (ICCSW 2017), 26-27 September 2017, London). 2017. 4:1-4:7
Outpatient care is a large share of total health care spending, making analysis of data on outpatient utilization an important part of understanding patterns and drivers of health care spending growth. Common features of outpatient utilization measures include zero-inflation, overdispersion, and skewness, all of which complicate statistical modeling. Mixture modeling is a popular approach because it can accommodate these features of health care utilization data. In this work, we add a nonparametric clustering component to such models. Our fully Bayesian model framework allows for an unknown number of mixing components, so that the data, rather than the researcher, determine the number of mixture components. We apply the modeling framework to data on visits to physicians by elderly individuals and show that each subgroup has different characteristics that allow easy interpretation and new insights.

Luzak, A.; Karrasch, S.; Thorand, B.; Nowak, D.; Holle, R.; Peters, A.; Schulz, H.
Association of physical activity with lung function in lung-healthy German adults: Results from the KORA FF4 study.
BMC Pulm. Med. 17:215 (2017)
BACKGROUND: In lung disease, physical activity (PA) yields beneficial health effects, but its association with the function of healthy lungs has rarely been studied. We investigated the association of accelerometer-based PA with spirometric indices, maximal inspiratory mouth pressure (PImax) and lung diffusion capacity in lung-healthy adults. METHODS: In total, 341 apparently lung-healthy participants from the population-based KORA (Cooperative Health Research in the Region of Augsburg) FF4 cohort study (45% male, aged 48-68 years, 47% never smokers) completed lung function testing and wore ActiGraph accelerometers over a one week period at the hip. In adjusted regression analyses, moderate to vigorous PA (MVPA) was characterized as: sex-specific activity quartiles, achieving ≥ 10 consecutive minutes (yes vs. no), and meeting the WHO PA recommendations (yes vs. no). RESULTS: Positive associations of MVPA-quartiles with forced expiratory volume in 1 s (FEV1), forced vital capacity (FVC), and corresponding Global Lung Function Initiative z-scores were found. Subjects in the most active quartile (> 47 or > 50 min/day for females and males, respectively) had 142 ml [95% CI: 23, 260] higher FEV1 and 155 ml [95% CI: 10, 301] higher FVC than those in the least active quartile (< 17 or < 21 min/day for females and males, respectively); however these associations were stronger among ex-/current smokers. Achieving at least once 10 consecutive minutes of MVPA was only associated with higher PImax [β-estimate: 0.57 kPa; 95% CI: 0.04, 1.10], remaining significant among never smokers. No associations were found with diffusion capacity or for reaching the WHO-recommended 150 min of MVPA/week in 10-min bouts. CONCLUSIONS: Although the effects were small, active subjects showed higher spirometric results. The observed associations were more pronounced among ever smokers suggesting a higher benefit of PA for subjects being at a higher risk for chronic lung diseases.
BMC Pulmonary Medicine

Szentes, B.L.; Kreuter, M.; Bahmer, T.; Birring, S.; Claussen, M.; Waelscher, J.; Schwarzkopf, L.
Quality of life assessment in ILD - a comparison of EQ-5D with the disease-specific K-bild.
Value Health 20, A649-A649 (2017)
Value in Health
Meeting abstract

Kirsch, F.; Becker, C.; Maier, W.; Schramm, A.
Effects of adherence to pharmacological secondary prevention after myocardial infarction on healthcare expenditures.
Value Health 20, A609-A609 (2017)
Value in Health
Meeting abstract

Walter, J.; Tufman, A.; Holle, R.; Schwarzkopf, L.
Comparison of costs and care of lung cancer patient at the end-of-life in Germany depending on the tome of survival after diagnosis.
Value Health 20, A511-A511 (2017)
Value in Health
Meeting abstract

Straubmeier, M.; Behrndt, E.M.; Seidl, H.; Özbe, D.; Luttenberger, K.; Graessel, A.
Nichtpharmakologische Therapie bei Menschen mit kognitiven Einschränkungen. Ergebnisse der randomisierten kontrollierten German-Day-Care-Studie.
Dtsch. Arztebl. Int. 114, 815-821 (2017)
BACKGROUND: A number of non-pharmacological methods are available to help elderly people with cognitive impairment. Unstructured and non-evidencebased interventions are commonly used. The multicomponent therapy MAKS (a German acronym for Motor, Activities of daily living, Cognitive, Social) has already been evaluated in nursing homes; in this study, we investigated its use in day care centers (DCCs). METHODS: A cluster-randomized, controlled, single-blinded trial involving a 6-month intervention phase was performed. 362 cognitively impaired persons in 32 DCCs took part in the trial. Multiple regression analyses were used to determine whether MAKS therapy led to any statistically significant and clinically relevant improvement over time (compared to membership in the control group) in these persons' cognitive abilities and activities of daily living (ADL) abilities, as assessed, respectively, with the Mini-Mental State Examination (MMSE) and the Erlangen Test of Activities of Daily Living in Persons with Mild Dementia or Mild Cognitive Impairment (ETAM). A primary per-protocol analysis was supplemented by an intention-to-treat analysis. Two secondary outcomes (social behavior and neuropsychiatric symptoms) were analyzed exploratively as well. Study registration: ISRCTN16412551. RESULTS: In the primary per-protocol analysis at 6 months, the intervention group had significantly better MMSE and ETAM scores than the control group (Cohen's d, 0.26 and 0.21, respectively; p = 0.012 for both). The same was found in the ITT analysis at 6 months (Cohen's d = 0.21, p = 0.033; and Cohen's d = 0.20, p = 0.019, respectively). Neuropsychiatric symptoms, one of the secondary outcomes, also evolved more favorably in the intervention group (Cohen's d = 0.23, p = 0.055). CONCLUSION: MAKS therapy is effective for persons with cognitive impairment ranging from mild cognitive impairment (MCI) to moderate dementia who live at home and regularly visit a day care center. The fact that 32 day care facilities from all over Germany participated in this study gives its findings high external validity.
Deutsches Ärzteblatt international

Kurz, C.F.

Tweedie distributions for fitting semicontinuous health care utilization cost data.
BMC Med. Res. Methodol. 17:171 (2017)
BACKGROUND: The statistical analysis of health care cost data is often problematic because these data are usually non-negative, right-skewed and have excess zeros for non-users. This prevents the use of linear models based on the Gaussian or Gamma distribution. A common way to counter this is the use of Two-part or Tobit models, which makes interpretation of the results more difficult. In this study, I explore a statistical distribution from the Tweedie family of distributions that can simultaneously model the probability of zero outcome, i.e. of being a non-user of health care utilization and continuous costs for users. METHODS: I assess the usefulness of the Tweedie model in a Monte Carlo simulation study that addresses two common situations of low and high correlation of the users and the non-users of health care utilization. Furthermore, I compare the Tweedie model with several other models using a real data set from the RAND health insurance experiment. RESULTS: I show that the Tweedie distribution fits cost data very well and provides better fit, especially when the number of non-users is low and the correlation between users and non-users is high. CONCLUSION: The Tweedie distribution provides an interesting solution to many statistical problems in health economic analyses.
BMC Medical Research Methodology

Maier, W.
Correction: Indizes Multipler Deprivation zur Analyse regionaler Gesundheitsunterschiede in Deutschland. Erfahrungen aus Epidemiologie und Versorgungsforschung.
Bundesgesundheitsbl.-Gesund. 60, 1455-1456 (2017)
Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz
Wacker, M.; Kitzing, K.; Jörres, R.A.; Leidl, R.; Schulz, H.; Karrasch, S.; Karch, A.; Koch, A.; Vogelmeier, C.F.; Holle, R.
The contribution of symptoms and comorbidities to the economic impact of COPD: An analysis of the German COSYCONET cohort.
Int. J. Chron. Obstruct. Pulmon. Dis. 12, 3437-3448 (2017)
Background: Although patients with COPD often have various comorbidities and symptoms, limited data are available on the contribution of these aspects to health care costs. This study analyzes the association of frequent comorbidities and common symptoms with the annual direct and indirect costs of patients with COPD. Methods: Self-reported information on 33 potential comorbidities and symptoms (dyspnea, cough, and sputum) of 2,139 participants from the baseline examination of the German COPD cohort COSYCONET was used. Direct and indirect costs were calculated based on self-reported health care utilization, work absence, and retirement. The association of comorbidities, symptoms, and COPD stage with annual direct/indirect costs was assessed by generalized linear regression models. Additional models analyzed possible interactions between COPD stage, the number of comorbidities, and dyspnea. Results: Unadjusted mean annual direct costs were €7,263 per patient. Other than COPD stage, a high level of dyspnea showed the strongest driving effect on direct costs (+33%). Among the comorbidities, osteoporosis (+38%), psychiatric disorders (+36%), heart disease (+25%), cancer (+24%), and sleep apnea (+21%) were associated with the largest increase in direct costs (p<0.01). A sub-additive interaction between advanced COPD stage and a high number of comorbidities reduced the independent cost-driving effects of these factors. For indirect costs, besides dyspnea (+34%), only psychiatric disorders (+32%) and age (+62% per 10 years) were identified as significant drivers of costs (p<0.04). In the subsequent interaction analysis, a high number of comorbidities was found to be a more crucial factor for increased indirect costs than single comorbidities. Conclusion: Detailed knowledge about comorbidities in COPD is useful not only for clinical purposes but also to identify relevant cost factors and their interactions and to establish a ranking of major cost drivers. This could help in focusing therapeutic efforts on both clinically and economically important comorbidities in COPD.
International Journal of Chronic Obstructive Pulmonary Disease

Arnold, M.
Simulation modeling for stratified breast cancer screening - a systematic review of cost and quality of life assumptions.
BMC Health Serv. Res. 17:802 (2017)
BACKGROUND: The economic evaluation of stratified breast cancer screening gains momentum, but produces also very diverse results. Systematic reviews so far focused on modeling techniques and epidemiologic assumptions. However, cost and utility parameters received only little attention. This systematic review assesses simulation models for stratified breast cancer screening based on their cost and utility parameters in each phase of breast cancer screening and care. METHODS: A literature review was conducted to compare economic evaluations with simulation models of personalized breast cancer screening. Study quality was assessed using reporting guidelines. Cost and utility inputs were extracted, standardized and structured using a care delivery framework. Studies were then clustered according to their study aim and parameters were compared within the clusters. RESULTS: Eighteen studies were identified within three study clusters. Reporting quality was very diverse in all three clusters. Only two studies in cluster 1, four studies in cluster 2 and one study in cluster 3 scored high in the quality appraisal. In addition to the quality appraisal, this review assessed if the simulation models were consistent in integrating all relevant phases of care, if utility parameters were consistent and methodological sound and if cost were compatible and consistent in the actual parameters used for screening, diagnostic work up and treatment. Of 18 studies, only three studies did not show signs of potential bias. CONCLUSION: This systematic review shows that a closer look into the cost and utility parameter can help to identify potential bias. Future simulation models should focus on integrating all relevant phases of care, using methodologically sound utility parameters and avoiding inconsistent cost parameters.
BMC Health Services Research

Bauer, J.; Groneberg, D.A.; Maier, W.; Manek, R.; Louwen, F.; Brüggmann, D.
Accessibility of general and specialized obstetric care providers in Germany and England: An analysis of location and neonatal outcome.
Int. J. Health Geogr. 16:44 (2017)
BACKGROUND: Health care accessibility is known to differ geographically. With this study we focused on analysing accessibility of general and specialized obstetric units in England and Germany with regard to urbanity, area deprivation and neonatal outcome using routine data. METHODS: We used a

floating catchment area method to measure obstetric care accessibility, the degree of urbanization (DEGURBA) to measure urbanity and the index of multiple deprivation to measure area deprivation. RESULTS: Accessibility of general obstetric units was significantly higher in Germany compared to England (accessibility index of 16.2 vs. 11.6; p < 0.001), whereas accessibility of specialized obstetric units was higher in England (accessibility index for highest level of care of 0.235 vs. 0.002; p < 0.001). We further demonstrated higher obstetric accessibility for people living in less deprived areas in Germany (r = - 0.31; p < 0.001) whereas no correlation was present in England. There were also urban-rural disparities present, with higher accessibility in urban areas in both countries (r = 0.37-0.39; p < 0.001). The analysis did not show that accessibility affected neonatal outcomes. Finally, our computer generated model for obstetric care provider demand in terms of birth counts showed a very strong correlation with actual birth counts at obstetric units (r = 0.91-0.95; p < 0.001). CONCLUSION: In Germany the focus of obstetric care seemed to be put on general obstetric units leading to higher accessibility compared to England. Regarding specialized obstetric care the focus in Germany was put on high level units whereas in England obstetric care seems to be more balanced between the different levels of care with larger units on average leading to higher accessibility.
International journal of health geographics

Italia, S.; Wolfenstetter, S.B.; Brüske, I.; Heinrich, J.; Berdel, D.; von Berg, A.; Lehmann, I.; Standl, M.; Teuner, C.M.
Prices of over-the-counter drugs used by 15-year-old adolescents in Germany and their association with socioeconomic background.
BMC Public Health 17:904 (2017)
BACKGROUND: In Germany, over-the-counter (OTC) drugs are normally reimbursed up to the age of 12 years only. The aim of this study was to analyse prices of over-the-counter drugs used by adolescents in Germany and their association with socioeconomic factors. METHODS: Based on the German GINIplus and LISAplus birth cohorts, data on drug utilization among 15-year-old adolescents (n = 4677) were collected using a self-administered questionnaire. The reported drugs were subdivided into prescription drugs and OTC drugs. The drugs' prices were tracked by the pharmaceutical identification numbers. RESULTS: Overall, 1499 OTC drugs with clearly identifiable prices were eligible for analysis. Their mean price was €9.75 (95% confidence interval: €9.27-10.22). About 75% of the OTC drugs cost less than €10. Higher mean prices were associated with residing in Munich (€10.74; 95% confidence interval: €9.97-11.52) and with higher paternal education (e.g. highest education level: €10.17; 95% confidence interval: €9.47-10.86). Adolescents residing in Munich (in comparison with the less wealthy region of Wesel) and adolescents with higher educated fathers were also significantly more likely to use OTC drugs costing ≥ €10 or ≥ €25, respectively. CONCLUSIONS: The price of €10 for non-reimbursable OTC drugs may represent a (psychological) threshold. Higher prices could discourage especially adolescents from a lower socioeconomic background from taking medically advisable but non-reimbursable OTC drugs.
BMC Public Health

Maier, W.
Indizes Multipler Deprivation zur Analyse regionaler Gesundheitsunterschiede in Deutschland. Erfahrungen aus Epidemiologie und Versorgungsforschung.
Bundesgesundheitsbl.-Gesund. 60, 1403–1412 (2017)
BACKGROUND: Deprivation indices allow material and social differences at the regional level to be described in a statistically efficient and concise manner and to use these in health analyses. Following the British example, Indices of Multiple Deprivation (IMDs) are now available for Germany, the German Index of Multiple Deprivation (GIMD) as well as its regional versions. In this study, empirical experiences based on the use of these indices in health studies will be presented. METHOD: The German IMDs consist of seven deprivation domains, which represent single aspects of deprivation (income, employment, and educational deprivation, municipal revenue deprivation, social capital deprivation, environment and security deprivation). Specific indicators were generated from data of official statistics and assigned to the deprivation domains. The weighted single domains were finally combined to an overall index. The German IMDs are available at a municipal level and at a district level. RESULTS: Analyses using the IMDs showed significant associations between regional deprivation and mortality, morbidity and aspects of health services research. Multilevel analyses showed significant associations with regional deprivation, independent of individual factors. CONCLUSIONS: The German IMDs are valid and efficient tools for the use in epidemiology and health services research, but also for health policy. When constructing deprivation indices, several methodological challenges have to be considered.
Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz

Farnham, A.; Kurz, C.F.; Ötzürk, M.A.; Solbiati, M.; Myllyntaus, O.; Meekes, J.; Pham, T.M.; Paz, C.; Langiewicz, M.; Andrews, S.; Kanninen, L.; Agbemabiese, C.; Guler, A.T.; Durieux, J.; Jasim, S.; Viessmann, O.; Frattini, S.; Yembergenova, D.; Benito, C.M.; Porte, M.; Grangeray-Vilmint, A.; Prieto Curiel, R.; Rehncrona, C.; Malas, T.; Esposito, F.; Hettne, K.
Early career researchers want Open Science.
Genome Biol. 18:221 (2017)
Open Science is encouraged by the European Union and many other political and scientific institutions. However, scientific practice is proving slow to change. We propose, as early career researchers, that it is our task to change scientific research into open scientific research and commit to Open Science principles.
Genome Biology
Sonstiges: Meinungsartikel
Other: Opinion

Lennerz, B.; Moss, A.; Brand, S.; Bickenbach, A.; Bollow, E.; Geisler, A.; Holl, R.W.; Holle, R.; Kiess, W.; Brintrup, D.L.; Muehlig, Y.; Neef, M.; Ose, C.; Reinehr, T.; Scherag, A.; Teuner, C.M.; Wiegand, S.; Wolters, B.; von Schnurbein, J.; Hebebrand, J.; Wabitsch, M.
Medical and psychosocial implications of adoelscent extreme obesity- acceptance and effects of structured care program - Yes Study. A consortium of the BMBF.
Horm. Res. Paediatr. 88, 161-161 (2017)
Hormone Research in Paediatrics
Meeting abstract

Mehring, M.; Donnachie, E.; Schneider, A.; Tauscher, M.; Gerlach, R.; Storr, C.; Linde, K.; Mielck, A.; Maier, W.

Impact of regional socioeconomic variation on coordination and cost of ambulatory care: investigation of claims data from Bavaria, Germany.
BMJ Open 7:e016218 (2017)
Objectives A considerable proportion of regional variation in healthcare use and health expenditures is to date still unexplained. The aim was to investigate regional differences in the gatekeeping role of general practitioners and to identify relevant explanatory variables at patient and district level in Bavaria, Germany. Design Retrospective routine data analysis using claims data held by the Bavarian Association of Statutory Health Insurance Physicians. Participants All patients who consulted a specialist in ambulatory practice within the first quarter of 2011 (n = 3 616 510). Outcomes measures Of primary interest is the effect of district-level measures of rurality, physician density and multiple deprivation on (1) the proportion of patients with general practitioner (GP) coordination of specialist care and (2) the mean amount in Euros claimed by specialist physicians. Results The proportion of patients whose use of specialist services was coordinated by a GP was significantly higher in rural areas and in highly deprived regions, as compared with urban and less deprived regions. The hierarchical models revealed that increasing age and the presence of chronic diseases are the strongest predictive factors for coordination by a GP. In contrast, the presence of mental illness, an increasing number of medical condition categories and living in a city are predictors for specialist use without GP coordination. The amount claimed per patient was (sic)10 to (sic)20 higher in urban districts and in regions with lower deprivation. Hierarchical models indicate that this amount is on average higher for patients living in towns and lower for patients in regions with high deprivation. Conclusion The present study shows that regional deprivation is closely associated with the way in which patients access primary and specialist care. This has clear consequences, both with respect to the role of the general practitioner and the financial costs of care.
BMJ Open

Radespiel-Tröger, M.; Geiss, K.; Twardella, D.; Maier, W.; Meyer, M.
Cancer incidence in urban, rural, and densely populated districts close to core cities in Bavaria, Germany.
Int. Arch. Occup. Environ. Health 91, 155–174 (2017)
An ecologic study on the level of districts was performed to evaluate the possible association between district type and risk of cancer in Bavaria, Southern Germany. Cancer incidence data for the years 2003-2012 were obtained from the population-based cancer registry Bavaria according to sex and cancer site. Data on district type, socio-economic area deprivation, particulate matter exposure, tobacco consumption, and alcohol consumption were obtained from publicly available sources. The possible association between district type and cancer risk adjusted for age, socio-economic area deprivation, particulate matter exposure, tobacco consumption, and alcohol consumption was evaluated using multivariable multi-level negative binomial regression. We found a significantly reduced cancer risk in densely populated districts close to core cities and/or rural districts compared to core cities with respect to the cancer sites mouth and pharynx (women only), liver (both sexes), larynx (both sexes), lung (both sexes), melanoma of the skin (both sexes), mesothelioma (men only), connective and soft tissue (both sexes), corpus uteri, other urinary tract (men only), urinary bladder (both sexes), and non-Hodgkin lymphoma (both sexes). Our findings require further monitoring. Since the apparently increased cancer risk in core cities may be related to lifestyle factors, preventive measures against lifestyle-related cancer could be specifically targeted at populations in deprived core cities.
International Archives of Occupational and Environmental Health

Bamberger, C.; Rossmeier, A.; Lechner, K.; Wu, L.; Waldmann, E.; Stark, R.G.; Altenhofer, J.; Henze, K.; Parhofer, K.G.
A walnut-enriched diet reduces lipids in healthy caucasian subjects, independent of recommended macronutrient replacement and time point of consumption: A prospective, randomized, controlled trial.
Nutrients 9:1097 (2017)
Studies indicate a positive association between walnut intake and improvements in plasma lipids. We evaluated the effect of an isocaloric replacement of macronutrients with walnuts and the time point of consumption on plasma lipids. We included 194 healthy subjects (134 females, age 63 ± 7 years, BMI 25.1 ± 4.0 kg/m2) in a randomized, controlled, prospective, cross-over study. Following a nut-free run-in period, subjects were randomized to two diet phases (8 weeks each). Ninety-six subjects first followed a walnut-enriched diet (43 g walnuts/day) and then switched to a nut-free diet. Ninety-eight subjects followed the diets in reverse order. Subjects were also randomized to either reduce carbohydrates (n = 62), fat (n = 65), or both (n = 67) during the walnut diet, and instructed to consume walnuts either as a meal or as a snack. The walnut diet resulted in a significant reduction in fasting cholesterol (walnut vs. control: −8.5 ± 37.2 vs. −1.1 ± 35.4 mg/dL; p = 0.002), non-HDL cholesterol (−10.3 ± 35.5 vs. −1.4 ± 33.1 mg/dL; p ≤ 0.001), LDL-cholesterol (−7.4 ± 32.4 vs. −1.7 ± 29.7 mg/dL; p = 0.029), triglycerides (−5.0 ± 47.5 vs. 3.7 ± 48.5 mg/dL; p = 0.015) and apoB (−6.7 ± 22.4 vs. −0.5 ± 37.7; p ≤ 0.001), while HDL-cholesterol and lipoprotein (a) did not change significantly. Neither macronutrient replacement nor time point of consumption significantly affected the effect of walnuts on lipids. Thus, 43 g walnuts/d improved the lipid profile independent of the recommended macronutrient replacement and the time point of consumption.
Nutrients

Azencott, C.; Aittokallio, T.; Roy, S.; Norman, T.; Friend, S.; Stolovitzky, G.; Goldenberg, A.; DREAM Idea Challenge Consortium (Huber, M.B.); DREAM Idea Challenge Consortium (Kurz, C.F.)
The inconvenience of data of convenience: Computational research beyond post-mortem analyses.
Nat. Methods 14, 937-938 (2017)
Nature Methods
Letter to the Editor
Letter to the Editor
Korber, K.; Becker, C.
Expert opinions on good practice in evaluation of health promotion and primary prevention measures related to children and adolescents in Germany.
BMC Public Health 17:764 (2017)
BACKGROUND: Determining what constitutes "good practice" in the measurement of the costs and effects of health promotion and disease prevention measures is of particular importance. The aim of this paper was to gather expert knowledge on

(economic) evaluations of health promotion and prevention measures for children and adolescents, especially on the practical importance, the determinants of project success, meaningful parameters for evaluations, and supporting factors, but also on problems in their implementation. This information is targeted at people responsible for the development of primary prevention or health promotion programs. METHODS: Partially structured open interviews were conducted by two interviewers and transcribed, paraphrased, and summarized for further use. Eight experts took part in the interviews. RESULTS: The interviewed experts saw evaluation as a useful tool to establish the effects of prevention programs, to inform program improvement and further development, and to provide arguments to decision making. The respondents' thought that determinants of a program's success were effectiveness with evidence of causality, cost benefit relation, target-group reach and sustainability. It was considered important that hard and soft factors were included in an evaluation; costs were mentioned only by one expert. According to the experts, obstacles to evaluation were lacking resources, additional labor requirements, and the evaluators' unfamiliarity with a program's contents. It was recommended to consider evaluation design before a program is launched, to co-operate with people involved in a program and to make use of existing structures. CONCLUSION: While in in this study only a partial view of expert knowledge is represented, it could show important points to consider when developing evaluations of prevention programs. By considering these points, researchers could further advance towards a more comprehensive approach of evaluation targeting measures in children and adolescents.
BMC Public Health

Wolf, K.; Popp, A.; Schneider, A.E.; Breitner, S.; Hampel, R.; Rathmann, W.; Herder, C.; Roden, M.; Koenig, W.; Meisinger, C.; Peters, A.
Erratum. Association between long-term exposure to air pollution and biomarkers related to insulin resistance, subclinical inflammation, and adipokines (vol 65, pg 3314, 2016).
Diabetes 66, 2725-2725 (2017)
In the article listed above, the last sentence of the abstract was erroneously stated as “Our results suggested an association between long-term exposure to air pollution and IR in the general population was attributable mainly to individuals with diabetes.” The sentence should have read: “Our results suggested an association between long-term exposure to air pollution and IR in the general population that was attributable mainly to individuals with prediabetes.” The editors apologize for this error. The online version has been updated to correct this error.
Diabetes

Kauhl, B.; Maier, W.; Schweikart, J.; Pieper, J.; Keste, A.; Moskwyn, M.
Anwendungsgebiete und Limitierungen der amtlichen Statistik für die regionale Versorgungsforschung. Ein Diskussionsbeitrag der AOK Nordost am Beispiel der koronaren Herzkrankheit.
Z. amt. Stat. Ber.-Brand., 1-23 (2017)
Regionale Analysen chronischer Erkrankungen in Abrechnungsdaten von Krankenkassen können einen entscheidenden Beitrag dazu leisten, zukünftige Versorgungsstrukturen bedarfsgerecht zu planen. Hierbei sind neben den Abrechnungsdaten selbst auch die Daten der amtlichen Statistik von zentraler Bedeutung: Erst die Analyse des Zusammenhangs zwischen Erkrankungslast und der demografischen und sozio-ökonomischen Zusammensetzung des Wohnortes erlaubt Rückschlüsse darüber, wie sich die Erkrankungslast in Zukunft entwickeln wird. Derzeit können die Daten der amtlichen Statistik allerdings aufgrund der maximalen räumlichen Gliederungstiefe bis zur Gemeindeebene nicht ihr volles Potenzial entfalten. Dieser Beitrag verfolgt mehrere Ziele: (i) Am Beispiel der koronaren Herzkrankheit unter den Versicherten der AOK Nordost in den Ländern Berlin, Brandenburg und Mecklenburg- Vorpommern soll die Verwendung von Daten der amtlichen Statistik beispielhaft vorgestellt werden, (ii) die daraus entstehenden Implikationen für die zukünftige Bedarfsplanung sollen erläutert werden und (iii) die derzeitigen Limitierungen von Daten der amtlichen Statistik sollen diskutiert und Anforderungen an diese Daten aus Sicht der Versorgungsforschung vorgestellt werden.
Zeitschrift für amtliche Statistik Berlin-Brandenburg

Maier, W.; Kurz, C.F.; Präger, M.; Laxy, M.
Einbeziehung von Informationen zur adipogenen Umwelt aus Geokodierungsdiensten in die Diabetes-Surveillance: eine Machbarkeitsstudie.
Gesundheitswesen 79, S. 671 (2017)
Gesundheitswesen, Das
Meeting abstract

Maier, W.; Lanzinger,, S.; Auzanneau,, M.; Bohn,, B.; Rosenbauer, J.; Holl, R.W.
Einfluss regionaler Deprivation auf Stoffwechseleinstellung und Pumpentherapie bei pädiatrischen Patienten mit Typ-1-Diabetes.
.
Gesundheitswesen 79, S. 723 (2017)
Gesundheitswesen, Das
Meeting abstract

Rabel, M.; Meisinger, C.; Peters, A.; Holle, R.; Laxy, M.
The longitudinal association between change in physical activity, weight, and health-related quality of life: Results from the population-based KORA S4/F4/FF4 cohort study.
PLoS ONE 12:e0185205 (2017)
INTRODUCTION: Longitudinal evidence on the association between physical activity (PA) or weight and health-related quality of life (HRQL) is sparse and studies describe inconclusive results. The aim of this study was to examine longitudinal associations between change in PA and HRQL as between change in weight and HRQL respectively. METHODS: Analyses are based on data from the KORA S4 cohort study (1999-2001; n = 4,261, mean age 49.0 ± 13.3 years) and the two follow-up examinations (F4: 2006-2008; FF4: 2013-2014). Information on PA was collected in standardized interviews. Weight was measured objectively. Mental and physical components of HRQL were assessed via the SF-12 questionnaire. First, change in HRQL was regressed on change in PA and weight. Second, hierarchical linear models were fitted, which allowed estimation of between-subject and within-subject effects. Analyses were adjusted for the covariates sex, baseline diseases, and education. RESULTS: A change to a physically more active lifestyle is positively associated with physical and mental HRQL. Although weight gain is associated with impairments in physical HRQL, the data show an inverse relationship between weight gain and mental HRQL. The results were consistent for both the change score analyses and the hierarchical linear models. DISCUSSION: Our findings stress the importance of

interventions on PA/weight. Nonetheless, more research is needed to reveal the causal relationship between PA/weight and HRQL.
PLoS ONE

von Philipsborn, P.; Stratil, J.; Schwettmann, L.; Laxy, M.; Rehfuess, E.A.; Hauner, H
Nichtübertragbare Krankheiten: Der Stellenwert der Prävention in der Politik.
Dtsch. Ärztebl. 114, 1700-1702 (2017)
Die Ausbreitung lebensstilbedingter, nichtübertragbarer Krankheiten ist eine der größten gesundheitspolitischen Herausforderungen. Die Politik hat das Thema aufgegriffen, wie eine Analyse der Wahlprogramme zur Bundestagswahl 2017 zeigt.
Deutsches Ärzteblatt

Laxy, M.; Stark, R.G.; Peters, A.; Hauner, H.; Holle, R.; Teuner, C.M.
The non-linear relationship between BMI and health care costs and the resulting cost fraction attributable to obesity.
Int. J. Environ. Res. Public Health 14:984 (2017)
This study aims to analyse the non-linear relationship between Body Mass Index (BMI) and direct health care costs, and to quantify the resulting cost fraction attributable to obesity in Germany. Five cross-sectional surveys of cohort studies in southern Germany were pooled, resulting in data of 6757 individuals (31-96 years old). Self-reported information on health care utilisation was used to estimate direct health care costs for the year 2011. The relationship between measured BMI and annual costs was analysed using generalised additive models, and the cost fraction attributable to obesity was calculated. We found a non-linear association of BMI and health care costs with a continuously increasing slope for increasing BMI without any clear threshold. Under the consideration of the non-linear BMI-cost relationship, a shift in the BMI distribution so that the BMI of each individual is lowered by one point is associated with a 2.1% reduction of mean direct costs in the population. If obesity was eliminated, and the BMI of all obese individuals were lowered to 29.9 kg/m², this would reduce the mean direct costs by 4.0% in the population. Results show a non-linear relationship between BMI and health care costs, with very high costs for a few individuals with high BMI. This indicates that population-based interventions in combination with selective measures for very obese individuals might be the preferred strategy.
International Journal of Environmental Research and Public Health

Timmer, A.; Stark, R.G.; Peplies, J.; Classen, M.; Laass, M.W.; Koletzko, S.
Current health status and medical therapy of patients with pediatric-onset inflammatory bowel disease: A survey-based analysis on 1280 patients aged 10-25 years focusing on differences by age of onset.
Eur. J. Gastroenterol. Hepatol. 29, 1276-1283 (2017)
OBJECTIVE: There are inconsistent reports on age-related differences in inflammatory bowel disease (IBD). On the basis of patient information, we describe the clinical presentation and therapy in relation to age at diagnosis in longstanding pediatric IBD. PATIENTS AND METHODS: Two surveys were conducted in children and young adults (age: 10-25 years) by pretested postal questionnaires. The main analyses are descriptive, showing proportions and distributions per grouped age of diagnosis. Exploratory logistic regression was used to identify sociodemographic and disease-related factors associated with prognosis. Recent disease course, use of biological therapy, and resecting surgery were chosen as indicators of disease severity. Patients with a diagnosis in infancy (<2 years of age) are presented as a case series. RESULTS: Information of 1280 cases was available [804 Crohn's disease (CD), 382 ulcerative colitis (UC), 94 IBD not specified] (response: 44.6 and 49.6%). Stable remission during the preceding year was reported by 675 (56.7%) patients; 825 (60.9%) patients reported feeling currenty well. Anti-tumor necrosis factor therapy was reported by 33% of CD patients and 9.3% of UC patients, immunomodulation in 82.1 and 63.2%, and corticosteroids by 78.4 and 76.1%, respectively (ever use). Age at diagnosis was not associated with indicators of severe disease. Diagnosis in infancy was reported by 37 patients. CONCLUSION: Our data do not support age at diagnosis-related differences in prognosis in pediatric-onset IBD.
European Journal of Gastroenterology & Hepatology

Karl, F.; Smith, J.; Piedt, S.; Turcotte, K.; Pike, I.
Applying the health action process approach to bicycle helmet use and evaluating a social marketing campaign.
Inj. Prev. 24, 288-295 (2017)
Background Bicycle injuries are of concern in Canada. Since helmet use was mandated in 1996 in the province of British Columbia, Canada, use has increased and head injuries have decreased. Despite the law, many cyclists do not wear a helmet. Health action process approach (HAPA) model explains intention and behaviour with self-efficacy, risk perception, outcome expectancies and planning constructs. The present study examines the impact of a social marketing campaign on HAPA constructs in the context of bicycle helmet use.Method A questionnaire was administered to identify factors determining helmet use. Intention to obey the law, and perceived risk of being caught if not obeying the law were included as additional constructs. Path analysis was used to extract the strongest influences on intention and behaviour. The social marketing campaign was evaluated through t-test comparisons after propensity score matching and generalised linear modelling (GLM) were applied to adjust for the same covariates.Results 400 cyclists aged 25-54 years completed the questionnaire. Self-efficacy and Intention were most predictive of intention to wear a helmet, which, moderated by planning, strongly predicted behaviour. Perceived risk and outcome expectancies had no significant impact on intention. GLM showed that exposure to the campaign was significantly associated with higher values in self-efficacy, intention and bicycle helmet use.Conclusion Self-efficacy and planning are important points of action for promoting helmet use. Social marketing campaigns that remind people of appropriate preventive action have an impact on behaviour.
Injury prevention

Pedron, S.; Winter, V.; Oppel, E.M.; Bialas, E.
Operating room efficiency before and after entrance in a benchmarking program for surgical process data.
J. Med. Syst. 41:151 (2017)
Operating room (OR) efficiency continues to be a high priority for hospitals. In this context the concept of benchmarking has gained increasing importance as a means to improve OR performance. The aim of this study was to investigate whether and how participation in a benchmarking and reporting program

for surgical process data was associated with a change in OR efficiency, measured through raw utilization, turnover times, and first-case tardiness. The main analysis is based on panel data from 202 surgical departments in German hospitals, which were derived from the largest database for surgical process data in Germany. Panel regression modelling was applied. Results revealed no clear and univocal trend of participation in a benchmarking and reporting program for surgical process data. The largest trend was observed for first-case tardiness. In contrast to expectations, turnover times showed a generally increasing trend during participation. For raw utilization no clear and statistically significant trend could be evidenced. Subgroup analyses revealed differences in effects across different hospital types and department specialties. Participation in a benchmarking and reporting program and thus the availability of reliable, timely and detailed analysis tools to support the OR management seemed to be correlated especially with an increase in the timeliness of staff members regarding first-case starts. The increasing trend in turnover time revealed the absence of effective strategies to improve this aspect of OR efficiency in German hospitals and could have meaningful consequences for the medium- and long-run capacity planning in the OR.
Journal of medical systems

Walter, J.; Brandes, A.; Sinner, M.F.; Rogowski, W.H.; Schwarzkopf, L.
A comparison of costs and complications of manual compression and vascular closing devices in gemoral cardiac catheterization interventions.
Inter. Cardio. J. 3:57 (2017)
Background: VCDs are used in femoral catheterization and said to be safer and less expensive than MC. This study aimed to compare complications and healthcare expenditures between VCD and MC, in diagnostic and interventional femoral catheterization from German claims data. Methods: The study population came from a German Statutory Health Insurance (SHI). We calculated odds ratios (OR) for complications with logistic regression models. Healthcare expenditures refer to overall SHI expenditures for the hospital stay and were modelled in Generalized Gamma regression models with recycled predictions and confidence intervals. All analyses were stratified by diagnostic or interventional catheterization and adjusted by age, gender, comorbidities, and antiplatelet and anticoagulant medication. Findings: We found a significantly lower probability for complications for VCD compared to MC in diagnostic catheterization (OR=0.31, p-value=0.02) but not in interventional catheterization (OR=0.98, p-value=0.90). Total adjusted healthcare expenditures were €2,657 for VCD and €2,664 for MC with a difference of €6 (CI=[-141.5, 121.7], p-value=0.92) in diagnostic catheterization. In interventional catheterization healthcare expenditures were €4,380 for VCD and €4,352 for MC with a difference of €28 (CI=[-107.0, 150.2], p-value=0.62). Conclusions: Our results implicate that using VCDs is associated with a significantly lower probability for complications in diagnostic catheterization, but has no significant association in interventional procedures. Healthcare expenditures for VCD and MC are comparable in both types of catheterization. These results suggest that the application of VCD is particularly beneficial in diagnostic catheterization from a payer perspective.
Interventional Cardiology Journal

Mühlig, Y.; Scherag, A.; Bickenbach, A.; Giesen, U.; Holl, R.; Holle, R.; Kiess, W.; Lennerz, B.; Lütke Brintrup, D.; Moss, A.; Neef, M.; Ose, C.; Reinehr, T.; Teuner, C.M.; Wiegand, S.; Wolters, B.; Wabitsch, M.; Hebebrand, J.
A structured, manual-based low-level intervention vs. treatment as usual evaluated in a randomized controlled trial for adolescents with extreme obesity - the STEREO trial.
Obes. Facts 10, 341-352 (2017)
BACKGROUND: To compare efficacy and safety of a manual-based low-level psychological intervention with treatment as usual (weight loss treatment). METHODS: A two-armed randomized controlled trial without blinding and computer-based stratified block randomization included adolescents and young adults (14.0-24.9 years) with a BMI ≥ 30 kg/m2 at five German university hospitals. Primary outcomes were adherence (participation rate ≥ 5/6 sessions) and quality of life (DISABKIDS-37) 6 months after randomization. Secondary outcomes included depression, self-esteem, and perceived stress scores. RESULTS: Of 397 screened adolescents, 119 (mean BMI 40.4 ± 7.0 kg/m2, 49.6% female) were randomized to the manual-based low-level intervention (n = 59) or treatment as usual (n = 60). We observed no group difference for adherence (absolute risk reduction 0.4%, 95% CI -14.7% to 15.5%; p = 1.0) or health-related quality of life (score difference 8.1, 95% CI -2.1 to 18.3; p = 0.11). Among all secondary outcomes, we detected explorative evidence for an effect on the DISABKIDS-37 'social exclusion' subscale (score difference 15.5; 95% CI 1.6-29.4; p = 0.03). 18/19 adverse events occurred in 26 participants, none were classified as serious. CONCLUSION: Adherence to a coping-oriented intervention was comparable to weight loss treatment, although it was weak in both interventions. Psychological interventions may help to overcome social isolation; further confirmation is required.
Obesity Facts

Laxy, M.; Wilson, E.C.F.; Boothby, C.E.; Griffin, S.J.
Incremental costs and cost-effectiveness of intensive treatment in individuals with type 2 diabetes detected by screening in the ADDITION-UK trial: An update with empirical trial-based cost data.
Value Health 20, 1288-1298 (2017)
Background: There is uncertainty about the cost-effectiveness of early intensive treatment versus routine care in individuals with type 2 diabetes detected by screening. Objectives: To derive a trial-informed estimate of the incremental costs of intensive treatment as delivered in the Anglo-Danish-Dutch Study of Intensive Treatment in People with Screen-Detected Diabetes in Primary Care-Europe (ADDITION) trial and to revisit the long-term cost-effectiveness analysis from the perspective of the UK National Health Service. Methods: We analyzed the electronic primary care records of a subsample of the ADDITION-Cambridge trial cohort (n = 173). Unit costs of used primary care services were taken from the published literature. Incremental annual costs of intensive treatment versus routine care in years 1 to 5 after diagnosis were calculated using multilevel generalized linear models. We revisited the long-term cost-utility analyses for the ADDITION-UK trial cohort and reported results for ADDITION-Cambridge using the UK Prospective Diabetes Study Outcomes Model and the trial-informed cost estimates according to a previously developed evaluation framework. Results: Incremental annual costs of intensive treatment over years 1 to 5 averaged £29.10 (standard error = £33.00) for

consultations with general practitioners and nurses and £54.60 (standard error = £28.50) for metabolic and cardioprotective medication. For ADDITION-UK, over the 10-, 20-, and 30-year time horizon, adjusted incremental quality-adjusted life-years (QALYs) were 0.014, 0.043, and 0.048, and adjusted incremental costs were £1,021, £1,217, and £1,311, resulting in incremental cost-effectiveness ratios of £71,232/QALY, £28,444/QALY, and £27,549/QALY, respectively. Respective incremental cost-effectiveness ratios for ADDITION-Cambridge were slightly higher. Conclusions: The incremental costs of intensive treatment as delivered in the ADDITION-Cambridge trial were lower than expected. Given UK willingness-to-pay thresholds in patients with screen-detected diabetes, intensive treatment is of borderline cost-effectiveness over a time horizon of 20 years and more.
Value in Health

Behrndt, E.M.; Straubmeier, M.; Seidl, H.; Book, S.; Graessel, E.; Luttenberger, K.
The German day-care study: Multicomponent non-drug therapy for people with cognitive impairment in day-care centres supplemented with caregiver counselling (DeTaMAKS) - study protocol of a cluster-randomised controlled trial.
BMC Health Serv. Res. 17:492 (2017)
BACKGROUND: It is the wish of both people with cognitive impairment and their informal caregivers for the impaired person to live at home for as long as possible. This is also in line with economic arguments about health. The existing structure of day-care services for the elderly can be used to achieve this. Due to the current lack of empirical evidence in this field, most day-care centres do not offer a scientifically evaluated, structured intervention, but instead offer a mixture of individual activities whose efficacy has not yet been established. Informal caregivers of people with dementia use day-care centres primarily to relieve themselves of their care tasks and as a support service. METHODS/DESIGN: The present study therefore investigates the effectiveness of a combination of a multicomponent activation therapy for people with mild cognitive impairment (MCI) or mild to moderate dementia at day-care centres and a brief telephone intervention for their informal caregivers. The study is conducted as a cluster-randomised intervention trial at 34 day-care centres in Germany with a 6-month treatment phase. The centres in the waitlist control group provide "care as usual". A power analysis indicated that 346 people should initially be included in the study. The primary endpoints of the study include the ability to perform activities of daily living (ADL) and cognitive capacities on the side of the day-care centre users and the subjectively perceived burden and well-being of the informal caregivers. The total duration of the study is 3 years, during which data are collected both by the psychometric testing of the people with cognitive impairment and by telephone interviews with informal caregivers. DISCUSSION: The project has three distinctive quality features. First, it is embedded in real care situations since the day-care services have already been established for this target group. Second, due to the large number of cases and the fact that the participating day-care centres are spread across the entire country, the results can be expected to be generalisable. Third, the interventions can be assumed to be implementable as they required only a one-day training event for the staff already working at the centres. TRIAL REGISTRATION: ISRCTN16412551 (Registration date: 30 July 2014, registered retrospectively).
BMC Health Services Research

Bozorgmehr, K.; Razum, O.; Szecsenyi, J.; Maier, W.; Stock, C.
Regional deprivation is associated with the distribution of vulnerable asylum seekers: A nationwide small area analysis in Germany.
J. Epidemiol. Community Health 71, 857-862 (2017)
BACKGROUND: Newly arriving asylum seekers in many European Union countries are assigned a place of residence based on administrative quota. This may have important consequences for the exposure to contextual health risks. We assessed the association between regional deprivation and the distribution of asylum seekers in Germany considered as vulnerable (women, children <7 years, persons >64 years) because of their increased health needs. METHODS: Using nationally representative data, we analysed the rates of observed to expected numbers of asylum seekers and vulnerable subgroups in Bayesian spatial models. Regional deprivation was measured by the German Index of Multiple Deprivation. The analyses were performed at the district level (N=402) and adjusted for district population size, effects of federal states as well as spatial effects. RESULTS: Of the 224 993 asylum seekers, 38.7% were women, 13.8% children aged <7 years and 19.8% aged >64 years. The adjusted number of asylum seekers (totals and vulnerable subgroups) was higher in more deprived districts (Q3, Q4 and Q5) relative to districts in the lowest deprivation quintile (Q1). The adjusted rate ratios for districts with highest relative to those with lowest deprivation were 1.26 (1.03-1.53) for women, 1.28 (1.04-1.58) for children aged <7 years and 1.50 (1.08-2.08) for older asylum seekers. CONCLUSION: The adjusted number of vulnerable asylum seekers was higher in districts with medium and highest deprivation compared with districts with lowest deprivation. The disproportionate distribution was highest for older asylum seekers and children <7 years. Vulnerable subgroups tend to be exposed to more deprived places of residence, which may further increase health risks and healthcare needs.
Journal of Epidemiology and Community Health

Lingner, H.; Aumann, I.; Wacker, M.; Kreuter, M.; Leidl, R.; von der Schulenburg, M.G.; Welte, T.
Gesundheitswissenschaftliche Forschung mit primärärztlichen Routinedaten der elektronischen Patientenakte: Das BeoNet-Register.
Gesundheitswesen, DOI: 10.1055/s-0043-108544 (2017)
Entscheidungen im Gesundheitswesen sollten sich auf verlässliche und aktuelle Daten stützen. Da solche Daten besonders aus dem ambulanten Sektor kaum vorhanden und/oder nur schwer und zeitverzögert zugänglich sind, soll das neu eingerichtete BeoNet-Register (BNR) die medizinische Versorgungsrealität und -qualität des ambulanten Sektors mithilfe von Routinedaten aus der elektronischen Patientenakte (eP) abbilden. Diese „real-world"-Daten sollen mit Primärerhebungen verknüpft eine breite Datenbasis zur Beantwortung von Fragen der Praxis, der Versorgungsforschung und Ökonomie bilden. Interessierte Praxisinhaber verpflichten sich zu einer längerfristigen Teilnahme an dem 2-phasigen Projekt (Pilot- und Roll-Out-Phase). Informationen der eP der Praxen werden pseudonymisiert, verschlüsselt und über standardisierte Schnittstellen zeitnah, vollständig und longitudinal in die Datenbank (DB) des BNR übertragen, ohne den Praxisbetrieb zu stören. Dafür wird die

Behandlungsdatentransfer-Schnittstelle (BDT) als gemeinsamer Nenner unterschiedlicher Arztinformationssysteme genutzt. Die kompilierten Variablen beinhalten Informationen zur Praxis, Stammdaten des Patienten und medizinische Parameter inklusive Angaben zu Diagnose, Therapie und Überweisungen. Ergänzt werden sie durch zusätzliche erhobene ‚patient-reported outcomes'. Datenerhebung und Datenschutz unterliegen strengen Anforderungen, die im Rahmen des Datenschutzkonzeptes und des Ethikantrages festgelegt und für alle Forscher bindend sind. Retrospektive Auswertungen seit der Einführung der eP sowie Analysen des aktuellen Erkrankungsspektrums des hausärztlichen, pneumologischen und pädiatrischen ambulanten Sektors sind möglich. Derzeit befinden sich 98 497 Patienten-IDs aus Hannover, München und Heidelberg nebst zugehörigen Informationen in der BNR- DB. Die BNR-Daten sind umfangreicher und detaillierter als die Abrechnungsdaten der Krankenkassen. (Semi-) automatisierte Daten- Prüfroutinen und regelmäßige Feedback-Berichte sowie Datenanalysen sind implementiert und werden kontinuierlich erweitert. Während der Pilotphase wurden 2 Anwendungsbeispiele des BNR erarbeitet. Hier wird das COPD-Projekt vorgestellt, dass die Inanspruchnahme von medizinischen Leistungen in Verbindung mit der Lebensqualität Betroffener analysiert. Die Roll-Out-Phase des Projektes startet 2016. Die Datenbasis des BNR für retro- und prospektive Querschnitts- und Längsschnittstudien wird Deutschlandweit und fortlaufend ausgeweitet.
Gesundheitswesen, Das

Stephan, A.J.; Strobl, R.; Holle, R.; Meisinger, C.; Schulz, H.; Ladwig, K.-H.; Thorand, B.; Peters, A.; Grill, E.
Male sex and poverty predict abrupt health decline: Deficit accumulation patterns and trajectories in the KORA-Age cohort study.
Prev. Med. 102, 31-38 (2017)
Ageing individuals differ both in their deficit accumulation (DA) trajectories and resulting DA patterns (improvement, stability, gradual or abrupt decline). This heterogeneity is still incompletely understood. The objectives of this study were thus to identify determinants of DA trajectories and DA patterns in people aged 65 and older. Data originates from the 2009 baseline assessment and 2012 follow-up of the KORA (Cooperative Health Research in the Region of Augsburg)-Age study from Southern Germany. DA was measured with a Frailty Index (FI). The effects of socio-demographic, socio-economic and lifestyle factors were analyzed using generalized linear mixed models and multinomial regressions. FI scores were available for 1076 participants at baseline (mean age 76years, 50% female) and 808 participants at follow-up. Higher baseline FI levels were significantly associated with higher age, female sex, lower physical activity, moderate alcohol consumption and obesity. Longitudinal increase in FI levels over 3years was 31% (CL: [-3%; 77%]) independent of all examined predictors. The most frequent DA patterns were stability (59%) and gradual decline (30%). Compared to stability, higher age, male sex and low income predicted (mostly fatal) abrupt decline. In conclusion, several factors are associated with FI levels at baseline whereas the change in FI levels over time seems hardly modifiable. Thus, future research should investigate if the same factors predicting older-age FI levels constitute predictors of DA onset earlier in life. Towards the end of life, being male with low income may increase the risk for abrupt decline, indicating need for early detection.
Preventive Medicine

Heijink, R.; Reitmeir, P.; Leidl, R.
International comparison of experience-based health state values at the population level.
Health Qual. Life Outcomes 15:138 (2017)
BACKGROUND: Decision makers need to know whether health state values, an important component of summary measures of health, are valid for their target population. A key outcome is the individuals' valuation of their current health. This experience-based perspective is increasingly used to derive health state values. This study is the first to compare such experience-based valuations at the population level across countries. METHODS: We examined the relationship between respondents' self-rated health as measured by the EQ-VAS, and the different dimensions and levels of the EQ-5D-3 L. The dataset included almost 32,000 survey respondents from 15 countries. We estimated generalized linear models with logit link function, including country-specific models and pooled-data models with country effects. RESULTS: The results showed significant and meaningful differences in the valuation of health states and individual health dimensions between countries, even though similarities were present too. Between countries, coefficients correlated positively for the values of mobility, self-care and usual activities, but not for the values of pain and anxiety, thus underlining structural differences. CONCLUSIONS: The findings indicate that, ideally, population-specific experience-based value sets are developed and used for the calculation of health outcomes. Otherwise, sensitivity analyses are needed. Furthermore, transferring the results of foreign studies into the national context should be performed with caution. We recommend future studies to investigate the causes of differences in experience-based health state values through a single international study possibly complemented with qualitative research on the determinants of valuation.
Health and Quality of Life Outcomes

Leidl, R.; Reitmeir, P.
An experience-based value set for the EQ-5D-5L in Germany.
Value Health 20, 1150-1156 (2017)
Objective: Valuation of health states provides a summary measure useful to health care decision makers. Results may depend on whether the currently experienced health state or a hypothetical health state is being evaluated. This study derives a value set for the EuroQoL Five-Dimensional Five-Level Questionnaire (EQ-5D-5L) by focusing on the individual's current experience. Data and Methods: Data include four pooled population surveys of the general German population in 2012-2015 (N = 8114). For valuation, a visual analogue scale (VAS) was used. Six specifications of a generalized linear model with binomial error distribution and constraint parameter estimation were analyzed. In each 1000 simulation runs, models were cross-validated after splitting the sample into an estimation part and a validation part. Predictive accuracy was measured by mean absolute error and sum of squared errors. Results: The models rendered a consistent set of parameters. With regard to predictive accuracy, the model considering all problem levels within the five dimensions and the highest problem level reached performed best overall. Discussion: Estimation proved to be feasible. Predictive accuracy exceeded that of a similar,

experience-based value set for the EQ-5D-3L. Compared with a Dutch value set for the EQ-5D-5L derived for hypothetical health states, experienced values tended to be slightly lower for mild health states and substantially higher for severe health states. Clinical relevance and usefulness of the value set remain to be determined in future studies. Conclusions: For decision makers who prioritize patient-relevant benefit, the experience-based value set provides a novel option to summarize health states, reflecting how health states experienced are valued in a population.
Value in Health

Ahlert, M.; Schwettmann, L.
Allocating health care resources: A questionnaire experiment on the predictive success of rules.
Int. J. Equity Health 16:112 (2017)
BACKGROUND: The topic of this paper is related to equity in health within a country. In public health care sectors of many countries decisions on priority setting with respect to treatment of different types of diseases or patient groups are implicitly or explicitly made. Priorities are realized by allocation decisions for medical resources where moral judgments play an important role with respect to goals and measures that should be applied. The aim of this study is to explore the moral intuitions held in the German society related to priorities in medical treatment. METHODS: We use an experimental questionnaire method established in the Empirical Social Choice literature. Participants are asked to make decisions in a sequence of distributive problems where a limited amount of treatment time has to be allocated to hypothetically described patients. The decision problems serve as an intuition pump. Situations are systematically varied with respect to patients' initial health levels, their ability to benefit from treatment time, and the amount of treatment time available. Subjects are also asked to describe their deliberations. We focus on the acceptance of different allocation principles including equity concepts and utilitarian properties. We investigate rule characteristics like order preservation or monotonicity with respect to resources, severity, or effectiveness. We check the consistency of individual choices with stated reasoning. RESULTS: The goals and allocation principles revealed show that the moral intuitions held by our experimental subjects are much more complex than the principles commonly applied in health economic theory. Especially, cost-utility principles are rarely applied, whereas the goal of equality of health gain is observed more often. The principle not to leave any patient untreated is very dominant. We also observe the degrees to which extent certain monotonicity principles, known from welfare economics, are followed. Subjects were able to describe their moral judgments in written statements. We also find evidence that they followed their respective intuitions very consistently in their decisions. CONCLUSIONS: Findings of the kind presented in this paper may serve as an important input for the public and political discussion when decisions on priorities in the public health care sector are formed.
International Journal for Equity in Health

Kahnert, K.; Lucke, T.; Biertz, F.; Lechner, A.; Alter, P.; Bals, R.; Watz, H.; Behr, J.; Holle, R.; Huber, R.M.; Karrasch, S.; Stubbe, B.; Wacker, M.; Söhler, S.; Wouters, E.F.M.; Vogelmeier, C.; Jörres, R.
Transfer factor for carbon monoxide in patients with COPD and diabetes: Results from the German Cosyconet Cohort.
Am. J. Respir. Crit. Care Med. 195 (2017)
American Journal of Respiratory and Critical Care Medicine
Meeting abstract

Kahnert, K.; Lucke, T.; Huber, R.M.; Behr, J.; Biertz, F.; Vogt, A.; Watz, H.; Alter, P.; Fähndrich, S.; Bals, R.; Holle, R.; Karrasch, S.; Söhler, S.; Wacker, M.; Ficker, J.H.; Parhofer, K.G.; Vogelmeier, C.; Jörres, R.A.
Relationship of hyperlipidemia to comorbidities and lung function in COPD: Results of the COSYCONET cohort.
PLoS ONE 12:e0177501 (2017)
Although hyperlipidemia is common in COPD, its relationship to comorbidities, risk factors and lung function in COPD has not been studied in detail. Using the baseline data of the COSYCONET cohort we addressed this question. Data from 1746 COPD patients (GOLD stage 1-4; mean age 64.6 y, mean FEV1%pred 57%) were evaluated, focusing on the comorbidities hyperlipidemia, diabetes and cardiovascular complex (CVC; including arterial hypertension, cardiac failure, ischemic heart disease). Risk factors comprised age, gender, BMI, and packyears of smoking. The results of linear and logistic regression analyses were implemented into a path analysis model describing the multiple relationships between parameters. Hyperlipidemia (prevalence 42.9%) was associated with lower intrathoracic gas volume (ITGV) and higher forced expiratory volume in 1 second (FEV1) when adjusting for its multiple relationships to risk factors and other comorbidities. These findings were robust in various statistical analyses. The associations between comorbidities and risk factors were in accordance with previous findings, thereby underlining the validity of our data. In conclusion, hyperlipidemia was associated with less hyperinflation and airway obstruction in patients with COPD. This surprising result might be due to different COPD phenotypes in these patients or related to effects of medication.
PLoS ONE

Schunk, M.; Reitmeir, P.; Rückert-Eheberg, I.-M.; Tamayo, T.; Schipf, S.; Meisinger, C.; Peters, A.; Scheidt-Nave, C.; Ellert, U.; Hartwig, S.; Kluttig, A.; Völzke, H.; Holle, R.
Longitudinal change in health-related quality of life in people with prevalent and incident type 2 diabetes compared to diabetes-free controls.
PLoS ONE 12:e0176895 (2017)
The objective of this analysis is to compare people with prevalent type 2 diabetes, incident type 2 diabetes and without diabetes with respect to longitudinal change in health-related quality of life (HRQOL) when adjusting for baseline determinants of HRQOL. Research design and methods Primary baseline and follow-up data from three regional and one national population-based cohort studies in Germany were pooled for analysis. HRQOL was measured using physical and mental health summary scores (PCS and MCS) from the German version of the Short Form Health Survey with 36 or 12 items. Mean score change per observation year was compared between the three groups (prevalent diabetes, incident diabetes, no diabetes) based on linear regression models. Results The analysis included pooled data from 5367 people aged 45-74 years at baseline. Of these, 85.5% reported no diabetes at baseline and follow-up, 6.3% reported diabetes at both baseline and follow-up (prevalent diabetes), and 8.2% reported diabetes only at followup (incident

diabetes). Over a mean observation period of 8.7 years, annual decline in HRQOL scores is pronounced at 0.27-0.32 (PCS) and 0.34-0.38 (MCS) in the group with prevalent diabetes compared with people without diabetes. Those with incident diabetes showed intermediate values but did not differ significantly from people without diabetes after adjustment for covariates in the full model. Conclusion Compared with data from cross-sectional analysis, the HRQOL loss associated with prevalent diabetes appears to be much larger than previously assumed.
PLoS ONE

Korber, K.; Wolfenstetter, S.B.
Erfassung und Bewertung der Kosten von Praventions- und GesundheitsforderungsmaSSnahmen - Entwicklung eines Konzepts am Beispiel Bewegungsforderung.
Gesundheitswesen, DOI: 10.1055/s-0042-120269 (2017)
Es ist sowohl ein medizinisches als auch gesundheitsökonomisches Ziel, mit gegebenen finanziellen Ressourcen die bestmöglichen gesundheitlichen Effekte zu erreichen. Das Abschätzen der Kosten von Interventionsprogrammen ist hierfür notwendig und nicht immer vorab möglich. Eine Möglichkeit, Informationen über Kosten, bzw. Kosteneffektivität bestimmter Maßnahmen zu erhalten, ist es, bereits existierende Programme diesbezüglich zu überprüfen. Ziel dieser Arbeit war es, eine einfache, gut verständliche und praktikable Möglichkeit zur Dokumentation von Kosten von Präventions- und Gesundheitsförderungsmaßnahmen zu schaffen. Basierend auf den wesentlichen Grundlagen, welche generell für eine Kostenerhebung nötig sind, wurden ein Fragebogen sowie ein Modul zur Erfassung der verbrauchten Ressourcen und der daraus resultierenden Kosten entwickelt. Diese wurden im Rahmen eines Pretests angewendet, überprüft und verbessert. Das entwickelte Kostenmodul ist wie folgt aufgebaut: In der linken Spalte sind 5 zentrale Kostenkategorien aufgelistet: Personal, Räumlichkeiten, Ausstattung und Ablauf, Verwaltung, Sonstiges. Das Kostenmodul ist ein Kompromiss zwischen mehreren nur schwer miteinander zu vereinbarenden Zielen. Einerseits sollten die Kosten so detailliert wie möglich erfasst werden und andererseits muss das Modul sehr einfach umzusetzen sein, da es sonst in der Praxis keine Anwendung findet. Hierfür könnte es auch sinnvoll sein, für jeden Akteur ein Modul zu entwickeln, dass so genau wie möglich auf sein spezielles Aktivitätsspektrum hin ausgerichtet ist. Es wurden alle Rückmeldungen und Vorschläge aus dem Pretest eingearbeitet, von denen einige jedoch projektspezifisch waren. Hier wurde versucht, einen Kompromiss aus Detailliertheit und Praktikabilität zu finden. Aus diesem Grund wurde vor allem die Anleitung um ausführlichere Beschreibungen und Beispiele erweitert. Das hier vorgestellte Modul ist allgemein gehalten. Das ist zugleich ein großer Vorteil da es damit für die Dokumentation der Kosten bei ganz unterschiedlichen Akteuren genutzt werden kann. Somit bietet das vorgestellte Grundgerüst zur Kostenerhebung einen zentralen, ersten Baustein für eine detaillierte Dokumentation der Programmkosten und bietet die Möglichkeit die Vergleichbarkeit sowie die Übertragbarkeit der Präventionsprogramme zu prüfen.
Gesundheitswesen, Das

Schultz, K.; Seidl, H.; Jelusic, D.; Wagner, R.; Wittmann, M.; Faller, H.; Nowak, D.; Schüler, M.
Effectiveness of pulmonary rehabilitation for patients with asthma: study protocol of a randomized controlled trial (EPRA).
BMC Pulm. Med. 17:49 (2017)
BACKGROUND: Asthma patients are enrolled in multimodal pulmonary rehabilitation (PR) programs. However, available data for the effectiveness of PR in asthma are sparse. Therefore, the primary aim of this randomized control trial (RCT) is to evaluate short-term (end of rehabilitation) and intermediate-term effectiveness (3 months after rehabilitation) of PR for patients with asthma regarding asthma control (primary outcome) and other outcomes. Secondly, moderator effects of gender, age, baseline asthma control, quality of life, and anxiety will be examined. Thirdly, a longitudinal follow-up study will explore the course of the outcomes over one year and the annual costs. METHODS: The EPRA study is a single-center randomized controlled waiting-list trial in the Bad Reichenhall Clinic. Inclusion criteria include a referral diagnosis for uncontrolled asthma, no cognitive impairment and no very severe co-morbidities that indicate significantly greater illness morbidity than asthma alone. In the intervention group (IG), participants will start PR within 4 weeks after randomization; participants of the control group (CG) will start PR 20 weeks after randomization. Data will be assessed at randomization (T0), after 4 weeks (T1; IG: begin of PR), 7 weeks (T2; IG: end of PR), and 20 weeks (T3, CG: begin of PR). The primary outcome is asthma control at T2/T3. Secondary outcomes are health-related quality of life, functional exercise capacity, dyspnea, anxiety, depression, subjective self-management skills, illness perceptions, sick leave and subjective work ability. Outcomes will be analyzed with analysis of covariance, including baseline values of the respective outcomes as covariates. Healthcare costs will be analyzed with a gamma model with a log-link. A longitudinal follow-up study will generate additional data at 3/6/9/12 months after PR for both IG and CG. Latent change models will be used to analyze the course of the primary and secondary outcomes. Annual cost differences before and after rehabilitation will be compared by paired t-test. DISCUSSION: This RCT will determine the effectiveness of a complex inpatient PR for asthma patients concerning asthma control. Furthermore, important medical and economic information regarding the effectiveness of PR as part of the long-term management of patients with uncontrolled asthma will be generated. TRIAL REGISTRATION: German Clinical Trials Register (DRKS00007740 , May 15, 2015). Protocol version: 1.0 (December, 23, 2016).
BMC Pulmonary Medicine

Müller, D.; Danner, M.; Rhiem, K.; Stollenwerk, B.; Engel, C.; Rasche, L.; Borsi, L.; Schmutzler, R.K.; Stock, S.
Cost-effectiveness of different strategies to prevent breast and ovarian cancer in German women with a BRCA 1 or 2 mutation.
Eur. J. Health Econ., 1-13 (2017)
BACKGROUND: Women with a BRCA1 or BRCA2 mutation are at increased risk of developing breast and/or ovarian cancer. This economic modeling study evaluated different preventive interventions for 30-year-old women with a confirmed BRCA (1 or 2) mutation. METHODS: A Markov model was developed to estimate the costs and benefits [i.e., quality-adjusted life years (QALYs), and life years gained (LYG)] associated with prophylactic bilateral mastectomy (BM), prophylactic bilateral salpingo-oophorectomy (BSO), BM plus BSO, BM plus BSO at age 40, and intensified surveillance. Relevant input data was obtained from a large German database including 5902 women with BRCA 1 or 2, and from the literature. The analysis was performed from the German Statutory Health Insurance (SHI)

perspective. In order to assess the robustness of the results, deterministic and probabilistic sensitivity analyses were performed. RESULTS: With costs of €29,434 and a gain in QALYs of 17.7 (LYG 19.9), BM plus BSO at age 30 was less expensive and more effective than the other strategies, followed by BM plus BSO at age 40. Women who were offered the surveillance strategy had the highest costs at the lowest gain in QALYs/LYS. In the probabilistic sensitivity analysis, the probability of cost-saving was 57% for BM plus BSO. At a WTP of 10,000 € per QALY, the probability of the intervention being cost-effective was 80%. CONCLUSIONS: From the SHI perspective, undergoing BM plus immediate BSO should be recommended to BRCA 1 or 2 mutation carriers due to its favorable comparative cost-effectiveness.
The European journal of health economics

Gaertner, W.; Schwettmann, L.; Xu, Y.
An experimental game of loss sharing.
In: ExCEN Working Papers Series - Experimental Economics Center No. 17-01. Georgia State University: Andrew Young School of Policy Studies, 2017. 36 S.
We conduct a lab-experimental study of bargaining over the distribution of monetary losses. Groups of four differently endowed participants must agree, as a group, on the contribution each participant will make to cover a financial loss imposed on the group. The study sheds light on burden sharing and what loss allocation rules groups adopt. Furthermore, we characterize a new theoretical model which contains the proportional rule and equality of losses as special cases but collides with the constrained equal awards rule. The combination of our model and the constrained equal awards rule can explain the majority of proposals made in our experiment.
Huber, M.B.; Felix, J.F.; Vogelmann, M.; Leidl, R.
Health-related quality of life of the general German population in 2015: Results from the EQ-5D-5L.
Int. J. Environ. Res. Public Health 14:426 (2017)
The EQ-5D-5L is a widely used generic instrument to measure health-related quality of life. This study evaluates health perception in a representative sample of the general German population from 2015. To compare results over time, a component analysis technique was used that separates changes in the description and valuation of health states. The whole sample and also subgroups, stratified by sociodemographic parameters as well as disease affliction, were analyzed. In total, 2040 questionnaires (48.4% male, mean age 47.3 year) were included. The dimension with the lowest number of reported problems was self-care (93.0% without problems), and the dimension with the highest proportion of impairment was pain/discomfort (71.2% without problems). Some 64.3% of the study population were identified as problem-free. The visual analog scale (VAS) mean for all participants was 85.1. Low education was connected with significantly lower VAS scores, but the effect was small. Depression, heart disease, and diabetes had a strong significant negative effect on reported VAS means. Results were slightly better than those in a similar 2012 survey; the most important driver was the increase in the share of the study population that reported to be problem-free. In international comparisons, health perception of the general German population is relatively high and, compared with previous German studies, fairly stable over recent years. Elderly and sick people continue to report significant reductions in perceived health states.
International Journal of Environmental Research and Public Health

Skordis-Worrall, J.; Round, J.; Arnold, M.; Abdraimova, A.; Akkazieva, B.; Beran, D.
Addressing the double-burden of diabetes and tuberculosis: Lessons from Kyrgyzstan.
Global. Health 13:16 (2017)
Background: The incidence of diabetes and tuberculosis co-morbidity is rising, yet little work has been done to understand potential implications for health systems, healthcare providers and individuals. Kyrgyzstan is a priority country for tuberculosis control and has a 5% prevalence of diabetes in adults, with many health system challenges for both conditions. Methods: Patient exit interviews collected data on demographic and socio-economic characteristics, health spending and care seeking for people with diabetes, tuberculosis and both diabetes and tuberculosis. Qualitative data were collected through semi-structured interviews with healthcare workers involved in diabetes and tuberculosis care, to understand delivery of care and how providers view effectiveness of care. Results: The experience of co-affected individuals within the health system is different than those just with tuberculosis or diabetes. Co-affected patients do not receive more care and also have different care for their tuberculosis than people with only tuberculosis. Very high levels of catastrophic spending are found among all groups despite these two conditions being included in the Kyrgyz state benefit package especially for medicines. Conclusions: This study highlights that different patterns of service provision by disease group are found. Although Kyrgyzstan has often been cited as an example in terms of health reforms and developing Primary Health Care, this study highlights the challenge of managing conditions that are viewed as "too complicated" for non-specialists and the impact this has on costs and management of individuals.
Globalization and health

Karl, F.; Holle, R.; Bals, R.; Greulich, T.; Jörres, R.A.; Karch, A.; Koch, A.; Karrasch, S.; Leidl, R.; Schulz, H.; Vogelmeier, C.; Wacker, M.
Costs and health-related quality of life in Alpha-1-antitrypsin deficient COPD patients.
Respir. Res. 18:60 (2017)
BACKGROUND: Alpha-1-Antitrypsin Deficiency (AATD) is an economically unexplored genetic disease. METHODS: Direct and indirect costs (based on self-reported information on healthcare utilization) and health-related quality of life (HRQL, as assessed by SGRQ, CAT, and EQ-5D-3 L) were compared between 131 AATD patients (106 with, 25 without augmentation therapy (AT)) and 2,049 COPD patients without AATD participating in the COSYCONET COPD cohort. The medication costs of AT were excluded from all analyses to reveal differences associated with morbidity profiles. The association of AATD (with/without AT) with costs or HRQL was examined using generalized linear regression modelling (GLM) adjusting for age, sex, GOLD grade, BMI, smoking status, education and comorbidities. RESULTS: Adjusted mean direct annual costs were €6,099 in AATD patients without AT, €7,117 in AATD patients with AT (excluding costs for AT), and €7,460 in COPD patients without AATD. AATD with AT was significantly associated with higher outpatient (+273%) but lower inpatient (-35%) and medication costs (-10%, disregarding AT) compared

with COPD patients without AATD. There were no significant differences between groups regarding indirect costs and HRQL. CONCLUSION: Apart from AT costs, AATD patients tended to have lower, though not significant, overall costs and similar HRQL compared to COPD patients without AATD. AT was not associated with lower costs or higher HRQL. TRIAL REGISTRATION: NCT01245933.
Respiratory Research

Luzak, A.; Heier, M.; Thorand, B.; Laxy, M.; Nowak, D.; Peters, A.; Schulz, H.
Physical activity levels, duration pattern and adherence to WHO recommendations in German adults.
PLoS ONE 12:e0172503 (2017)
BACKGROUND: Intensity and duration of physical activity are associated with the achievement of health benefits. Our aim was to characterize physical activity behavior in terms of intensity, duration pattern, and adherence to the WHO physical activity recommendations in a population-based sample of adults from southern Germany. Further, we investigated associations between physical activity and sex, age, and body mass index (BMI), considering also common chronic diseases. METHODS: We analyzed 475 subjects (47% males, mean age 58 years, range 48-68 years) who wore ActiGraph accelerometers for up to seven days. Measured accelerations per minute obtained from the vertical axis (uniaxial) and the vector magnitude of all three axes (triaxial) were classified as sedentary, light or moderate-to-vigorous physical activity (MVPA) according to predefined acceleration count cut-offs. The average minutes/day spent in each activity level per subject served as outcome. Associations of sex, age, BMI, and seven chronic diseases or health limitations, with the activity levels were analyzed by negative binomial regression. RESULTS: Most of the wear time was spent in sedentarism (median 61%/day), whereas the median time spent in MVPA was only 3%, with men achieving more MVPA than women (35 vs. 28 minutes/day, $p<0.05$). Almost two thirds of MVPA was achieved in short bouts of less than 5 minutes, and 35% of the subjects did not achieve a single 10-minute bout. Hence, only 14% adhered to the WHO recommendation of 2.5 hours of MVPA/week in at least 10-minute bouts. Females, older subjects and obese subjects spent less time in MVPA ($p<0.05$), but no clear association with hypertension, asthma, diabetes, chronic obstructive pulmonary disease, anxiety/depression, pain or walking difficulties was observed in regression analyses with MVPA as outcome. CONCLUSIONS: Activity behavior among middle-aged German adults was highly insufficient, indicating a further need for physical activity promotion in order to gain health benefits.
PLoS ONE

Islam, S.M.S.; Lechner, A.; Ferrari, U.; Laxy, M.; Seissler, J.; Brown, J.; Niessen, L.W.; Holle, R.
Healthcare use and expenditure for diabetes in Bangladesh.
BMJ Glob. Health 2:e000033 (2017)
Background Diabetes imposes a huge social and economic impact on nations. However, information on the costs of treating and managing diabetes in developing countries is limited. The aim of this study was to estimate healthcare use and expenditure for diabetes in Bangladesh. Methods We conducted a matched case–control study between January and July 2014 among 591 adults with diagnosed diabetes mellitus (DMs) and 591 age-matched, sex-matched and residence-matched persons without diabetes mellitus (non-DMs). We recruited DMs from consecutive patients and non-DMs from accompanying persons in the Bangladesh Institute of Health Science (BIHS) hospital in Dhaka, Bangladesh. We estimated the impact of diabetes on healthcare use and expenditure by calculating ratios and differences between DMs and non-DMs for all expenses related to healthcare use and tested for statistical difference using Student's t-tests. Results DMs had two times more days of inpatient treatment, 1.3 times more outpatient visits, and 9.7 times more medications than non-DMs (all $p<0.005$). The total annual per capita expenditure on medical care was 6.1 times higher for DMs than non-DMs (US$635 vs US$104, respectively). Among DMs, 9.8% reported not taking any antidiabetic medications, 46.4% took metformin, 38.7% sulfonylurea, 40.8% insulin, 38.7% any antihypertensive medication, and 14.2% took anti-lipids over the preceding 3 months. Conclusions Diabetes significantly increases healthcare use and expenditure and is likely to impose a huge economic burden on the healthcare systems in Bangladesh. The study highlights the importance of prevention and optimum management of diabetes in Bangladesh and other developing countries, to gain a strong economic incentive through implementing multisectoral approach and cost-effective prevention strategies.
BMJ Global Health

Schwarzkopf, L.; Holle, R.; Schunk, M.
Effects of nursing home residency on diabetes care in individuals with dementia: An explorative analysis based on German claims data.
Dement. Geriatr. Cogn. Disord. 7, 41-51 (2017)
Aims: This claims data-based study compares the intensity of diabetes care in community dwellers and nursing home residents with dementia. Methods: Delivery of diabetes-related medical examinations (DRMEs) was compared via logistic regression in 1,604 community dwellers and 1,010 nursing home residents with dementia. The intra-individual effect of nursing home transfer was evaluated within mixed models. Results: Delivery of DRMEs decreases with increasing care dependency, with more community-living individuals receiving DRMEs. Moreover, DRME provision decreases after nursing home transfer. Conclusion: Dementia patients receive fewer DRMEs than recommended, especially in cases of higher care dependency and particularly in nursing homes. This suggests lacking awareness regarding the specific challenges of combined diabetes and dementia care.
Dementia and Geriatric Cognitive Disorders

Kowall, B.; Rathmann, W.G.; Stang, A.; Bongaerts, B.; Kuss, O.; Herder, C.; Roden, M.; Quante, A.S.; Holle, R.; Huth, C.; Peters, A.; Meisinger, C.
Perceived risk of diabetes seriously underestimates actual diabetes risk: The KORA FF4 study.
PLoS ONE 12:e0171152 (2017)
Objective: Early detection of diabetes and prediabetic states is beneficial for patients, but may be delayed by patientś being overly optimistic about their own health. Therefore, we assessed how persons without known diabetes perceive their risk of having or developing diabetes, and we identified factors associated with perception of diabetes risk. Research design and methods: 1,953 participants without previously known diabetes from the population-based, German KORA FF4 Study (59.1 years, 47.8% men) had an oral glucose tolerance test. They estimated their

probability of having undiagnosed diabetes mellitus (UDM) on a six category scale, and assessed whether they were at risk of developing diabetes in the future. We cross-tabulated glycemic status with risk perception, and fitted robust Poisson regression models to identify determinants of diabetes risk perception. Results: 74% (95% CI: 65-82) of persons with UDM believed that their probability of having undetected diabetes was low or very low. 72% (95% CI: 69-75) of persons with prediabetes believed that they were not at risk of developing diabetes. In people with prediabetes, seeing oneself at risk of diabetes was associated with self-rated poor general health (prevalence ratio (PR) = 3.1 (95% CI: 1.4-6.8), parental diabetes (PR = 2.6, 1.9-3.4), high educational level (PR = 1.9 (1.4-2.5)), lower age (PR = 0.7, 0.6-0.8, per 1 standard deviation increase), female sex (PR = 1.2, 0.9-1.5) and obesity (PR = 1.5, 1.2-2.0). Conclusions: People with undiagnosed diabetes or prediabetes considerably underestimate their probability of having or developing diabetes. Contrary to associations with actual diabetes risk, perceived diabetes risk was lower in men, lower educated and older persons. Copyright:
PLoS ONE

Bauer, J.; Müller, P.; Maier, W.; Groneberg, D.
Orthopedic workforce planning in Germany – an analysis of orthopedic accessibility.
PLoS ONE 12:e0171747 (2017)
In Germany, orthopedic workforce planning relies on population-to-provider-ratios represented by the 'official degree of care provision'. However, with geographic information systems (GIS), more sophisticated measurements are available. By utilizing GIS-based technologies we analyzed the current state of demand and supply of the orthopedic workforce in Germany (orthopedic accessibility) with the integrated Floating Catchment Area method. The analysis of n = 153,352,220 distances revealed significant geographical variations on national scale: 5,617,595 people (6.9% of total population) lived in an area with significant low orthopedic accessibility (average z-score = -4.0), whereas 31,748,161 people (39.0% of total population) lived in an area with significant high orthopedic accessibility (average z-score = 8.0). Accessibility was positively correlated with the degree of urbanization ($r = 0.49$; $p<0.001$) and the official degree of care provision ($r = 0.33$; $p<0.001$) and negatively correlated with regional social deprivation ($r = -0.47$; $p<0.001$). Despite advantages of simpler measures regarding implementation and acceptance in health policy, more sophisticated measures of accessibility have the potential to reduce costs as well as improve health care. With this study, significant geographical variations were revealed that show the need to reduce oversupply in less deprived urban areas in order to enable adequate care in more deprived rural areas.
PLoS ONE

Markevych, I.; Maier, W.; Fuertes, E.; Lehmann, I.; von Berg, A.; Bauer, C.P.; Koletzko, S.; Berdel, D.; Sugiri, D.; Standl, M.; Heinrich, J.
Neighbourhood greenness and income of occupants in four German areas: GINIplus and LISAplus.
Urban for. urban gree. 21, 88-95 (2017)
Objective We investigated whether families with lower individual-level socioeconomic status (SES) reside in less green neighbourhoods in four areas in Germany. Methods Data were collected within two German birth cohorts – GINIplus and LISAplus. Net equivalent household income was categorized into study area-specific tertiles and used as a proxy for individual-level SES. Neighbourhood greenness was calculated in 500-m buffers around home addresses as: 1) the mean normalized difference vegetation index (NDVI); 2) percent tree cover. Associations between income and neighbourhood greenness were assessed per study area using adjusted linear regression models. Results In the Munich and Leipzig areas, families in the low and medium income tertiles resided in neighbourhoods with lower NDVI compared to those in the high income tertile (mean percent change in NDVI: −4.0 (95% confidence interval = −6.7 to −1.3) and −5.5 (−10.9 to −0.2), respectively). In contrast, in the Wesel area, families in the low income tertile resided in neighbourhoods with higher NDVI (2.9 (0.5–5.3)). Only the association in the Munich area was replicated when using tree cover instead of the NDVI. Conclusions This study provides suggestive evidence that the presence and direction of associations between greenness and SES is region-specific in Germany. The degree of urbanization did not clarify this heterogeneity completely.
Urban forestry & urban greening

Seidl, H.; Hunger, M.; Meisinger, C.; Kirchberger, I.; Kuch, B.; Leidl, R.; Holle, R.
The 3-year cost-effectiveness of a nurse-based case management versus usual care for elderly patients with myocardial infarction: Results from the KORINNA follow-up study.
Value Health 20, 441-450 (2017)
Objectives: To assess the 3-year cost-effectiveness of a nurse-based case management intervention in elderly patients with myocardial infarction from a societal perspective. Methods: The intervention consisted of one home visit and quarterly telephone calls in the first year, and semi-annual calls in the following 2 years. The primary effect measures were quality-adjusted life-years (QALYs), on the basis of the EuroQol five-dimensional questionnaire (EQ-5D-3L) and adjusted life-years from patients' self-rated health states according to the visual analogue scale (VAS-ALs). A linear regression model was used for adjusted life-years and a gamma model for costs. Estimation uncertainty was addressed by cost-effectiveness acceptability curves, which indicate the likelihood of cost-effectiveness for a given value of willingness to pay. The secondary objective was to examine EQ-5D-3L utility scores and VAS scores among survivors using linear mixed models. Results: Primary outcomes regarding QALY gains (+0.0295; . P = 0.76) and VAS-AL gains (+0.1332; . P = 0.09) in the intervention group were not significant. The overall cost difference was -€2575 (P = 0.30). The probability of cost-effectiveness of the case management at a willingness-to-pay value of €0 per QALY was 84% in the case of QALYs and 81% in the case of VAS-ALs. Secondary outcomes concerning survivors' quality of life were significantly better in the intervention group (EQ-5D-3L utilities: +0.104, . P = 0.005; VAS: +8.15, . P = 0.001) after 3 years. Conclusions: The case management was cost-neutral and led to an important and significant improvement in health status among survivors. It was associated with higher QALYs and lower costs but the differences in costs and QALYs were not statistically significant.
Value in Health

Hoogendoorn, M.; Feenstra, T.L.; Asukai, Y.; Briggs, A.H.; Hansen, R.N.; Leidl, R.; Risebrough, N.; Samyshkin, Y.; Wacker, M.; Rutten-van Mölken, M.P.
External validation of health economic decision models for chronic obstructive pulmonary disease (COPD): Report of the third COPD modeling meeting.
Value Health 20, 397-403 (2017)
Objectives: To validate outcomes of presently available chronic obstructive pulmonary disease (COPD) cost-effectiveness models against results of two large COPD trials-the 3-year TOwards a Revolution in COPD Health (TORCH) trial and the 4-year Understanding Potential Long-term Impacts on Function with Tiotropium (UPLIFT) trial. Methods: Participating COPD modeling groups simulated the outcomes for the placebo-treated groups of the TORCH and UPLIFT trials using baseline characteristics of the trial populations as input. Groups then simulated treatment effectiveness by using relative reductions in annual decline in lung function and exacerbation frequency observed in the most intensively treated group compared with placebo as input for the models. Main outcomes were (change in) total/severe exacerbations and mortality. Furthermore, the absolute differences in total exacerbations and quality-adjusted life-years (QALYs) were used to approximate the cost per exacerbation avoided and the cost per QALY gained. Result: Of the six participating models, three models reported higher total exacerbation rates than observed in the TORCH trial (1.13/patient-year) (models: 1.22-1.48). Four models reported higher rates than observed in the UPLIFT trial (0.85/patient-year) (models: 1.13-1.52). Two models reported higher mortality rates than in the TORCH trial (15.2%) (models: 20.0% and 30.6%) and the UPLIFT trial (16.3%) (models: 24.8% and 36.0%), whereas one model reported lower rates (9.8% and 12.1%, respectively). Simulation of treatment effectiveness showed that the absolute reduction in total exacerbations, the gain in QALYs, and the cost-effectiveness ratios did not differ from the trials, except for one model. Conclusions: Although most of the participating COPD cost-effectiveness models reported higher total exacerbation rates than observed in the trials, estimates of the absolute treatment effect and cost-effectiveness ratios do not seem different from the trials in most models.
Value in Health

Kahnert, K.; Lucke, T.; Biertz, F.; Lechner, A.; Watz, H.; Alter, P.; Bals, R.; Behr, J.; Holle, R.; Huber, R.M.; Karrasch, S.; Stubbe, B.; Wacker, M.; Söhler, S.; Wouters, E.F.M.; Vogelmeier, C.; Jörres, R.A.
Transfer factor for carbon monoxide in patients with COPD and diabetes: Results from the German COSYCONET cohort.
Respir. Res. 18:14 (2017)
Background: An impairment of CO diffusing capacity has been shown in diabetic patients without lung disease. We analyzed how diffusing capacity in patients with COPD is affected by the concurrent diagnosis of diabetes. Methods: Data from the initial visit of the German COPD cohort COSYCONET were used for analysis. 2575 patients with complete lung function data were included, among them 358 defined as diabetics with a reported physician diagnosis of diabetes and/or specific medication. Pairwise comparisons between groups and multivariate regression models were used to identify variables predicting the CO transfer factor (TLCO%pred) and the transfer coefficient (KCO%pred). Results: COPD patients with diabetes differed from those without diabetes regarding lung function, anthropometric, clinical and laboratory parameters. Moreover, gender was an important covariate. After correction for lung function, gender and body mass index (BMI), TLCO%pred did not significantly differ between patients with and without diabetes. The results for the transfer coefficient KCO were similar, demonstrating an important role of the confounding factors RV%pred, TLC%pred, ITGV%pred, FEV1%pred, FEV1/FVC, age, packyears, creatinine and BMI. There was not even a tendency towards lower values in diabetes. Conclusion: The analysis of data from a COPD cohort showed no significant differences of CO transport parameters between COPD patients with and without diabetes, if BMI, gender and the reduction in lung volumes were taken into account. This result is in contrast to observations in lung-healthy subjects with diabetes and raises the question which factors, among them potential anti-inflammatory effects of anti-diabetes medication are responsible for this finding.
Respiratory Research

Gaertner, W.; Schwettmann, L.
Burden sharing in deficit countries: A questionnaire-experimental investigation.
SERIEs 8, 113-144 (2017)
This paper studies the problem of burden sharing in countries that were forced to introduce severe budget cuts after the collapse of Lehman Brothers in 2008 which had unleashed a financial crisis in many industrialised countries of the Western world. We do not ask how the burden was actually split in each country examined but how the burden should have been shared among different income groups of society. In order to answer this question, a questionnaire-experimental investigation was run among students from Cyprus, Greece, Ireland, Italy, Portugal, and Spain. Our study offered the students seven different schemes of taxation amongst which we had specified a proportional rule and two progressive schemes of differing severity. A key result within our investigation is the finding that a large majority of students in all countries involved rarely opted for a proportional rule of burden sharing but picked one of the two progressive schemes instead. However, there were differences between countries with respect to the frequencies of these three rules, whereby Greece and Ireland were polar cases. The other rules received only minor support.
SERIEs

Reitmeir, P.; Linkohr, B.°; Heier, M.; Molnos, S.; Strobl, R.; Schulz, H.; Breier, M.; Faus-Kessler, T.; Küster, D.M.; Wulff, A.; Grallert, H.; Grill, E.; Peters, A.; Graw, J.°
Common eye diseases in older adults of Southern Germany: Results from the KORA-Age Study.
Age Ageing 46, 481-486 (2017)
Purpose a population-based study in the region of Augsburg (Germany, KORA) was used to identify the prevalence of eye diseases and their risk factors in a sample of aged individuals. Methods data originated from the KORA-Age study collected in 2012 and 822 participants (49.6% women, 50.4% men, aged 68–96 years) were asked standardised questions about eye diseases. Positive answers were validated and specified by treating ophthalmologists. Additional information came from laboratory data. Polymorphic markers were tested for candidate genes. Results we received validations and specifications for 339 participants. The most frequent eye diseases were cataracts (299 cases, 36%), dry eyes (120 cases, 15%), glaucoma (72

cases, 9%) and age-related macular degeneration (AMD) (68 cases, 8%). Almost all participants suffering from glaucoma or from AMD also had cataracts. Cataract surgery was associated with diabetes (in men; OR = 2.24; 95% confidence interval [CI] 1.11–4.53; P = 0.025) and smoking (in women; OR = 6.77; CI 1.62–28.35; P = 0.009). In men, treatments in airway diseases was associated with cataracts (glucocorticoids: OR = 5.29, CI 1.20–23.37; P = 0.028; sympathomimetics: OR = 4.57, CI 1.39–15.00; P = 0.012). Polymorphisms in two genes were associated with AMD (ARMS2: OR = 2.28, CI 1.48–3.51; P = 0.005; CFH: OR = 2.03, CI 1.35–3.06; P = 0.010). Conclusion combinations of eye diseases were frequent at old age. The importance of classical risk factors like diabetes, hypertension and airway diseases decreased either due to a survivor bias leaving healthier survivors in the older age group, or due to an increased influence of other up to now unknown risk factors.
Age and Ageing

Seyednasrollah, F.; Köstler, D.C.; Wang, T.; Piccolo, S.R.; Vega, R.; Greiner, R.; Fuchs, C.; Gofer, E.; Kumar, L.; Wolfinger, R.D.; Kanigel-Winner, K.; Bare, C.; Neto, E.C.; Yu, T.; Shen, L.; Abdallah, K.; Norman, T.; Stolovitzky, G.; Soule, H.; Sweeney, C.J.; Ryan, C.J.; Scher, H.I.; Sartor, O,; Elo, L.L.; Zhou, F.L.; Guinney, J.; Costello, J.C.; Prostate Cancer Challenge DREAM Community (Kondofersky, I.; Krautenbacher, N.; Laimighofer, M.; Scherb, H.; Söllner, J.F.; Kurz, C.F.)
A DREAM challenge to build prediction models for short-term discontinuation of docetaxel in metastatic castration-resistant prostate cancer.
JCO Clin. Can. Inform. 1, 1-15 (2017)
Background: Docetaxel has a demonstrated survival benefit for metastatic castration-resistant prostate cancer (mCRPC). However, 10-20% of patients discontinue docetaxel prematurely because of toxicity-induced adverse events, and managing risk factors for toxicity remains an ongoing challenge for health care providers and patients. Prospective identification of high-risk patients for early discontinuation has the potential to assist clinical decision-making and can improve the design of more efficient clinical trials. In partnership with Project Data Sphere (PDS), a non-profit initiative facilitating clinical trial data-sharing, we designed an open-data, crowdsourced DREAM (Dialogue for Reverse Engineering Assessments and Methods) Challenge for developing models to predict early discontinuation of docetaxel. Methods: Data from the comparator arms of four phase III clinical trials in first-line mCRPC were obtained from PDS, including 476 patients treated with docetaxel and prednisone from the ASCENT2 trial, 598 patients treated with docetaxel, prednisone/prednisolone, and placebo in the VENICE trial, 526 patients treated with docetaxel, prednisone, and placebo in the MAINSAIL trial, and 528 patients treated with docetaxel and placebo in the ENTHUSE 33 trial. Early discontinuation was defined as treatment stoppage within three months due to adverse treatment effects. Over 150 clinical features including laboratory values, medical history, lesion measures, prior treatment, and demographic variables were curated and made freely available for model building for all four trials. The ASCENT2, VENICE, and MAINSAIL trial data sets formed the training set that also included patient discontinuation status. The ENTHUSE 33 trial, with patient discontinuation status hidden, was used as an independent validation set to evaluate model performance. Prediction performance was assessed using area under the precision-recall curve (AUPRC) and the Bayes factor was used to compare the performance between prediction models. Results: The frequency of early discontinuation was similar between training (ASCENT2, VENICE, and MAINSAIL) and validation (ENTHUSE 33) sets, 12.3% versus 10.4% of docetaxel-treated patients, respectively. In total, 34 independent teams submitted predictions from 61 different models. AUPRC ranged from 0.088 to 0.178 across submissions with a random model performance of 0.104. Seven models with comparable AUPRC scores (Bayes factor ≤ 3) were observed to outperform all other models. A post-challenge analysis of risk predictions generated by these seven models revealed three distinct patient subgroups: patients consistently predicted to be at high-risk or low-risk for early discontinuation and those with discordant risk predictions. Early discontinuation events were two-times higher in the high- versus low-risk subgroup and baseline clinical features such as presence/absence of metastatic liver lesions, and prior treatment with analgesics and ACE inhibitors exhibited statistically significant differences between the high- and low-risk subgroups (adjusted P < 0.05). An ensemble-based model constructed from a post-Challenge community collaboration resulted in the best overall prediction performance (AUPRC = 0.230) and represented a marked improvement over any individual Challenge submission. Findings: Our results demonstrate that routinely collected clinical features can be used to prospectively inform clinicians of mCRPC patients' risk to discontinue docetaxel treatment early due to adverse events and to the best of our knowledge is the first to establish performance benchmarks in this area. This work also underscores the "wisdom of crowds" approach by demonstrating that improved prediction of patient outcomes is obtainable by combining methods across an extended community. These findings were made possible because data from separate trials were made publicly available and centrally compiled through PDS.
JCO Clinical Cancer Informatics

Guinney, J.; Wang, T.; Laajala, T.D.; Kanigel-Winner, K.; Bare, C.; Neto, E.C.; Khan, S.; Peddinti, K.; Airola, A.; Pahikkala, T.; Mirtti, T.; Yu, T.; Bot, B.M.; Shen, L.; Abdallah, K.; Norman, T.; Friend, S.; Stolovitzky, G.; Soule, H.; Sweeney, C.J.; Ryan, C.J.; Scher, H.I.; Sartor, O,; Xie, Y.; Aittokallio, T.; Zhou, F.L.; Costello, J.C.; Prostate Cancer Challenge DREAM Community (Kondofersky, I.; Krautenbacher, N.; Laimighofer, M.; Scherb, H.; Kurz, C.F.; Fuchs, C.; Söllner, J.)
Prediction of overall survival for patients with metastatic castration-resistant prostate cancer: Development of a prognostic model through a crowdsourced challenge with open clinical trial data.
Lancet Oncol. 18, 132-142 (2017)
Background Improvements to prognostic models in metastatic castration-resistant prostate cancer have the potential to augment clinical trial design and guide treatment strategies. In partnership with Project Data Sphere, a not-for-profit initiative allowing data from cancer clinical trials to be shared broadly with researchers, we designed an open-data, crowdsourced, DREAM (Dialogue for Reverse Engineering Assessments and Methods) challenge to not only identify a better prognostic model for prediction of survival in patients with metastatic castration-resistant prostate cancer but also engage a community of international data scientists to study this disease. Methods Data from the comparator arms of four phase 3 clinical trials in first-line metastatic castration-resistant prostate cancer were obtained from Project Data Sphere, comprising 476 patients

treated with docetaxel and prednisone from the ASCENT2 trial, 526 patients treated with docetaxel, prednisone, and placebo in the MAINSAIL trial, 598 patients treated with docetaxel, prednisone or prednisolone, and placebo in the VENICE trial, and 470 patients treated with docetaxel and placebo in the ENTHUSE 33 trial. Datasets consisting of more than 150 clinical variables were curated centrally, including demographics, laboratory values, medical history, lesion sites, and previous treatments. Data from ASCENT2, MAINSAIL, and VENICE were released publicly to be used as training data to predict the outcome of interest—namely, overall survival. Clinical data were also released for ENTHUSE 33, but data for outcome variables (overall survival and event status) were hidden from the challenge participants so that ENTHUSE 33 could be used for independent validation. Methods were evaluated using the integrated time-dependent area under the curve (iAUC). The reference model, based on eight clinical variables and a penalised Cox proportional-hazards model, was used to compare method performance. Further validation was done using data from a fifth trial—ENTHUSE M1—in which 266 patients with metastatic castration-resistant prostate cancer were treated with placebo alone. Findings 50 independent methods were developed to predict overall survival and were evaluated through the DREAM challenge. The top performer was based on an ensemble of penalised Cox regression models (ePCR), which uniquely identified predictive interaction effects with immune biomarkers and markers of hepatic and renal function. Overall, ePCR outperformed all other methods (iAUC 0·791; Bayes factor >5) and surpassed the reference model (iAUC 0·743; Bayes factor >20). Both the ePCR model and reference models stratified patients in the ENTHUSE 33 trial into high-risk and low-risk groups with significantly different overall survival (ePCR: hazard ratio 3·32, 95% CI 2·39–4·62, p<0·0001; reference model: 2·56, 1·85–3·53, p<0·0001). The new model was validated further on the ENTHUSE M1 cohort with similarly high performance (iAUC 0·768). Meta-analysis across all methods confirmed previously identified predictive clinical variables and revealed aspartate aminotransferase as an important, albeit previously under-reported, prognostic biomarker. Interpretation Novel prognostic factors were delineated, and the assessment of 50 methods developed by independent international teams establishes a benchmark for development of methods in the future. The results of this effort show that data-sharing, when combined with a crowdsourced challenge, is a robust and powerful framework to develop new prognostic models in advanced prostate cancer. Funding Sanofi US Services, Project Data Sphere.
Lancet Oncology, The

Houben-Wilke, S.; Jörres, R.A.; Bals, R.; Franssen, F.M.; Gläser, S.; Holle, R.; Karch, A.; Koch, A.; Magnussen, H.; Obst, A.; Schulz, H.; Spruit, M.A.; Wacker, M.; Welte, T.; Wouters, E.F.; Vogelmeier, C.; Watz, H.
Peripheral artery disease and its clinical relevance in patients with chronic obstructive pulmonary disease in the COPD and systemic consequences-comorbidities network study.
Am. J. Respir. Crit. Care Med. 195, 189-197 (2017)
RATIONALE: Knowledge about the prevalence of objectively assessed peripheral artery disease (PAD) and its clinical relevance in patients with COPD is scarce. OBJECTIVES: We aimed (1) to assess the prevalence of PAD in COPD compared to distinct control groups and (2) to study the association between PAD and functional capacity as well as health status. METHODS: The ankle-brachial index (ABI) was used to diagnose PAD (ABI≤0.9). 6-Minute-Walk-Distance (6MWD), health status (St. George's Respiratory Questionnaire [SGRQ]), COPD Assessment Test [CAT] and EuroQol-5-Dimensions [EQ-5D-3L] were assessed in patients enrolled in the German COPD and Systemic Consequences-Comorbidities Network (COSYCONET) cohort study. Control groups were derived from the Study of Health in Pomerania (SHIP). MEASUREMENTS AND MAIN RESULTS: 2,088 patients with COPD (61.1% male, mean [SD] age 65.3 [8.2] years GOLD stage I,II,III,IV: 9.4%,42.5%,37.5%,10.5%, respectively) were included. 184 patients (8.8%; GOLD stage I,II,III,IV: 5.1%,7.4%,11.1%,9.5%, respectively, versus 5.9% in patients with GOLD stage 0 in COSYCONET) had PAD. In SHIP, PAD ranged from 1.8% to 4.2%. COPD patients with PAD had a significantly shorter 6MWD (356 [108] vs 422 [103] m, p<0.001) and worse health status (SGRQ: 49.7 [20.1] vs 42.7 [20.0] points, p<0.001, CAT: 19.6 [7.4] vs 17.9 [7.4] points, p=0.004, EQ-5D VAS: 51.2 (19.0) vs 7.2 (19.6), p<0.001). Differences remained significant after correction for several confounders. CONCLUSIONS: In a large cohort of patients with COPD, 8.8% were diagnosed with PAD which is higher than the prevalence in non-COPD controls. PAD was associated with a clinically relevant reduction in functional capacity and health status.
American Journal of Respiratory and Critical Care Medicine

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Bozorgmehr, K.; Razum, O.; Szecsenyi, J.; Maier, W.; Stock, C.
Multiple deprivation and distribution of vulnerable asylum-seekers: A small-area analysis in Germany.
Eur. J. Public Health 26, 1 (2016)
European Journal of Public Health
Meeting abstract

Danner, M.; Müller, D.; Schmutzler, R.K.; Rhiem, K.; Engel, C.; Stollenwerk, B.; Stock, S.; Wassermann, K.

Economic modeling of risk-adapted screen-and-treat strategies in women at high-risk for breast or ovarian cancer.
Value Health 19, A737-A738 (2016)
Value in Health
Meeting abstract

Szentes, B.L.; Witt, S.; Bush, A.; Cunningham, S.; Emiraliouglu, N.; Goldbeck, L.; Griese, M.; Hengst, M.; Kiper, N.; Krenke, K.; Lange, J.; Leidl, R.; Schwerk, N.; Schwarzkopf, L.
Current practice of drug treatment in children with ILD: First insights from the child-EU registry.
Value Health 19, A558-A558 (2016)
Value in Health
Meeting abstract

Leidl, R.; Reitmeir, P.
Analyzing a German index for the EQ-5D-5L based on experienced health.
Value Health 19, A386-A386 (2016)
Value in Health
Meeting abstract

Yates, N.; Teuner, C.M.; Hunger, M.; Holle, R.; Stark, R.G.; Laxy, M.; Hauner, H.; Peters, A.; Wolfenstetter, S.B.
The economic burden of obesity in Germany: Results from the population-based KORA studies.
Obes. Facts 9, 397-409 (2016)
Objective: To estimate the excess costs of obese compared to normal-weight persons in Germany based on self-reported resource utilisation and work absence. Methods: Five cross sectional surveys of cohort studies in southern Germany were pooled resulting in 9,070 observations for 6,731 individuals (31-96 years). BMI was measured in the study centre. Self-reported health care utilisation and work absence was used to estimate direct and indirect costs for the year 2011 based on unit costs. Using regression analyses, adjusted costs for different BMI groups were calculated. Results: Overweight and obese people showed significantly higher odds of health care utilisation and productivity losses compared with normal-weight people in most categories. Total direct/indirect costs were significantly higher with increasing severity of obesity (pre-obese (1.05 (0.90-1.23) / 1.38 (1.11-1.71)), obesity level I (1.18 (1.00-1.39) / 1.33 (1.02-1.73)), obesity level II (1.46 (1.14-1.87) / 1.77 (1.18-2.65)) or level III (2.04 (1.40-2.97) / 1.99 (1.20-3.30)) compared to normal-weight participants. In particular, higher obesity classes were significantly associated with increased costs for medication, general practitioner utilisation and work absence. Conclusion: Our results show that overweight and obesity are associated with enormous societal direct and indirect costs in Germany. This supports the evidence from previous top-down studies, but provides important new information based on a large pooled data set and measured BMI.
Obesity Facts

Wacker, M.E.; Jörres, R.A.; Schulz, H.; Heinrich, J.; Karrasch, S.; Karch, A.; Koch, A.; Leidl, R.; Vogelmeier, C.; Holle, R.
How do symptoms and comorbidities affect healthcare costs in patients with COPD? Results from the new German cosyconet cohort.
Am. J. Respir. Crit. Care Med. 193 (2016)
American Journal of Respiratory and Critical Care Medicine
Meeting abstract

Krack, G.; Zeidler, H.; Zeidler, J.
Claims data analysis of tumor necrosis factor inhibitor treatment dosing among patients with rheumatoid arthritis: A systematic review of methods.
Drugs Real World Outcomes 3, 265-278 (2016)
Background With tumor necrosis factor inhibitors, changes of dosing, switching between drugs, insufficient adherence, and persistence are frequent in rheumatoid arthritis. Because this is often associated with decreased efficiency and increased costs, dosage analyses based on claims data are of increasing interest for healthcare providers and payers. Nevertheless, no standardized methods exist to ensure high-quality research. Objective In this review, we compare and discuss applied methods in claims data-based dosage analyses of tumor necrosis factor inhibitor prescriptions in patients with rheumatoid arthritis. Methods A systematic review was performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement. The dosage analysis methods performed within the selected studies were classified into switching, persistence, adherence, and dosage-change analyses, and were then compared and finally discussed. Results A total of 45 studies were found to be relevant. In most studies, a change in dose or persistence was evaluated, followed by switching and adherence analyses. Analyses of changed dose exhibit the most extensive variation of methods. We divided them into three principal methods, where a specified reference dose is compared with (1) the last dose, (2) any dose, or (3) all doses. Conclusion The systematic review identified a high variation of methods. Our results may be helpful for choosing appropriate methods in future studies. The results also demonstrate the need for evidence-based recommendations of methods used in claims data research.
Drugs - real world outcomes

Kurz, C.F.
Survival prediction with limited features: A top performing approach from the DREAM ALS Stratification Prize4Life challenge.
In: (30th Conference on Neural Information Processing Systems (NIPS 2016), Barcelona Spain). 2016.
Survival prediction with small sets of features is a highly relevant topic for decision-making in clinical practice. I describe a method for predicting survival of amyotrophic lateral sclerosis (ALS) patients that was developed as a submission to the DREAM ALS Stratification Prize4Life Challenge held in summer 2015 to find the most accurate prediction of ALS progression and survival. ALS is a neurodegenerative disease with very heterogeneous survival times. Based on patient data from two national registries, solvers were asked to predict survival for three different time intervals, which was then evaluated on undisclosed information from additional data. I describe methods used to generate new features from existing ones from longitudinal data, selecting the most predictive features, and developing the best survival model. I show that easily obtainable engineered features can significantly improve prediction and could be incorporated into clinical practice. Furthermore, my prediction model confirms previous reports suggesting that past disease progression measured by the ALSFRS (ALS functional rating scale score), time since disease onset, onset site, and age are strong predictors for survival. Regarding prediction accuracy, this approach ranked second.

Arvandi, M.; Strasser, B.; Meisinger, C.; Volaklis, K.A.; Matteucci Gothe, R.; Siebert, U.; Ladwig, K.-H.; Grill, E.; Horsch, A.; Laxy, M.; Peters, A.; Thorand, B.
Gender differences in the association between grip strength and mortality in older adults: Results from the KORA-age study.
BMC Geriatr. 16:201 (2016)
Background Reduced muscular strength in the old age is strongly related to activity impairment and mortality. However, studies evaluating the gender-specific association between muscularity and mortality among older adults are lacking. Thus, the objective of the present study was to examine gender differences in the association between muscular strength and mortality in a prospective population-based cohort study. Methods Data used in this study derived from the Cooperative Health Research in the Region of Augsburg (KORA)-Age Study. The present analysis includes 1,066 individuals (mean age 76 ± 11 SD years) followed up over 3 years. Handgrip strength was measured using the Jamar Dynamometer. A Cox proportional hazard model was used to determine adjusted hazard ratios of mortality with 95% confidence intervals (95% CI) for handgrip strength. Potential confounders (i.e. age, nutritional status, number of prescribed drugs, diseases and level of physical activity) were pre-selected according to evidence-based information. Results During the follow-up period, 56 men (11%) and 39 women (7%) died. Age-adjusted mortality rates per 1,000 person years (95% CI) were 77 (59–106), 24 (13–41) and 14 (7–30) for men and 57 (39–81), 14 (7–27) and 1 (0–19) for women for the first, second and third sex-specific tertile of muscular strength, respectively. Low handgrip strength was significantly associated with all-cause mortality among older men and women from the general population after controlling for significant confounders. Hazard ratios (95% CI) comparing the first and second tertile to the third tertle were 3.33 (1.53–7.22) and 1.42 (0.61-3.28), respectively. Respective hazard ratios (95% CI) for mortality were higher in women than in men ((5.23 (0.67–40.91) and 2.17 (0.27–17.68) versus 2.36 (0.97–5.75) and 0.97 (0.36–2.57)). Conclusions Grip strength is inversely associated with mortality risk in older adults, and this association is independent of age, nutritional status, number of prescribed drugs, number of chronic diseases and level of physical activity. The association between muscular strength and all-cause mortality tended to be stronger in women. It seems to be particularly important for the weakest to enhance their levels of muscular strength in order to reduce the risk of dying early.
BMC Geriatrics

Ulrich, S.; Holle, R.; Wacker, M.; Stark, R.; Icks, A.; Thorand, B.; Peters, A.; Laxy, M.
The cost burden of type 2 diabetes in Germany – Results from the population-based KORA Studies.
BMJ Open 6:e012527 (2016)
Objective To examine the impact of type 2 diabetes on direct and indirect costs and to describe the effect of relevant diabetes-related factors, such as type of treatment or glycaemic control on direct costs. Design Bottom-up excess cost analysis from a societal perspective based on population-based survey data. Participants 9160 observations from 6803 individuals aged 31–96 years (9.6% with type 2 diabetes) from the population-based KORA (Cooperative Health Research in the Region of Augsburg) studies in Southern Germany. Outcome measures Healthcare usage, productivity losses, and resulting direct and indirect costs. Methods Information on diabetes status, biomedical/sociodemographic variables, medical history and on healthcare usage and productivity losses was assessed in standardised interviews and examinations. Healthcare usage and productivity losses were costed with reference to unit prices and excess costs of type 2 diabetes were calculated using generalised linear models. Results Individuals with type 2 diabetes had 1.81 (95% CI 1.56 to 2.11) times higher direct (€3352 vs €1849) and 2.07 (1.51 to 2.84) times higher indirect (€4103 vs €1981) annual costs than those without diabetes. Cardiovascular complications, a long diabetes duration and treatment with insulin were significantly associated with increased direct costs; however, glycaemic control was only weakly insignificantly associated with costs. Conclusions This study illustrates the substantial direct and indirect societal cost burden of type 2 diabetes in Germany. Strong effort is needed to optimise care to avoid progression of the disease and costly complications.
BMJ Open

Sauer, S.; Buettner, R.; Heidenreich, T.; Lemke, J.R.; Berg, C.; Kurz, C.F.
Mindful machine learning. Using machine learning algorithms to predict the practice of mindfulness.
Eur. J. Psy. Ass., DOI: 10.1027/1015-5759/a000312 (2016)
Mindfulness refers to a stance of nonjudgmental awareness of present-moment experiences. A growing body of research suggests that mindfulness may increase cognitive resources, thereby buffering stress. However, existing models have not achieved a consensus on how mindfulness should be operationalized. As the sound measurement of mindfulness is the foundation needed before substantial hypotheses can be supported, we propose a novel way of gauging the psychometric quality of a mindfulness measurement instrument (the Freiburg Mindfulness Inventory; FMI). Specifically, we employed 10 predictive algorithms to scrutinize the measurement quality of the FMI. Our criterion of measurement quality was the degree to which an algorithm separated mindfulness practitioner from nonpractitioners in a sample of N = 276. A high predictive accuracy of class membership can be taken as an indicator of the psychometric quality of the instrument. In sum, two findings are of interest. First, over and above some items of the FMI were able to reliably predict class membership. However, some items appeared to be uninformative. Second, from an applied methodological point of view, it appears that machine learning algorithms can outperform traditional predictive methods such as logistic regression. This finding may generalize to other branches of research.
European journal of psychological assessment

Brandes, A.; Koerber, F.; Schwarzkopf, L.; Hunger, M.; Rogowski, W.H.; Waidelich, R.
Costs of conservative management of early-stage prostate cancer compared to radical prostatectomy-a claims data analysis.
BMC Health Serv. Res. 16:664 (2016)
Background: Due to widespread PSA testing incidence rates of localized prostate cancer increase but curative treatment is often not required. Overtreatment imposes a substantial economic burden on health care systems. We compared the direct medical costs of conservative management and radical therapy for the management of early-stage prostate cancer in routine care. Methods: An observational study design is chosen based on

claims data of a German statutory health insurance fund for the years 2008-2011. Three hundred fifty-three age-matched men diagnosed with prostate cancer and treated with conservative management and radical prostatectomy, are included. Individuals with diagnoses of metastases or treatment of advanced prostate cancer are excluded. In an excess cost approach direct medical costs are considered from an insured community perspective for in- and outpatient care, pharmaceuticals, physiotherapy, and assistive technologies. Generalized linear models adjust for comorbidity by Charlson comorbidity score and recycled predictions method calculates per capita costs per treatment strategy. Results: After follow-up of 2.5 years per capita costs of conservative management are €6611 lower than costs of prostatectomy ([−9734;−3547], $p < 0.0001$). Complications increase costs of assistive technologies by 30% ($p = 0.0182$), but do not influence any other costs. Results are robust to cost outliers and incidence of prostate cancer diagnosis. The short time horizon does not allow assessing long-term consequences of conservative management. Conclusions: At a time horizon of 2.5 years, conservative management is preferable to radical prostatectomy in terms of costs. Claims data analysis is limited in the selection of comparable treatment groups, as clinical information is scarce and bias due to non-randomization can only be partly mitigated by matching and confounder adjustment.
BMC Health Services Research

Kondofersky, I.; Laimighofer, M.; Kurz, C.F.; Krautenbacher, N.; Söllner, J.F.; Dargatz, P.; Scherb, H.; Ankerst, D.P.; Fuchs, C.
Three general concepts to improve risk prediction: Good data, wisdom of the crowd, recalibration.
F1000 Res. 5:2671 (2016)
In today's information age, the necessary means exist for clinical risk prediction to capitalize on a multitude of data sources, increasing the potential for greater accuracy and improved patient care. Towards this objective, the Prostate Cancer DREAM Challenge posted comprehensive information from three clinical trials recording survival for patients with metastatic castration-resistant prostate cancer treated with first-line docetaxel. A subset of an independent clinical trial was used for interim evaluation of model submissions, providing critical feedback to participating teams for tailoring their models to the desired target. Final submitted models were evaluated and ranked on the independent clinical trial. Our team, called "A Bavarian Dream", utilized many of the common statistical methods for data dimension reduction and summarization during the trial. Three general modeling principles emerged that were deemed helpful for building accurate risk prediction tools and ending up among the winning teams of both sub-challenges. These principles included: first, good data, encompassing the collection of important variables and imputation of missing data; second, wisdom of the crowd, extending beyond the usual model ensemble notion to the inclusion of experts on specific risk ranges; and third, recalibration, entailing transfer learning to the target source. In this study, we illustrate the application and impact of these principles applied to data from the Prostate Cancer DREAM Challenge.
Faculty of 1000 Research

Mielck, A.
Suche nach der „Regel“ oder Suche nach der „Ausnahme“? Über das Selbstverständnis der sozial-epidemiologischen Forschung.
In: Normative Aspekte von Public Health. 2016. 173-178 (; 55)
Mielck, A.; Kilian, H.; Lehmann, F
Interventionen zur Verringerung der gesundheitlichen Ungleichheit. Der kommunale Partnerprozess „Gesundheit für alle“.
In: Normative Aspekte von Public Health. 2016. 75-90 (; 55)
Mielck, A.
Welches Argument wird von welcher sozialen Gruppe betont, und warum?
In: Normative Aspekte von Public Health. 2016. 65-70 (; 55)
Lucke, T.; Herrera, M.; Wacker, M.; Holle, R.; Biertz, F.; Nowak, D.; Huber, R.; Söhler, S.; Vogelmeier, C.; Ficker, J.H.; Mückter, H.; Jörres, R.A.
Systematic analysis of self-reported comorbidities in large cohort studies - A novel stepwise approach by evaluation of medication.
PLoS ONE 11:e0163408 (2016)
Objective In large cohort studies comorbidities are usually self-reported by the patients. This way to collect health information only represents conditions known, memorized and openly reported by the patients. Several studies addressed the relationship between self-reported comorbidities and medical records or pharmacy data, but none of them provided a structured, documented method of evaluation. We thus developed a detailed procedure to compare self-reported comorbidities with information on comorbidities derived from medication inspection. This was applied to the data of the German COPD cohort COSYCONET. Methods Approach I was based solely on ICD10-Codes for the diseases and the indications of medications. To overcome the limitations due to potential non-specificity of medications, Approach II was developed using more detailed information, such as ATC-Codes specific for one disease. The relationship between reported comorbidities and medication was expressed by a four-level concordance score. Results Approaches I and II demonstrated that the patterns of concordance scores markedly differed between comorbidities in the COSYCONET data. On average, Approach I resulted in more than 50% concordance of all reported diseases to at least one medication. The more specific Approach II showed larger differences in the matching with medications, due to large differences in the disease-specificity of drugs. The highest concordance was achieved for diabetes and three combined cardiovascular disorders, while it was substantial for dyslipidemia and hyperuricemia, and low for asthma. Conclusion Both approaches represent feasible strategies to confirm self-reported diagnoses via medication. Approach I covers a broad spectrum of diseases and medications but is limited regarding disease-specificity. Approach II uses the information from medications specific for a single disease and therefore can reach higher concordance scores. The strategies described in a detailed and reproducible manner are generally applicable in large studies and might be useful to extract as much information as possible from the available data.
PLoS ONE

Safita, N.; Islam, S.M.S.; Chow, C.K.; Niessen, L.W.; Lechner, A.; Holle, R.; Laxy, M.
The impact of type 2 diabetes on health related quality of life in Bangladesh: Results from a matched study comparing treated cases with non-diabetic controls.

Health Qual. Life Outcomes 14:129 (2016)
Background: Little is known about the association between diabetes and health related quality of life (HRQL) in lower-middle income countries. This study aimed to investigate HRQL among individuals with and without diabetes in Bangladesh. Methods: The analysis is based on data of a case-control study, including 591 patients with type 2 diabetes (cases) who attended an outpatient unit of a hospital in Dhaka and 591 age -and sex-matched individuals without diabetes (controls). Information about socio-demographic characteristics, health conditions, and HRQL were assessed in a structured interview. HRQL was measured with the EuroQol (EQ) visual analogue scale (VAS) and the EQ five-dimensional (5D) descriptive system. The association between diabetes status and quality of life was examined using multiple linear and logistic regression models. Results: Mean EQ-VAS score of patients with diabetes was 11.5 points lower (95 %-CI: -13.5, -9.6) compared to controls without diabetes. Patients with diabetes were more likely to report problems in all EQ-5D dimensions than controls, with the largest effect observed in the dimensions 'self-care' (OR = 5.9; 95 %-CI: 2.9, 11.8) and 'mobility' (OR = 4. 5; 95 %-CI: 3.0, -6.6). In patients with diabetes, male gender, high education, and high-income were associated with higher VAS score and diabetes duration and foot ulcer associated with lower VAS scores. Other diabetes-related complications were not significantly associated with HRQL. Conclusions: Our findings suggest that the impact of diabetes on HRQL in the Bangladeshi population is much higher than what is known from western populations and that unlike in western populations comorbidities/complications are not the driving factor for this effect.
Health and Quality of Life Outcomes

Laxy, M.; Knoll, G.; Schunk, M.; Meisinger, C.; Huth, C.; Holle, R.
Quality of diabetes care in Germany improved from 2000 to 2007 to 2014, but improvements diminished since 2007. Evidence from the population-based KORA Studies.
PLoS ONE 11:e0164704 (2016)
OBJECTIVE: Little is known about the development of the quality of diabetes care in Germany. The aim of this study is to analyze time trends in patient self-management, physician-delivered care, medication, risk factor control, complications and quality of life from 2000 to 2014. METHODS: Analyses are based on data from individuals with type 2 diabetes of the population-based KORA S4 (1999-2001, n = 150), F4 (2006-2008, n = 203), FF4 (2013/14, n = 212) cohort study. Information on patient self-management, physician-delivered care, medication, risk factor control and quality of life were assessed in standardized questionnaires and examinations. The 10-year coronary heart disease (CHD) risk was calculated using the UKPDS risk engine. Time trends were analyzed using multivariable linear and logistic regression models adjusted for age, sex, education, diabetes duration, and history of cardiovascular disease. RESULTS: From 2000 to 2014 the proportion of participants with type 2 diabetes receiving oral antidiabetic/cardio-protective medication and of those reaching treatment goals for glycemic control (HbA1c<7%, 60% to 71%, p = 0.09), blood pressure (<140/80 mmHg, 25% to 69%, p<0.001) and LDL cholesterol (<2.6 mmol/l, 13% to 27%, p<0.001) increased significantly. However, improvements were generally smaller from 2007 to 2014 than from 2000 to 2007. Modeled 10-year CHD risk decreased from 30% in 2000 to 24% in 2007 to 19% in 2014 (p<0.01). From 2007 to 2014, the prevalence of microvascular complications decreased and quality of life increased, but no improvements were observed for the majority of indicators of self-management. CONCLUSION: Despite improvements, medication and risk factor control has remained suboptimal. The flattening of improvements and deteriorations in quality of (self-) care since 2007 indicate that more effort is needed to improve quality of care and patient self-management. Due to selection or lead time bias an overestimation of quality of care improvements cannot be ruled out.
PLoS ONE

Kirsch, F.
Economic evaluations of multicomponent disease management programs with Markov models: A systematic review.
Value Health 19, 1039-1054 (2016)
Abstract Background Disease management programs (DMPs) for chronic diseases are being increasingly implemented worldwide. Objectives To present a systematic overview of the economic effects of DMPs with Markov models. The quality of the models is assessed, the method by which the DMP intervention is incorporated into the model is examined, and the differences in the structure and data used in the models are considered. Methods A literature search was conducted; the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement was followed to ensure systematic selection of the articles. Study characteristics e.g. results, the intensity of the DMP and usual care, model design, time horizon, discount rates, utility measures, and cost-of-illness were extracted from the reviewed studies. Model quality was assessed by two researchers with two different appraisals: one proposed by Philips et al. (Good practice guidelines for decision-analytic modelling in health technology assessment: a review and consolidation of quality asessment. Pharmacoeconomics 2006;24:355-71) and the other proposed by Caro et al. (Questionnaire to assess relevance and credibility of modeling studies for informing health care decision making: an ISPOR-AMCP-NPC Good Practice Task Force report. Value Health 2014;17:174-82). Results A total of 16 studies (9 on chronic heart disease, 2 on asthma, and 5 on diabetes) met the inclusion criteria. Five studies reported cost savings and 11 studies reported additional costs. In the quality, the overall score of the models ranged from 39% to 65%, it ranged from 34% to 52%. Eleven models integrated effectiveness derived from a clinical trial or a meta-analysis of complete DMPs and only five models combined intervention effects from different sources into a DMP. The main limitations of the models are bad reporting practice and the variation in the selection of input parameters. Conclusions Eleven of the 14 studies reported cost-effectiveness results of less than $30,000 per quality-adjusted life-year and the remaining two studies less than $30,000 per life-year gained. Nevertheless, if the reporting and selection of data problems are addressed, then Markov models should provide more reliable information for decision makers, because understanding under what circumstances a DMP is cost-effective is an important determinant of efficient resource allocation.
Value in Health

Chen, B.H.; Marioni, R.E.; Colicino, E.; Peters, M.J.; Ward-Caviness, C.K.; Tsai, P.C.; Roetker, N.S.; Just, A.C.; Demerath, E.W.; Guan, W.; Bressler, J.; Fornage, M.; Studenski, S.; Vandiver, A.R.; Moore, A.Z.; Tanaka, T.; Kiel, D.P.; Liang, L.; Vokonas, P.; Schwartz, J.; Lunetta, K.L.; Murabito, J.M.;

Bandinelli, S.; Hernandez, D.G.; Melzer, D.; Nalls, M.; Pilling, L.C.; Price, T.R.; Singleton, A.B.; Gieger, C.; Holle, R.; Kretschmer, A.; Kronenberg, F.; Kunze, S.; Linseisen, J.; Meisinger, C.; Rathmann, W.G.; Waldenberger, M.; Visscher, P.M.; Shah, S.; Wray, N.R.; McRae, A.F.; Franco, O.H.; Hofman, A.; Uitterlinden, A.G.; Absher, D.; Assimes, T.L.; Levine, M.E.; Lu, A.T.; Tsao, P.S.; Hou, L.; Manson, J.E.; Carty, C.L.; LaCroix, A.Z.; Reiner, A.P.; Spector, T.D.; Feinberg, A.P.; Levy, D.; Baccarelli, A.; van Meurs, J.B.; Bell, J.T.; Peters, A.; Deary, I.J.; Pankow, J.S.; Ferrucci, L.; Horvath, S.
DNA methylation-based measures of biological age: Meta-analysis predicting time to death.
Aging 8, 1844-1865 (2016)
Estimates of biological age based on DNA methylation patterns, often referred to as "epigenetic age", "DNAm age", have been shown to be robust biomarkers of age in humans. We previously demonstrated that independent of chronological age, epigenetic age assessed in blood predicted all-cause mortality in four human cohorts. Here, we expanded our original observation to 13 different cohorts for a total sample size of 13,089 individuals, including three racial/ethnic groups. In addition, we examined whether incorporating information on blood cell composition into the epigenetic age metrics improves their predictive power for mortality. All considered measures of epigenetic age acceleration were predictive of mortality (p≤8.2x10(-9)), independent of chronological age, even after adjusting for additional risk factors (p<5.4x10(-4)), and within the racial/ethnic groups that we examined (non-Hispanic whites, Hispanics, African Americans). Epigenetic age estimates that incorporated information on blood cell composition led to the smallest p-values for time to death (p=7.5x10(-43)). Overall, this study a) strengthens the evidence that epigenetic age predicts all-cause mortality above and beyond chronological age and traditional risk factors, and b) demonstrates that epigenetic age estimates that incorporate information on blood cell counts lead to highly significant associations with all-cause mortality.
Aging

Maier, W.; Schwarzkopf, L.
Methodenworkshop der AGENS 2016: Routinedatenforscher tagen in München.
Gesundheitswesen 78, S. 353 (2016)
Gesundheitswesen, Das
Sonstiges: Nachrichtenmeldung
Other: News Item
Abbas, S.; Ihle, P.; Adler, J.B.; Engel, S.; Günster, C.; Holtmann, M.; Kortevoss, A.; Linder, R.; Maier, W.; Lehmkuhl, G.; Schubert, I.
Predictors of non-drug psychiatric/psychotherapeutic treatment in children and adolescents with mental or behavioural disorders.
Eur. Child Adolesc. Psych. 26, 433–444 (2016)
Children and adolescents with mental health problems need effective and safe therapies to support their emotional and social development and to avoid functional impairment and progress of social deficits. Though psychotropic drugs seem to be the preferential treatment, psychotherapy and psychosocial interventions are essential in mental health care. For Germany, current data on the utilization of psychotherapy and psychosocial interventions in children with mental health problems is lacking. To analyse why certain children and adolescents with mental or behavioural disorders do and others do not receive non-drug treatment, we assessed predictors associated with specific non-drug psychiatric/psychotherapeutic treatment including psychosocial interventions, psychotherapy and other non-drug treatments. The study is based on data of two large German health insurance funds, AOK and TK, comprising 30 % of the German child and adolescent population. Predictors of non-drug psychiatric/psychotherapeutic treatment were analysed for 23,795 cases and two controls for every case of the same age and sex in children aged 0-17 years following a new diagnosis of mental or behavioural disorder in 2010. Predictors were divided according to Andersen's behavioural model into predisposing, need and enabling factors. The most prominent and significant predictors positively associated with non-drug psychiatric/psychotherapeutic treatment were the residential region as predisposing factor; specific, both ex- and internalizing, mental and behavioural disorders, psychiatric co-morbidity and psychotropic drug use as need factors; and low area deprivation and high accessibility to outpatient physicians and inpatient institutions with non-drug psychiatric/psychotherapeutic department as enabling factors. In conclusion, the present study suggests that the residential region as proxy for supply of therapist and socioeconomic situation is an influencing factor for the use of psychotherapy. The analysis sheds further light on predisposing, need and enabling factors as predictors of non-drug psychotherapeutic/psychiatric treatment in children and adolescents with mental or behavioural health disorders in Germany. More research is needed to further understand the factors promoting the gap between the need and utilization of mental health care.
European Child and Adolescent Psychiatry

Wolf, K.; Popp, A.; Schneider, A.E.; Breitner, S.; Hampel, R.; Rathmann, W.G.; Herder, C.; Roden, M.; Koenig, W.; Meisinger, C.; Peters, A.; KORA Study Group (Heinrich, J.; Holle, R.; Leidl, R.; Meisinger, C.; Strauch, K.)
Association between long-term exposure to air pollution and biomarkers related to insulin resistance, subclinical inflammation and adipokines.
Diabetes 65, 3314-3326 (2016)
Insulin resistance (IR) is present long before the onset of type 2 diabetes and results not only from inherited and lifestyle factors but likely also from environmental conditions. We investigated the association between modelled long-term exposure to air pollution at residence and biomarkers related to IR, subclinical inflammation and adipokines.Data was based on 2,944 participants of the KORA (Cooperative Health Research in the Region Augsburg) F4 study conducted in southern Germany (2006-2008). We analysed associations between individual air pollution concentration estimated by land use regression and HOMA-IR, glucose, insulin, HbA1c, leptin, and hs-CRP from fasting samples using multivariable linear regression models. Effect estimates were calculated for the whole study population and subgroups of non-diabetic, pre-diabetic and diabetic individuals.Among all participants, a 7.9µg/m(3) increment in particulate matter <10µm was associated with higher HOMA-IR (15.6% [95%-CI: 4.0;28.6]) and insulin (14.5% [3.6;26.5]).Nitrogen dioxide was associated with HOMA-IR, glucose, insulin, and leptin. Effect estimates for pre-diabetic individuals were much larger and highly statistically significant, while non-diabetic and diabetic individuals showed rather weak associations. No association was seen for HbA1cOur results suggested an association between long-term exposure to air

pollution and IR in the general population mainly attributable to pre-diabetic individuals.
Diabetes

Schwarzkopf, L.; Wacker, M.; Ertl, J.; Hapfelmeier, J.; Larisch, K.; Leidl, R.
Impact of chronic ischemic heart disease on the health care costs of COPD patients – An analysis of German claims data.
Respir. Med. 118, 112-118 (2016)
Objectives Chronic Obstructive Pulmonary Disease (COPD) has a substantial impact on health care systems worldwide. Particularly, cardiovascular diseases such as ischemic heart disease (IHD) are frequent in individuals with COPD, but the economic consequences of combined COPD and IHD are by large unknown. Therefore, our study has the objective to investigate excess costs of IHD in COPD patients. Methods Out of German Statutory Health Insurance claims data we identified 26,318 COPD patients with and 10,287 COPD patients without IHD based on ICD-10 codes (COPD J44; IHD I2[0,1,2,5]) of the year 2011 and matched 9986 of them in a 1:1 ratio based on age and gender. Then, we investigated health care service expenditures in 2012 via Generalized Linear Models. Moreover, we evaluated a potential non-linear association between health care expenditures and age in a gender-stratified Generalized Additive Model. Results The prevalence of IHD in individuals with COPD increases with rising age up to a share of 50%. COPD patients with IHD cause adjusted mean annual per capita health care service expenditures of ca. €7400 compared with ca. €5800 in COPD patients without IHD. Moreover, excess costs of IHD have an inverse u-shape, peaking in the early (men) respectively late seventies (women). Conclusions IHD in COPD patients is associated with excess costs of ca. € 1,500, with the exact amount varying age- and gender-dependently. Subgroups with high excess costs indicate medical need that calls for efficient care strategies, considering COPD and IHD together particularly between 70 and 80 years of age.
Respiratory Medicine

Koerber, F.; Gapp, O.; Schellhorn, H.; John, J.
Aufnahme von Leistungen in die Vergütung.
In: Rogowski, W.H. [Eds.]: Business Planning im Gesundheitswesen : Die Bewertung neuer Gesundheitsleistungen aus unternehmerischer Perspektive. Berlin; Heidelberg: Springer, 2016. 177-204
Das achte Kapitel widmet sich den folgenden Fragen: (Wie) kann für das Produkt die Erstattung durch Kostenträger erreicht werden? Welche Wege in die Vergütung gibt es bzw. welche Institutionen spielen eine Rolle? Welche Kriterien spielen bei der Entscheidung eine Rolle? Neben der Aufnahme neuer Leistungen in die Versorgung der privaten Krankenversicherung wird insbesondere der Prozess der Aufnahme neuer Leistungen in der ambulant-ärztlichen Versorgung, in den Heil- und Hilfsmittelkatalog, und in die Erstattung neuer Arzneimittel beschrieben. Zudem wird auf neue Versorgungsformen und neue Leistungen in der stationären Versorgung eingegangen.
Koerber, F.; von Planta, C.; John, J.; Rogowski, W.H.
Marktpotenzial der Innovation.
In: Rogowski, W.H. [Eds.]: Business Planning im Gesundheitswesen : Die Bewertung neuer Gesundheitsleistungen aus unternehmerischer Perspektive. Berlin; Heidelberg: Springer, 2016. 99-123
Das fünfte Kapitel widmet sich der Frage, wie die Zahl der potenziellen Kunden bestimmt werden kann, sowie welche weiteren Kennzahlen für die Marktanalyse wichtig sind und wie sie ermittelt werden können. Neben einer allgemeinen Darstellung des Themas „Marktanalyse" für die Gesundheitswirtschaft wird auch auf Spezifika im Gesundheitswesen eingegangen. Zudem gibt das Kapitel einen Überblick über relevante Informationsquellen.
Koerber, F.; Dienst, R.C.; John, J.; Rogowski, W.H.
Einführung.
In: Rogowski, W.H. [Eds.]: Business Planning im Gesundheitswesen : Die Bewertung neuer Gesundheitsleistungen aus unternehmerischer Perspektive. Berlin; Heidelberg: Springer, 2016. 1-24
Das erste Kapital adressiert die Fragen: Welchen Zweck hat Business Planning und was ist dabei in der Gesundheitswirtschaft besonders zu beachten? Wie kann eine Geschäftsidee in der Gesundheitswirtschaft profitabel umgesetzt werden? Hierzu wird neben einer Einführung in die Gesundheitswirtschaft und dessen Abgrenzung von Selbstzahlermarkt und öffentlich finanziertem Gesundheitswesen insbesondere ein Überblick über die Argumente der Gewinnformel gegeben, die der Gliederung dieses Lehrbuches zugrunde liegen.
Rogowski, W.H.; Bartoschek, S.; John, J.
Mehrwert der Innovation.
In: Rogowski, W.H. [Eds.]: Business Planning im Gesundheitswesen : Die Bewertung neuer Gesundheitsleistungen aus unternehmerischer Perspektive. Berlin; Heidelberg: Springer, 2016. 39-64
Das dritte Kapitel widmet sich der Frage, wie man die Attraktivität eines neuen Produktes bzw. einer neuen Dienstleistung für den, der sie nutzen (und bezahlen) soll erkennt. Zudem geht es näher darauf ein, welche Art von Nutzen am wichtigsten im Gesundheitswesen ist und nach welchen Kategorien wird über die Leistungsfinanzierung entschieden wird. Hierzu wird nach einer allgemeinen Einführung in das wichtige Thema „Mehrwert" für die Gesundheitswirtschaft im Allgemeinen ein Überblick über die wichtigsten Gruppen von Leistungsfinanzierern und Leistungserbringern gegeben.
Dröschel, D.; Rogowski, W.H.; John, J.
Derzeitige Finanzierung der Versorgung.
In: Rogowski, W.H. [Eds.]: Business Planning im Gesundheitswesen : Die Bewertung neuer Gesundheitsleistungen aus unternehmerischer Perspektive. Berlin; Heidelberg: Springer, 2016. 147-175
Das siebte Kapitel widmet sich der Analyse, wie und und wie hoch die gegenwärtige Lösung des Problems vergütet wird und der Frage, welche Finanzierungsform für die neue Lösung in Frage kommt. Dazu wird zum einen auf die Zahlung aus der eigenen Tasche in der deutschen Gesundheitsversorgung eingegangen, die in Form von Leistungen mit freier Preisgestaltung, privatärztlicher Abrechnung, und der Erstattung der Privaten Krankenversicherungen relevant ist. Zudem wird ein Überblick über die wichtigsten Vergütungsformen der deutschen Gesetzlichen Krankenversicherung gegeben – dem Einheitlichen Bewertungsmaßstab für ambulante Leistungen, dem Fallpauschalensystem für stationäre Leistungen, der Erstattung von Arzneimitteln, sowie der Erstattung von Heil- und Hilfsmitteln.
Walzer, S.; Gerber-Grote, A.; John, J.; Rogowski, W.H.
Vergütungshöhe und Preissetzung.

In: Rogowski, W.H. [Eds.]: Business Planning im Gesundheitswesen : Die Bewertung neuer Gesundheitsleistungen aus unternehmerischer Perspektive. Berlin; Heidelberg: Springer, 2016. 205-234
Kapitel neun untersucht, mit welchen Konzepten und Methoden der Preis für ein neues Gesundheitsgut im Allgemeinen bestimmt werden kann, und was dabei im Gesundheitswesen zu beachten ist. Sowohl für die Gesundheitswirtschaft im Allgemeinen wie auch für das Gesundheitswesen wird hierbei insbesondere auf kostenbasierte Preissetzung, wertbasierte Preissetzung, sowie ergänzende strategische Erwägungen der Preissetzung eingegangen.

Olden, M.; Holle, R.; Heid, I.; Stark, K.
IDGenerator: Unique identifier generator for epidemiologic or clinical studies.
BMC Med. Res. Methodol. 16:120 (2016)
BACKGROUND: Creating study identifiers and assigning them to study participants is an important feature in epidemiologic studies, ensuring the consistency and privacy of the study data. The numbering system for identifiers needs to be random within certain number constraints, to carry extensions coding for organizational information, or to contain multiple layers of numbers per participant to diversify data access. Available software can generate globally-unique identifiers, but identifier-creating tools meeting the special needs of epidemiological studies are lacking. We have thus set out to develop a software program to generate IDs for epidemiological or clinical studies. RESULTS: Our software IDGenerator creates unique identifiers that not only carry a random identifier for a study participant, but also support the creation of structured IDs, where organizational information is coded into the ID directly. This may include study center (for multicenter-studies), study track (for studies with diversified study programs), or study visit (baseline, follow-up, regularly repeated visits). Our software can be used to add a check digit to the ID to minimize data entry errors. It facilitates the generation of IDs in batches and the creation of layered IDs (personal data ID, study data ID, temporary ID, external data ID) to ensure a high standard of data privacy. The software is supported by a user-friendly graphic interface that enables the generation of IDs in both standard text and barcode 128B format. CONCLUSION: Our software IDGenerator can create identifiers meeting the specific needs for epidemiologic or clinical studies to facilitate study organization and data privacy. IDGenerator is freeware under the GNU General Public License version 3; a Windows port and the source code can be downloaded at the Open Science Framework website: https://osf.io/urs2g/ .
BMC Medical Research Methodology

Beyerlein, A.; Koller, D.; Ziegler, A.-G.; Lack, N.; Maier, W.
Does charge-free screening improve detection of gestational diabetes in women from deprived areas: A cross-sectional study.
BMC Pregnancy Childbirth 16:266 (2016)
Background Gestational diabetes mellitus (GDM) occurs in 2–6 % of all pregnancies. We investigated whether area level deprivation is associated with a higher risk for GDM and whether GDM detection rates in deprived regions changed after the introduction of charge-free GDM screening in Germany in 2012. Methods We analyzed population-based data from Bavaria, Germany, comprising n = 587,621 deliveries in obstetric units between 2008 and 2014. Area level deprivation was assessed municipality-based using the Bavarian Index of Multiple Deprivation (BIMD), divided into quintiles and assigned to each mother based on her residential address. We estimated annual odds ratios (ORs) for GDM diagnosis by BIMD quintile with adjustment for maternal obesity, maternal age, migration background and single mother status. Results Women from the most deprived regions were less likely to be diagnosed with GDM before introduction of charge-free GDM screening (OR = 0.76 [95 % confidence interval: 0.66, 0.86] compared to least deprived areas), in 2008. In contrast, high area level deprivation was associated with significantly increased risk of GDM diagnosis in 2013 (OR [95 % confidence interval] = 1.15 [1.02, 1.29]). The OR was also elevated, although not significantly, in 2014 (OR [95 % confidence interval] = 1.05 [0.93, 1.18]). Conclusions The prevalence of GDM seems to have been underreported in women from highly deprived areas before introduction of the charge-free GDM screening in Germany. In fact, women living in deprived regions seem to have an increased risk for GDM and may profit from access to charge-free GDM screening.Gestational diabetes mellitus Area level deprivation Bavarian index of multiple deprivation Charge-free screening.
BMC Pregnancy and Childbirth

Italia, S.; Brüske, I.; Heinrich, J.; Berdel, D.; von Berg, A.; Lehmann, I.; Standl, M.; Wolfenstetter, S.B.
Complementary and alternative medicine use among chronically Ill adolescents from 2 German birth cohorts.
Forsch. Komplementmed. 23, 246-252 (2016)
Pediatric use of complementary and alternative medicine (CAM) is popular in Europe, and utilization may be even more prevalent in chronically ill children/adolescents. This study's aim is to assess CAM use among adolescents with chronic conditions. Methods: Data on drug utilization (past 4 weeks) and consultation with CAM providers (past year) were collected using a self-administered questionnaire from 4,677 adolescents from the German GINIplus/LISAplus birth cohorts. All reported drugs were classified into therapeutic categories (conventional drugs, homeopathy, herbal drugs, etc.). Additionally, participants were asked to list any chronic diseases (that were parent-reported, physician-verified diagnoses such as allergies, atopic dermatitis, asthma, or other chronic diseases) that they had had over the previous 5 years. Results: Compared with the total sample, drug utilization in general (60.1% vs. 41.1%), homeopathy use (11.1% vs. 8.1%), and consultation with CAM providers (16.9% vs. 10.9%) was significantly more prevalent among chronically ill adolescents. However, chronically ill adolescents used relatively (proportion of the defined therapeutic category among all drugs used) more conventional drugs than healthy adolescents. Conclusion: Compared with healthy adolescents, CAM use is more prevalent among adolescents with chronic conditions. Nevertheless, CAM may predominantly be used as a complementary treatment option rather than substituting conventional drugs.
Forschende Komplementärmedizin

Mielck, A.; Kilian, H.; Lehmann, F.; Richter-Kornweitz, A.; Kaba-Schönstein, L.
German cooperation-network 'equity in health' - Health promotion in settings.
Health Prom. Int. 33, 318-324 (2016)
In 2003, the German Federal Centre for Health Education (BZgA) initiated the national Cooperation-Network (CN) 'Equity in Health'. The CN is constantly increasing in size and scope,

supporting setting approaches aimed at reducing health inequalities. A detailed description of the CN has not yet been available in English. The CN comprises a total of 66 institutional cooperation partners. Information concerning the structure and activities can be found on a special website. Coordination Centres (CC) have been established in the 16 federal states, for the coordination of all state-specific activities. Funding for the CN and CC is provided by the BZgA, the German statutory sickness funds and by the state-specific ministries of health. These partners also support the continuous quality improvement, which is based on the good-practice criteria developed by the Advisory Committee of the CN. In 2011, the 'Municipal Partner Process (MPP)' has been launched, specifically supporting local partners and integrated life-course approaches focussing on children. In 2015, the focus has been widened to include all age-groups. In July 2015, a new national health law concerning health promotion and prevention has been ratified by the federal Parliament, with a focus on reducing health inequalities. Currently, the details of its implementation are discussed on a nationwide basis. The CN has long advocated for such a law, and today the CN is a well-accepted partner providing concepts, methods and a strong and long-standing network. The article closes with future challenges faced by the CN.
Health Promotion International

Karrasch, S.; Brüske, I.; Smith, M.; Thorand, B.; Huth, C.; Ladwig, K.-H.; Kronenberg, F.; Heinrich, J.; Holle, R.; Peters, A.; Schulz, H.
What is the impact of different spirometric criteria on the prevalence of spirometrically defined COPD and its comorbidities? Results from the population-based KORA study.
Int. J. Chron. Obstruct. Pulmon. Dis. 11, 1881-1894 (2016)
BACKGROUND: There is an ongoing debate about the appropriate spirometric criterion for airway obstruction to detect COPD. Furthermore, the association of different criteria with comorbidity prevalence and inflammatory biomarkers in advanced age is unclear. MATERIALS AND METHODS: Spirometry was performed in a population-based study (n=2,256) covering an age range of 41-90 years. COPD was spirometrically determined either by a fixed ratio (FR) of <0.7 for forced expiratory volume in 1 second (FEV1)/forced vital capacity (FVC) or by FEV1/FVC below the lower limit of normal (LLN). Comorbidity prevalences and circulating biomarker levels (C-reactive protein [CRP], interleukin [IL]-6) were compared between subjects with or without COPD by the two criteria using logistic and multiple regression models, adjusting for sex and age. RESULTS: The prevalence of spirometrically defined COPD by FR increased with age from 10% in subjects aged <65 years to 26% in subjects aged ≥75 years. For LLN-defined COPD, it remained below 10% for all age groups. Overall, COPD diagnosis was not associated with specific comorbidities, except for a lower prevalence of obesity in both FR- and LLN-defined cases. Both CRP and IL-6 tended to be higher in cases by both criteria. CONCLUSION: In a population-based cohort of adults up to the age of 90 years, the prevalence of spirometrically defined COPD was higher for the FR criterion than for the LLN criterion. This difference increased with age. Neither prevalences of common comorbidities nor levels of the biomarkers, CRP or IL-6, were conclusively associated with the selection of the COPD criterion. Results have to be considered in light of the predominantly mild cases of airway obstruction in the examined study population.
International Journal of Chronic Obstructive Pulmonary Disease

Markevych, I.; Standl, M.; Sugiri, D.; Harris, C.; Maier, W.; Berdel, D.; Heinrich, J.
Residential greenness and blood lipids in children: A longitudinal analysis in GINIplus and LISAplus.
Environ. Res. 151, 168-173 (2016)
INTRODUCTION: There is some evidence of decreased cardiovascular disease (CVD) mortality and morbidity among adults residing in greener places. Among others, blood lipids are well established risk factors for CVD. In our previous study, we observed the inverse association between greenness and blood pressure in 10-year-old children. In the current study, we investigated whether there is also a link between residential greenness and blood lipids in 10- and 15-year-old children. METHODS: Complete data on blood lipids (total cholesterol, HDL, LDL and triglyceride), residential greenness (NDVI in 100-m, 300- and 500-m buffers around residences) and confounders were available for 1,552 participants at 10 and 15 years of age, residing in two study areas of two German birth cohorts - GINIplus and LISAplus. Longitudinal associations between NDVI and blood lipids were assessed by generalized estimation equations. RESULTS: No associations were observed between residential greenness in any of the chosen buffers and blood lipids in children (e.g., change in blood lipids per interquartile increase in NDVI in 100-m buffer for total cholesterol and LDL: means ratio=1.00 (95% confidence interval: 0.99-1.01), for triglyceride: 0.98 (0.96-1.00)). No area- or sex-varying effects were evident. Change of the residence between 10 and 15 years also did not yield any consistent associations. CONCLUSIONS: There is no evidence of an association between greenness and blood lipids in 10- and 15-years old children.
Environmental Research

Bozzani, F.M.; Arnold, M.; Colbourn, T.; Lufesi, N.; Nambiar, B.; Masache, G.; Skordis-Worrall, J.
Measurement and valuation of health providers' time for the management of childhood pneumonia in rural Malawi: An empirical study.
BMC Health Serv. Res. 16:314 (2016)
Background: Human resources are a major cost driver in childhood pneumonia case management. Introduction of 13-valent pneumococcal conjugate vaccine (PCV-13) in Malawi can lead to savings on staff time and salaries due to reductions in pneumonia cases requiring admission. Reliable estimates of human resource costs are vital for use in economic evaluations of PCV-13 introduction. Methods: Twenty-eight severe and twenty-four very severe pneumonia inpatients under the age of five were tracked from admission to discharge by paediatric ward staff using self-administered timesheets at Mchinji District Hospital between June and August 2012. All activities performed and the time spent on each activity were recorded. A monetary value was assigned to the time by allocating a corresponding percentage of the health workers' salary. All costs are reported in 2012 US$. Results: A total of 1,017 entries, grouped according to 22 different activity labels, were recorded during the observation period. On average, 99 min (standard deviation, SD = 46) were spent on each admission: 93 (SD = 38) for severe and 106 (SD = 55) for very severe cases. Approximately 40 % of activities involved monitoring and stabilization, including administering non-drug therapies such as oxygen. A further 35 % of the time was spent on injecting antibiotics. Nurses provided 60

% of the total time spent on pneumonia admissions, clinicians 25 % and support staff 15 %. Human resource costs were approximately US$ 2 per bed-day and, on average, US$ 29.5 per severe pneumonia admission and US$ 37.7 per very severe admission. Conclusions: Self-reporting was successfully used in this context to generate reliable estimates of human resource time and costs of childhood pneumonia treatment. Assuming vaccine efficacy of 41 % and 90 % coverage, PCV-13 introduction in Malawi can save over US$ 2 million per year in staff costs alone.
BMC Health Services Research

Fairburn, J.; Maier, W.; Braubach, M.
Incorporating environmental justice into second generation indices of multiple deprivation: Lessons from the UK and progress internationally.
Int. J. Environ. Res. Public Health 13:750 (2016)
Second generation area-based indices of multiple deprivation have been extensively used in the UK over the last 15 years. They resulted from significant developments in political, technical, and conceptual spheres for deprivation data. We review the parallel development of environmental justice research and how and when environmental data was incorporated into these indices. We explain the transfer of these methods from the UK to Germany and assess the progress internationally in developing such indices. Finally, we illustrate how billions of pounds in the UK was allocated by using these tools to tackle neighbourhood deprivation and environmental justice to address the determinants of health.
International Journal of Environmental Research and Public Health

Mutowo, M.P.; Lorgelly, P.K.; Laxy, M.; Renzaho, A.M.N.; Mangwiro, J.C.; Owen, A.J.
The hospitalization costs of diabetes and hypertension complications in Zimbabwe: Estimations and correlations.
J. Diabetes Res. 2016:9754230 (2016)
Objective: Treating complications associated with diabetes and hypertension imposes significant costs on health care systems. This study estimated the hospitalization costs for inpatients in a public hospital in Zimbabwe. Methods. The study was retrospective and utilized secondary data from medical records. Total hospitalization costs were estimated using generalized linear models. Results. The median cost and interquartile range (IQR) for patients with diabetes, $994 (385-1553) mean $1319 (95% CI: 981-1657), was higher than patients with hypertension, $759 (494-1147) mean $914 (95% CI: 825-1003). Female patients aged below 65 years with diabetes had the highest estimated mean costs ($1467 (95% CI: 1177-1828)). Wound care had the highest estimated mean cost of all procedures, $2884 (95% CI: 2004-4149) for patients with diabetes and $2239 (95% CI: 1589-3156) for patients with hypertension. Age below 65 years, medical procedures (amputation, wound care, dialysis, and physiotherapy), the presence of two or more comorbidities, and being prescribed two or more drugs were associated with significantly higher hospitalization costs. Conclusion. Our estimated costs could be used to evaluate and improve current inpatient treatment and management of patients with diabetes and hypertension and determine the most cost-effective interventions to prevent complications and comorbidities.
Journal of Diabetes Research

Walter, J.; Vogl, M.; Holderried, M.; Becker, C.; Brandes, A.; Sinner, M.F.; Rogowski, W.H.; Maschmann, J.
Manual compression versus vascular closing device for closing access puncture site in femoral left-heart catheterization and percutaneous coronary interventions: A retrospective cross-sectional comparison of costs and effects in inpatient care.
Value Health 20, 769-776 (2016)
Objectives: To compare complication rates, length of hospital stay, and resulting costs between the use of manual compression and a vascular closing device (VCD) in both diagnostic and interventional catheterization in a German university hospital setting. Methods: A stratified analysis according to risk profiles was used to compare the risk of complications in a retrospective cross-sectional single-center study. Differences in costs and length of hospital stay were calculated using the recycled predictions method, based on regression coefficients from generalized linear models with gamma distribution. All models were adjusted for propensity score and possible confounders, such as age, sex, and comorbidities. The analysis was performed separately for diagnostic and interventional catheterization. Results: The unadjusted relative risk (RR) of complications was not significantly different in diagnostic catheterization when a VCD was used (RR = 0.70; 95% confidence interval [CI] 0.22-2.16) but significantly lower in interventional catheterization (RR = 0.44; 95% CI 0.21-0.93). Costs were on average €275 lower in the diagnostic group (95% CI -€478.0 to -€64.9; P = 0.006) and around €373 lower in the interventional group (95% CI -€630.0 to -€104.2; P = 0.014) when a VCD was used. The adjusted estimated average length of stay did not differ significantly between the use of a VCD and manual compression in both types of catheterization. Conclusions: In interventional catheterization, VCDs significantly reduced unadjusted complication rates, as well as costs. A significant reduction in costs also supports their usage in diagnostic catheterization on a larger scale.
Value in Health

Schmiedl, S.; Thürmann, P.; Fischer, R.; Rottenkolber, D.; Rottenkolber, M.
Response to Wise et al. (Tiotropium safety in real life populations).
Br. J. Clin. Pharmacol. 82, 564-565 (2016)
British Journal of Clinical Pharmacology
Letter to the Editor
Letter to the Editor
Wacker, M.; Jörres, R.A.; Karch, A.; Koch, A.; Heinrich, J.; Karrasch, S.; Schulz, H.; Peters, A.; Gläser, S.; Ewert, R.; Baumeister, S.E.; Vogelmeier, C.; Leidl, R.; Holle, R.
Relative impact of COPD and comorbidities on generic health-related quality of life: A pooled analysis of the COSYCONET patient cohort and control subjects from the KORA and SHIP studies.
Respir. Res. 17:81 (2016)
BACKGROUND: Health-related quality of life (HRQL) is an important patient-reported outcome measure used to describe the burden of chronic obstructive pulmonary disease (COPD) which is often accompanied by comorbid conditions. METHODS: Data from 2275 participants in the COPD cohort COSYCONET and from 4505 lung-healthy control subjects from the population-based KORA and SHIP studies were pooled. Main outcomes were the five dimensions of the generic EQ-5D-3 L questionnaire

and two EQ-5D index scores using a tariff based on valuations from the general population and an experience-based tariff. The association of COPD in GOLD grades 1-4 and of several comorbid conditions with the EQ-5D index scores was quantified by multiple linear regression models while adjusting for age, sex, education, body mass index (BMI), and smoking status. RESULTS: For all dimensions of the EQ-5D, the proportion of participants reporting problems was higher in the COPD group than in control subjects. COPD was associated with significant reductions in the EQ-5D index scores (-0.05 points for COPD grades 1/2, -0.09 for COPD grade 3, -0.18 for COPD grade 4 according to the preference-based utility tariff, all p < 0.0001). Adjusted mean index scores were 0.89 in control subjects and 0.85, 0.84, 0.81, and 0.72 in COPD grades 1-4 according to the preference-based utility tariff and 0.76, 0.71, 0.68, 0.64, and 0.58 for control subjects and COPD grades 1-4 for the experience-based tariff respectively. Comorbidities had additive negative effects on the index scores; the effect sizes for comorbidities were comparable to or smaller than the effects of COPD grade 3. No statistically significant interactions between COPD and comorbidities were observed. Score differences between COPD patients and control subjects were most pronounced in younger age groups. CONCLUSIONS: Compared with control subjects, the considerable reduction of HRQL in patients with COPD was mainly due to respiratory limitations, but observed comorbidities added linearly to this effect. Younger COPD patients showed a greater loss of HRQL and may therefore be in specific need of comprehensive disease management. TRIAL REGISTRATION: NCT01245933.
Respiratory Research

Schremser, K.; Butzke, B.; Wilman, N.; Brandes, A.; Rogowski, W.H.
Managed Entry Agreements in Deutschland: Konzepte, rechtliche Grundlagen und systematischer Review.
Gesundheitsökon. Qualitätsmanag., DOI: 10.1055/s-0042-109798 (2016)
Zielsetzung: Ziel dieser Arbeit ist es, den Stand der Evidenz bezüglich der Nutzung von Managed Entry Agreements (MEAs) in Deutschland in der Literatur zu ermitteln. Einführend soll zudem ein Überblick über die gesundheitsökonomische Literatur zu MEAs sowie zu den relevanten rechtlichen Grundlagen auf der Basis ergänzender, explorativer Reviews gegeben werden. Methodik: Es wurde eine umfangreiche Literaturrecherche zu publizierten Fallstudien und Übersichtsarbeiten in PubMed, Google, auf fachspezifischen Internetseiten von 53 Stakeholdern (Krankenkassen, Pharmaunternehmen, weitere gesundheitspolitisch relevante Institutionen) sowie auf ausgewählten deutschsprachigen Fachzeitschriften durchgeführt. Ergebnisse: Es konnten insgesamt 23 potenzielle MEAs identifiziert werden (10 gesundheitsorientierte, 13 kostenorientierte MEAs). Zu zehn dieser potenziellen MEAs lagen jedoch nur unzureichende Informationen zur Abgrenzung von anderen Vertragsmodellen vor. Schlussfolgerung: Aufgrund des eingeschränkten Zugangs der Öffentlichkeit zu Vertragsinformationen sind die Möglichkeiten einer umfassenden Darstellung begrenzt. Es besteht weiterer ökonomischer, juristischer und ethischer Forschungsbedarf, um das Potenzial von MEAs für den Kontext des deutschen Gesundheitswesens voll nutzbar zu machen.
Gesundheitsökonomie & Qualitätsmanagement

Iglesias, C.P.; Thompson, A.; Rogowski, W.H.; Payne, K.
Reporting guidelines for the use of expert judgement in model-based economic evaluations.
Pharmacoeconomics 34, 1161-1172 (2016)
INTRODUCTION: Expert judgement has a role in model-based economic evaluations (EEs) of healthcare interventions. This study aimed to produce reporting criteria for two types of study design to use expert judgement in model-based EE: (i) an expert elicitation (quantitative) study; and (ii) a Delphi study to collate (qualitative) expert opinion. METHODS: A two-round online Delphi process identified the degree of consensus for four core definitions (expert; expert parameter values; expert elicitation study; expert opinion) and two sets of reporting criteria in a purposive sample of experts. The initial set of reporting criteria comprised 17 statements for reporting a study to elicit parameter values and/or distributions and 11 statements for reporting a Delphi survey to obtain expert opinion. Fifty experts were invited to become members of the Delphi process panel by e-mail. Data analysis summarised the extent of agreement (using a pre-defined 75 % 'consensus' threshold) on the definitions and suggested reporting criteria. Free-text comments were analysed using thematic analysis. RESULTS: The final panel comprised 12 experts. Consensus was achieved for the definitions of expert (88 %); expert parameter values (83 %); and expert elicitation study (83 %). The panel recommended criteria to use when reporting an expert elicitation study (16 criteria) and a Delphi study to collate expert opinion (11 criteria). CONCLUSION: This study has produced guidelines for reporting two types of study design to use expert judgement in model-based EE: (i) an expert elicitation study requiring 16 reporting criteria; and (ii) a Delphi study to collate expert opinion requiring 11 reporting criteria.
PharmacoEconomics

Vogl, M.; Warnecke, G.; Haverich, A.; Gottlieb, J.; Welte, T.; Hatz, R.A.; Hunger, M.; Leidl, R.; Lingner, H.; Behr, J.; Winter, H.; Schramm, R.; Zwissler, B.; Hagl, C.; Strobl, N.; Jaeger, C.; Preissler, G.
Lung transplantation in the spotlight: Reasons for high-cost procedures.
J. Heart Lung Transpl. 35, 1227-1236 (2016)
BACKGROUND: Hospital treatment costs of lung transplantation are insufficiently analyzed. Accordingly, it remains unknown, whether current Diagnosis Related Groups, merely accounting for 3 ventilation time intervals and length of hospital stay, reproduce costs properly, even when an increasing number of complex recipients are treated. Therefore, in this cost determination study, actual costs were calculated and cost drivers identified. METHODS: A standardized microcosting approach allowed for individual cost calculations in 780 lung transplant patients taken care of at Hannover Medical School and University of Munich from 2009 to 2013. A generalized linear model facilitated the determination of characteristics predictive for inpatient costs. RESULTS: Lung transplantation costs varied substantially by major diagnosis, with a mean of €85,946 (median €52,938 ± 3,081). Length of stay and ventilation time properly reproduced costs in many cases. However, complications requiring prolonged ventilation or reinterventions were identified as additional significant cost drivers, responsible for high costs. CONCLUSIONS: Diagnosis Related Groups properly reproduce actual lung transplantation costs in straightforward cases, but costs in complex cases may remain underestimated. Improved grouping should consider major

diagnosis, a higher gradation of ventilation time, and the number of reinterventions to allow for more reasonable reimbursement.
Journal of Heart and Lung Transplantation, The

Riedl, A.; Vogt, S.; Holle, R.; de Las Heras Gala, T.; Laxy, M.; Peters, A.; Thorand, B.
Comparison of different measures of obesity in their association with health-related quality of life in older adults - results from the KORA-Age study.
Public Health Nutr. 19, 3276-3286 (2016)
OBJECTIVE: As ageing is associated with changes in body composition, BMI may not be the appropriate obesity measure for older adults. To date, little is known about associations between obesity measures and health-related quality of life (HRQoL). Thus, we aimed to compare different obesity measures in their association with HRQoL and self-rated physical constitution (SRPC) in older adults. DESIGN: Seven obesity measures (BMI, waist circumference (WC), waist-to-hip ratio, waist-to-height ratio, fat mass percentage based on bioelectrical impedance analysis, hypertriglyceridaemic waist (HTGW) and sarcopenic obesity) were assessed at baseline in 2009. HRQoL, using the EQ-5D questionnaire, and SRPC, using one single question, were collected at baseline and at the 3-year follow-up in 2012. Linear and logistic regression analyses were used to examine the associations between the obesity measures and both outcomes. Model comparisons were conducted by area under the receiver-operating characteristic curve, R 2, Akaike and Schwarz Bayesian information criteria. SETTING: KORA-Age study in Southern Germany (2009-2012). SUBJECTS: Older adults (n 883; aged >65 years). RESULTS: Nearly all obesity measures were significantly inversely associated with both outcomes in cross-sectional analyses. Concerning HRQoL, the WC model explained most of the variance and had the best model adaption, followed by the BMI model. Regarding SRPC, the HTGW and BMI models were best as rated by model quality criteria, followed closely by the WC model. Longitudinal analyses showed no significant associations. CONCLUSIONS: These results suggest that, with regard to HRQoL/SRPC, simple anthropometric measures are sufficient to determine obesity in older adults in medical practice.
Public Health Nutrition

Schneider, A.; Donnachie, E.; Tauscher, M.; Gerlach, R.; Maier, W.; Mielck, A.; Linde, K.; Mehring, M.
Costs of coordinated versus uncoordinated care in Germany: Results of a routine data analysis in Bavaria.
BMJ Open 6:e011621 (2016)
OBJECTIVES: The efficiency of a gatekeeping system for a health system, as in Germany, remains unclear particularly as access to specialist ambulatory care is not restricted. The aim was to compare the costs of coordinated versus uncoordinated patients (UP) in ambulatory care; with additional subgroup analysis of patients with mental disorders. DESIGN: Retrospective routine data analysis of patients with statutory health insurance, using claims data held by the Bavarian Association of Statutory Health Insurance Physicians. A patient was defined as uncoordinated if he or she visited at least 1 specialist without a referral from a general practitioner within a quarter. Outcomes were compared with propensity score matching analysis. PARTICIPANTS: The study encompassed all statutorily insured patients in Bavaria contacting at least 1 ambulatory specialist in the first quarter of 2011 (n=3 616 510). PRIMARY AND SECONDARY OUTCOME MEASURES: Primary outcome was total costs of ambulatory care; secondary outcomes were financial claims of general physicians, specialists and for medication. RESULTS: The average age was 55.3 years for coordinated patients (CP, n=1 629 302), 48.3 years for UP (n=1 825 840). CP more frequently had chronic diseases (85.4%) as compared with UP (67.5%). The total unadjusted financial claim per patient was higher for UP (€234.52) than for CP (€224.41); the total adjusted difference was -€9.65 (95% CI -11.64 to -7.67), indicating lower costs for CP. The cost differences increased with increasing age. Total adjusted difference per patient with mental diseases as documented with an International Classification of Diseases (ICD)-10 F-diagnosis, was -€20.31 (95% CI -26.43 to -14.46). CONCLUSIONS: Coordination of care is associated with lower ambulatory healthcare expenditures and is of particular importance for patients who are more vulnerable to medical interventions, especially for elderly and patients with mental disorders. The role of general practitioners as coordinators should be strengthened to improve care for these patients as this could also help to frame a more efficient health system.
BMJ Open

Voko, Z.; Cheung, K.L.; Józwiak-Hagymásy, J.; Wolfenstetter, S.B.; Jones, T.; Muñoz, C.; Evers, S.M.; Hiligsmann, M.; de Vries, H.; Pokhrel, S.
Similarities and differences between stakeholders' opinions on using Health Technology Assessment (HTA) information across five European countries: Results from the EQUIPT survey.
Health Res. Policy Syst. 14:38 (2016)
BACKGROUND: The European-study on Quantifying Utility of Investment in Protection from Tobacco (EQUIPT) project aimed to study transferability of economic evidence by co-creating the Tobacco Return On Investment (ROI) tool, previously developed in the United Kingdom, for four sample countries (Germany, Hungary, Spain and the Netherlands). The EQUIPT tool provides policymakers and stakeholders with customized information about the economic and wider returns on the investment in evidence-based tobacco control, including smoking cessation interventions. A Stakeholder Interview Survey was developed to engage with the stakeholders in early phases of the development and country adaptation of the ROI tool. The survey assessed stakeholders' information needs, awareness about underlying principles used in economic analyses, opinion about the importance, effectiveness and cost-effectiveness of tobacco control interventions, and willingness to use a Health Technology Assessment (HTA) tool such as the ROI tool. METHODS: A cross sectional study using a mixed method approach was conducted among participating stakeholders in the sample countries and the United Kingdom. The individual questionnaire contained open-ended questions as well as single choice and 7- or 3-point Likert-scale questions. The results corresponding to the priority and needs assessment and to the awareness of stakeholders about underlying principles used in economic analysis are analysed by country and stakeholder categories. RESULTS: Stakeholders considered it important that the decisions on the investments in tobacco control interventions should be supported by scientific evidence, including prevalence of smoking, cost of smoking, quality of life, mortality due to smoking, and effectiveness, cost-effectiveness and budget impact of smoking cessation interventions. The proposed ROI tool was required to provide this granularity of information. The

majority of the stakeholders were aware of the general principles of economic analyses used in decision making contexts but they did not appear to have in-depth knowledge about specific technical details. Generally, stakeholders' answers showed larger variability by country than by stakeholder category. CONCLUSIONS: Stakeholders across different European countries viewed the use of HTA evidence to be an important factor in their decision-making process. Further, they considered themselves to be capable of interpreting the results from a ROI tool and were highly motivated to use it.
Health Research Policy and Systems

Hoogendoorn, M.; Feenstra, T.; Asukai, Y.; Briggs, A.; Borg, S.; dal Negro, R.; Hansen, R.N.; Jansson, S.A.; Leidl, R.; Risebrough, N.; Samyshkin, Y.; Wacker, M.; Rutten van-Mölken, M.
Patient heterogeneity in health economic decision models for Chronic Obstructive Pulmonary Disease: Are current models suitable to evaluate personalized medicine?.
Value Health 19, 800-810 (2016)
Objectives To assess how suitable current chronic obstructive pulmonary disease (COPD) cost-effectiveness models are to evaluate personalized treatment options for COPD by exploring the type of heterogeneity included in current models and by validating outcomes for subgroups of patients. Methods A consortium of COPD modeling groups completed three tasks. First, they reported all patient characteristics included in the model and provided the level of detail in which the input parameters were specified. Second, groups simulated disease progression, mortality, quality-adjusted life-years (QALYs), and costs for hypothetical subgroups of patients that differed in terms of sex, age, smoking status, and lung function (forced expiratory volume in 1 second [FEV1] % predicted). Finally, model outcomes for exacerbations and mortality for subgroups of patients were validated against published subgroup results of two large COPD trials. Results Nine COPD modeling groups participated. Most models included sex (seven), age (nine), smoking status (six), and FEV1% predicted (nine), mainly to specify disease progression and mortality. Trial results showed higher exacerbation rates for women (found in one model), higher mortality rates for men (two models), lower mortality for younger patients (four models), and higher exacerbation and mortality rates in patients with severe COPD (four models). Conclusions Most currently available COPD cost-effectiveness models are able to evaluate the cost-effectiveness of personalized treatment on the basis of sex, age, smoking, and FEV1% predicted. Treatment in COPD is, however, more likely to be personalized on the basis of clinical parameters. Two models include several clinical patient characteristics and are therefore most suitable to evaluate personalized treatment, although some important clinical parameters are still missing.
Value in Health

Wacker, M.; Jörres, R.A.; Karch, A.; Wilke, S.; Heinrich, J.; Karrasch, S.; Koch, A.; Schulz, H.; Watz, H.; Leidl, R.; Vogelmeier, C.; Holle, R.; COSYCONET Consortium ()
Assessing health-related quality of life in COPD: Comparing generic and disease-specific instruments with focus on comorbidities.
BMC Pulm. Med. 16:70 (2016)
BACKGROUND: Chronic Obstructive Pulmonary Disease (COPD) influences different aspects of patient's health-related quality of life (HRQL). While disease-specific HRQL instruments focus on symptoms and functional impairments, generic instruments cover a broader view on health. This study compares the generic EQ-5D-3 L and two disease-specific questionnaires (St.-George's Respiratory Questionnaire (SGRQ-C), COPD Assessment Test (CAT)) in a comprehensive spectrum of COPD disease grades with particular attention on comorbidities and assesses the discriminative abilities of these instruments. METHODS: Using data from the baseline visit of the German COPD cohort COSYCONET, mean HRQL scores in different COPD grades were compared by linear regression models adjusting for age, sex, education, smoking status, BMI, and low vs. high number of comorbidities or a list of several self-reported comorbid conditions. Discriminative abilities of HRQL instruments to differentiate between COPD grades were assessed by standardized mean differences. RESULTS: In 2,291 subjects in COPD GOLD grades 1-4 EQ-5D-3 L utility, EQ-5D VAS, SGRQ, and CAT were found able to discriminate between COPD grades, with some limitations for the EQ-5D utility in mild disease. Both generic and disease-specific HRQL instruments reflected the burden of comorbid conditions. The SGRQ showed the best discrimination between COPD grades and was less influenced by comorbidities, while EQ-5D utility put a higher weight on comorbid conditions. For all instruments, psychiatric disorders and peripheral artery disease showed the strongest negative associations with HRQL. CONCLUSION: All HRQL instruments considered reflect considerable impairment of HRQL in COPD patients, worsening with increasing COPD grade and number of comorbidities. Findings may support clinical assessment, choice of HRQL instrument in future studies, and parameterization of decision-analytic models.
BMC Pulmonary Medicine

Arnold, M.; Beran, D.; Haghparast-Bidgoli, H.; Batura, N.; Akkazieva, B.; Abdraimova, A.; Skordis-Worrall, J.
Coping with the economic burden of diabetes, TB and co-prevalence: Evidence from Bishkek, Kyrgyzstan.
BMC Health Serv. Res. 16:118 (2016)
Background: The increasing number of patients co-affected with Diabetes and TB may place individuals with low socio-economic status at particular risk of persistent poverty. Kyrgyz health sector reforms aim at reducing this burden, with the provision of essential health services free at the point of use through a State-Guaranteed Benefit Package (SGBP). However, despite a declining trend in out-of-pocket expenditure, there is still a considerable funding gap in the SGBP. Using data from Bishkek, Kyrgyzstan, this study aims to explore how households cope with the economic burden of Diabetes, TB and co-prevalence. Methods: This study uses cross-sectional data collected in 2010 from Diabetes and TB patients in Bishkek, Kyrgyzstan. Quantitative questionnaires were administered to 309 individuals capturing information on patients' socioeconomic status and a range of coping strategies. Coarsened exact matching (CEM) is used to generate socio-economically balanced patient groups. Descriptive statistics and logistic regression are used for data analysis. Results: TB patients are much younger than Diabetes and co-affected patients. Old age affects not only the health of the patients, but also the patient's socio-economic context. TB patients are more likely to be employed and to have higher incomes while Diabetes patients are more likely to be retired. Co-affected patients, despite being in the same age group as Diabetes patients, are less likely to receive pensions but often

earn income in informal arrangements. Out-of-pocket (OOP) payments are higher for Diabetes care than for TB care. Diabetes patients cope with the economic burden by using social welfare support. TB patients are most often in a position to draw on income or savings. Co-affected patients are less likely to receive social welfare support than Diabetes patients. Catastrophic health spending is more likely in Diabetes and co-affected patients than in TB patients. Conclusions: This study shows that while OOP are moderate for TB affected patients, there are severe consequences for Diabetes affected patients. As a result of the underfunding of the SGBP, Diabetes and co-affected patients are challenged by OOP. Especially those who belong to lower socio-economic groups are challenged in coping with the economic burden.
BMC Health Services Research

Dreger, S.; Krille, L.; Maier, W.; Pokora, R.; Blettner, M.; Zeeb, H.
Regional deprivation and non-cancer related computed tomography use in pediatric patients in Germany: Cross-sectional analysis of cohort data.
PLoS ONE 11:e0153644 (2016)
BACKGROUND: Conflicting findings were observed in recent studies assessing the association between patients' area-level socio-economic status and the received number of computed tomography (CT) examinations in children. The aim was to investigate the association between area-level socio-economic status and variation in CT examination practice for pediatric patients in Germany. METHODS: Data from Radiology Information Systems for children aged 0 to < 15 years without cancer who had at least one CT examination between 2001 and 2010 were extracted in 20 hospitals across Germany. The small-area German Index of Multiple Deprivation (GIMD) was used to assess regional deprivation. The GIMD scores were classified into least, medium and most deprived areas and linked with the patient's last known postal code. A multinomial logistic regression model was used to assess the association between patients' CT numbers and regional deprivation adjusting for age, sex, and location of residence (urban/rural). RESULTS: A total of 37,810 pediatric patients received 59,571 CT scans during the study period. 27,287 (72%) children received only one CT, while n = 885 (2.3%) received six or more. Increasing numbers of CT examinations in non-cancer patients were significantly associated with higher regional deprivation, which increased, although CI overlap, for higher CT categories: '2-3 CT' odds ratio (OR) = 1.45, 95%CI: 1.40-1.50; '4-5 CT' OR = 1.48, 95%CI: 1.38-1.59; '6+CT' OR = 1.54, 95%CI: 1.41-1.69. In addition, male sex, higher age categories, and specific body regions were positively associated with increased numbers of CT examinations. CONCLUSION: We observed a positive association between regional deprivation and CT numbers in non-cancer pediatric patients. Limitations of the ecological approach and the lack of differentiation of CT details have to be acknowledged. More information on CT indications is necessary for a full assessment of this finding. In addition, further work on ways to assess socio-economic status more accurately may be required.
PLoS ONE

Karch, A.; Vogelmeier, C.; Welte, T.; Bals, R.; Kauczor, H.U.; Biederer, J.; Heinrich, J.; Schulz, H.; Gläser, S.; Holle, R.; Watz, H.; Korn, S.; Adaskina, N.; Biertz, F.; Vogel, C.; Vestbo, J.; Wouters, E.F.M.; Rabe, K.F.; Söhler, S.; Koch, A.°; Jörres, R.A.°
The German COPD cohort COSYCONET: Aims, methods and descriptive analysis of the study population at baseline.
Respir. Med. 114, 27-37 (2016)
Background The German COPD cohort study COSYCONET ("COPD and SYstemic consequences-COmorbidities NETwork") investigates the interaction of lung disease, comorbidities and systemic inflammation. Recruitment took place from 2010 to 2013 in 31 study centers. In addition to the baseline visit, follow-up visits are scheduled at 6, 18, 36 and 54 months after baseline. The study also comprises a biobank, image bank, and includes health economic data. Here we describe the study design of COSYCONET and present baseline data of our COPD cohort. Methods Inclusion criteria were broad in order to cover a wide range of patterns of the disease. In each visit, patients undergo a large panel of assessments including e.g. clinical history, spirometry, body plethysmography, diffusing capacity, blood samples, 6-min walk-distance, electrocardiogram and echocardiography. Chest CTs are collected if available and CTs and MRIs are performed in a subcohort. Data are entered into eCRFs and subjected to several stages of quality control. Results Overall, 2741 subjects with a clinical diagnosis of COPD were included (59% male; mean age 65 ± 8.6 years (range 40-90)). Of these, 8/35/32/9% presented with GOLD stages I-IV; 16% were uncategorized, including the former GOLD-0 category. 24% were active smokers, 68% ex-smokers and 8% never-smokers. Data completeness was 96% for the baseline items. Conclusion The German COPD cohort comprises patients with advanced and less advanced COPD. This is particularly useful for studying the time course of COPD in relation to comorbidities. Baseline data indicate that COSYCONET offers the opportunity to investigate our research questions in a large-scale, high-quality dataset.
Respiratory Medicine

Huber, M.B.; Reitmeir, P.; Vogelmann, M.; Leidl, R.
EQ-5D-5L in the general German population: Comparison and evaluation of three yearly cross-section surveys.
Int. J. Environ. Res. Public Health 13:343 (2016)
Health-related quality of life (HRQoL) is a key measure for evaluating health status in populations. Using the recent EQ-5D-5L for measurement, this study analyzed quality of life results and their stability over consecutive population surveys. Three cross-section surveys for representative samples of the general German population from 2012, 2013, and 2014 were evaluated using the EQ-5D-5L descriptive system and valuation by the Visual Analog Scale (VAS). Aggregated sample size reached 6074. The dimension with the highest prevalence of problems was pain/discomfort (31.7%). Compared with 2012 (59.3%), the percentage of participants in the best health state increased slightly in 2013 (63.4%) and 2014 (62%). Over the 3-year period, diabetes and heart disease had the strongest negative influence on mean VAS result. The number of reported chronic diseases cumulatively reduced mean VAS. Extreme problems in one or more dimensions were stated by only 0.1%-0.2% of patients. Of the potential 247 health states with a problem score ≥20, only six were observed in the aggregated sample. HRQoL results were fairly stable over the 3 years, but the share of the population with no problems was not. Results from the aggregated sample may serve as updated reference values for the general German population.

International Journal of Environmental Research and Public Health

Leidl, R.; Schweikert, B.; Hahmann, H.; Steinacker, J.M.; Reitmeir, P.
Assessing quality of life in a clinical study on heart rehabilitation patients: How well do value sets based on given or experienced health states reflect patients' valuations?
Health Qual. Life Outcomes 14:48 (2016)
BACKGROUND: Quality of life as an endpoint in a clinical study may be sensitive to the value set used to derive a single score. Focusing on patients' actual valuations in a clinical study, we compare different value sets for the EQ-5D-3L and assess how well they reproduce patients' reported results. METHODS: A clinical study comparing inpatient (n = 98) and outpatient (n = 47) rehabilitation of patients after an acute coronary event is re-analyzed. Value sets include: 1. Given health states and time-trade-off valuation (GHS-TTO) rendering economic utilities; 2. Experienced health states and valuation by visual analog scale (EHS-VAS). Valuations are compared with patient-reported VAS rating. Accuracy is assessed by mean absolute error (MAE) and by Pearson's correlation ρ. External validity is tested by correlation with established MacNew global scores. Drivers of differences between value sets and VAS are analyzed using repeated measures regression. RESULTS: EHS-VAS had smaller MAEs and higher ρ in all patients and in the inpatient group, and correlated best with MacNew global score. Quality-adjusted survival was more accurately reflected by EHS-VAS. Younger, better educated patients reported lower VAS at admission than the EHS-based value set. EHS-based estimates were mostly able to reproduce patient-reported valuation. Economic utility measurement is conceptually different, produced results less strongly related to patients' reports, and resulted in about 20 % longer quality-adjusted survival. CONCLUSION: Decision makers should take into account the impact of choosing value sets on effectiveness results. For transferring the results of heart rehabilitation patients from another country or from another valuation method, the EHS-based value set offers a promising estimation option for those decision makers who prioritize patient-reported valuation. Yet, EHS-based estimates may not fully reflect patient-reported VAS in all situations.
Health and Quality of Life Outcomes

Rogowski, W.H.; John, J.; Ijzerman, M.
Translational health economics.
In: World Scientific Handbook of Global Health Economics and Public Policy. World Scientific, 2016. 405-440
Rosenbauer, J.; Tamayo, T.; Bächle, C.; Stahl-Pehe, A.; Landwehr, S.; Sugiri, D.; Krämer, U.; Maier, W.; Hermann, J.M.; Holl, R.W.; Rathmann, W.
Re: Ambient air pollution and early manifestation of type 1 diabetes.
Epidemiology 27, E25-E26 (2016)
Epidemiology
Sonstiges: Meinungsartikel
Other: Opinion
Brandes, A.; Schwarzkopf, L.; Rogowski, W.H.
Using claims data for evidence generation in managed entry agreements.
Int. J. Technol. Assess. Health Care 32, 69-77 (2016)
OBJECTIVES: This study assesses the use of routinely collected claims data for managed entry agreements (MEA) in the illustrative context of German statutory health insurance (SHI) funds. METHODS: Based on a nonsystematic literature review, the data needs of different MEA were identified. A value-based typology to classify MEA on the basis of these data needs was developed. The typology is oriented toward health outcomes and utilization and costs, key components of a new technology's value. For each MEA type, the suitability of claims data in establishing evidence of the novel technology's value in routine care was systematically assessed. Assessment criteria were data availability, completeness, timeliness, confidentiality, reliability, and validity. RESULTS: Claims data are better suited to MEA addressing uncertainty regarding the utilization and costs of a novel technology in routine care. In schemes where safety aspects or clinical effectiveness are assessed, the role of claims data is limited because clinical information is not included in sufficient detail. CONCLUSIONS: The suitability of claims data depends on the source of uncertainty and, in consequence, the outcome measures chosen in the agreements. In all schemes, the validity of claims data should be judged with caution as data are collected for billing purposes. This framework may support manufacturers and payers in selecting the most suitable contract type and agreeing on contract conditions. More research is necessary to validate these results and to address remaining medical, economic, legal, and ethical questions of using claims data for MEA.
International Journal of Technology Assessment in Health Care

Schmiedl, S.; Fischer, R.; Ibáñez, L.; Fortuny, J.; Thuermann, P.A.; Ballarin, E.; Ferrer, P.; Sabaté, M.; Rottenkolber, D.; Gerlach, R.; Tauscher, M.; Reynolds, R.; Hasford, J.; Rottenkolber, M.
Tiotropium Respimat© vs. HandiHaler©: Real-life usage and TIOSPIR trial generalizability.
Br. J. Clin. Pharmacol. 81, 379-388 (2016)
Aim: Two inhaler devices (Respimat (R) and HandiHaler (R)) are available for tiotropium, a long acting anticholinergic agent. We aimed to analyze drug utilization, off-label usage and generalizability of the TIOSPIR trial results for both devices. MethodsPatients aged 18years exhibiting at least one documented prescription of tiotropium in the database of the Association of Statutory Health Insurance Physicians, Bavaria, Germany, were included (years 2004-2008). Annual period prevalence rates (PPRs) were calculated stratified by age, gender and inhaler devices. Off-label usage (patients lacking a chronic obstructive pulmonary disease (COPD) diagnosis) and the proportion of patients meeting the inclusion and exclusion criteria of the TIOSPIR trial were analyzed. ResultsBetween 2004 and 2008, PPRs increased and varied between 49.2 and 74.5 per 10000 persons for HandiHaler (R) and between 1.5 and 9.3 per 10000 persons for Respimat (R). Small differences regarding patient characteristics existed between the two inhaler devices. Only about 30% (HandiHaler (R) 32.1%, Respimat (R) 30.0%) of the database patients receiving tiotropium could be theoretically included in the TIOSPIR trial. ConclusionsComparing the two tiotropium devices, no clinically relevant differences regarding patient and prescribing characteristics were revealed. Results of the TIOSPIR trial were generalizable only to a minority of our study patients, underlining the need for real-life data.
British Journal of Clinical Pharmacology

Leidl, R.; Wacker, M.; Schwarzkopf, L.

Better understanding of the health care costs of lung cancer and the implications.
Expert Rev. Respir. Med. 10, 373-375 (2016)
Expert Review of Respiratory Medicine
Editorial
Editorial
Stephan, A.J.; Strobl, R.; Müller, M.; Holle, R.; Autenrieth, C.S.; Thorand, B.; Linkohr, B.; Peters, A.; Grill, E.
A high level of household physical activity compensates for lack of leisure time physical activity with regard to deficit accumulation: Results from the study KORA-Age.
Prev. Med. 86, 64-69 (2016)
INTRODUCTION: Aging is associated with increasing loss of physiological resilience and successive accumulation of physiological deficits. This can be measured through a frailty index which sums up symptoms, health conditions and impairments. One possible factor in preventing or delaying deficit accumulation is physical activity. The effect of leisure time physical activity on health is well investigated; however, the effect of household physical activity is less clear. The objective of this cross-sectional study was to examine the association of household physical activity with deficit accumulation while controlling for level of leisure time physical activity. METHODS: Data originates from the 2008 baseline assessment of the KORA-Age study (Cooperative Health Research in the Region of Augsburg) from Southern Germany. A frailty index of deficit accumulation (Deficit Accumulation Index, DAI) was constructed from 31 age-related health deficits. Physical activity was measured with the Physical Activity Scale for the Elderly (PASE). The association of deficit accumulation and physical activity was analyzed using negative binomial regression analysis. RESULTS: The participants' (n=960, mean age 76years, 49.0% female) DAI ranged from 0.00 to 0.68. Higher levels of both types of physical activity were statistically significantly associated with less deficit accumulation. Participants in the highest household (leisure time) physical activity quartile had 29% (30%) less deficits than participants in the respective lowest quartiles. CONCLUSION: High levels of household physical activity might compensate for low levels of leisure time physical activity in the prevention of deficit accumulation. Further research efforts investigating the temporal sequence of this association are needed.
Preventive Medicine

Herzog, B.[#]; Lacruz, M.E.[#]; Haerting, J.; Hartwig, S.; Tiller, D.; Medenwald, D.; Vogt, S.; Thorand, B.; Holle, R.; Bachlechner, U.; Boeing, H.; Merz, B.; Nöthlings, U.; Schlesinger, S.; Schipf, S.; Ittermann, T.; Aumann, N.; Schienkiewitz, A.; Haftenberger, M.; Greiser, K.H.; Neamat-Allah, J.; Katzke, V.A.; Kluttig, A.
Socioeconomic status and anthropometric changes - a meta-analytic approach from seven German cohorts.
Obesity 24, 710-718 (2016)
OBJECTIVE: To study the association between socioeconomic status (SES) and annual relative change in anthropometric markers in the general German adult population. METHODS: Longitudinal data of 56,556 participants aged 18-83 years from seven population-based German cohort studies (CARLA, SHIP, KORA, DEGS, EPIC-Heidelberg, EPIC-Potsdam, PopGen) were analyzed by meta-analysis using a random-effects model. The indicators of SES were education and household income. RESULTS: On average, all participants gained weight and increased their waist circumference over the study's follow-up period. Men and women in the low education group had a 0.1 percentage points greater annual increase in weight (95% CI men: 0.06-0.20; and women: 0.06-0.12) and waist circumference (95% CI men: 0.01-0.45; and women: 0.05-0.22) than participants in the high education group. Women with low income had a 0.1 percentage points higher annual increase in weight (95% CI 0.00-0.15) and waist circumference (95% CI 0.00-0.14) than women with high income. No association was found for men between income and obesity markers. CONCLUSIONS: Participants with lower SES (education and for women also income) gained more weight and waist circumference than those with higher SES. These results underline the necessity to evaluate the risk of weight gain based on SES to develop more effective preventive measures.
Obesity

Hartwig, S.[#]; Kluttig, A.[#]; Tiller, D.; Fricke, J.; Müller, G.; Schipf, S.; Völzke, H.; Schunk, M.; Meisinger, C.; Schienkiewitz, A.; Heidemann, C.; Moebus, S.; Pechlivanis, S.; Werdan, K.; Kuss, O.; Tamayo, T.; Haerting, J.; Greiser, K.H.
Anthropometric markers and their association with incident type 2 diabetes mellitus: Which marker is best for prediction? Pooled analysis of four German population-based cohort studies and comparison with a nationwide cohort study.
BMJ Open 6:e009266 (2016)
OBJECTIVE: To compare the association between different anthropometric measurements and incident type 2 diabetes mellitus (T2DM) and to assess their predictive ability in different regions of Germany. METHODS: Data of 10 258 participants from 4 prospective population-based cohorts were pooled to assess the association of body weight, body mass index (BMI), waist circumference (WC), waist-to-hip-ratio (WHR) and waist-to-height-ratio (WHtR) with incident T2DM by calculating HRs of the crude, adjusted and standardised markers, as well as providing receiver operator characteristic (ROC) curves. Differences between HRs and ROCs for the different anthropometric markers were calculated to compare their predictive ability. In addition, data of 3105 participants from the nationwide survey were analysed separately using the same methods to provide a nationally representative comparison. RESULTS: Strong associations were found for each anthropometric marker and incidence of T2DM. Among the standardised anthropometric measures, we found the strongest effect on incident T2DM for WC and WHtR in the pooled sample (HR for 1 SD difference in WC 1.97, 95% CI 1.75 to 2.22, HR for WHtR 1.93, 95% CI 1.71 to 2.17 in women) and in female DEGS participants (HR for WC 2.24, 95% CI 1.91 to 2.63, HR for WHtR 2.10, 95% CI 1.81 to 2.44), whereas the strongest association in men was found for WHR among DEGS participants (HR 2.29, 95% CI 1.89 to 2.78). ROC analysis showed WHtR to be the strongest predictor for incident T2DM. Differences in HR and ROCs between the different markers confirmed WC and WHtR to be the best predictors of incident T2DM. Findings were consistent across study regions and age groups (<65 vs ≥65 years). CONCLUSIONS: We found stronger associations between anthropometric markers that reflect abdominal obesity (ie, WC and WHtR) and incident T2DM than for BMI and weight. The use of these measurements in risk prediction should be encouraged.
BMJ Open

Wagner, C.J.; Metzger, F.G.; Sievers, C.; Marschall, U.; L'hoest, H.; Stollenwerk, B.; Stock, S.

Depression-related treatment and costs in Germany: Do they change with comorbidity? A claims data analysis.
J. Affect. Disord. 193, 257-266 (2016)
BACKGROUND: Existing diverse bottom-up estimations of direct costs associated with depression in Germany motivated a detailed patient-level analysis of depression-related treatment (DRT), -costs (DRC) and Comorbidity. METHODS: A large sickness fund's claims data was used to retrospectively identify patients aged 18-65 years with new-onset depression treatment between January 1st and February 15th 2010, and follow them until December 31st 2010, describe DRT, estimate associated DRC, and predict DRC with a generalised linear model. RESULTS: A total of 18,139 patients were analysed. Mean direct DRC were €783. Predictors of DRC regarding psychiatric comorbidities were: "Delusion, psychotic disorders and personality disorders" (DRC-ratio 1.72), "Alcohol/drug addiction" (1.82), "abuse of alcohol/drugs" (1.57). Predictors of DRC regarding medical comorbidities were: "Rheumatoid arthritis" (0.77), "atherosclerosis" (0.65), "pregnancy" (0.66), and "Osteoarthritis" (1.87). Of all patients, 60.8% received their most intense/specialised DRT from a general practitioner, a medical specialist (23.7%), a psychotherapist (8.0%), a medical specialist and psychotherapist (2.9%), or in hospital (4.6%). Serious psychiatric comorbidity nearly tripled depression-related hospitalisation rates. LIMITATIONS: Seasonal affective disorder and missing psychiatric outpatient clinic data must be considered. CONCLUSIONS: Estimated DRC are significantly below the assessment of the German national guideline. Differing definitions of observation period and cost attribution might explain differing German DRC results. Signs of hospital psychiatric comorbidity bias indicate overestimation of hospital DRC. Identified associations of DRC with certain medical diseases in older adults warrant further research. Up to one quarter of patients with severe depression diagnosis might lack specialist treatment.
Journal of Affective Disorders

Wacker, M.; Jörres, R.A.; Schulz, H.; Heinrich, J.; Karrasch, S.; Karch, A.; Koch, A.; Peters, A.; Leidl, R.; Vogelmeier, C.; Holle, R.
Direct and indirect costs of COPD and its comorbidities: Results from the German COSYCONET study.
Respir. Med. 111, 39-46 (2016)
Background: Reliable up-to-date estimates regarding the economic impact of chronic obstructive pulmonary disease (COPD) are lacking. This study investigates COPD excess healthcare utilization, work absenteeism, and resulting costs within the German COPD cohort COSYCONET. Methods: Data from 2139 COPD patients in GOLD grade 1-4 from COSYCONET were compared with 1537 lung-healthy control subjects from the population-based KORA platform. Multiple generalized linear models analyzed the association of COPD grades with healthcare utilization, work absence, and costs from a societal perspective while adjusting for sex, age, education, smoking status, body mass index (BMI), and several comorbidities. Results: COPD was significantly associated with excess healthcare utilization, work absence, and premature retirement. Adjusted annual excess cost of COPD in 2012 for GOLD grade 1-4 amounted to €2595 [1770-3678], €3475 [2966-4102], €5955 [5191-6843], and €8924 [7190-10,853] for direct costs, and €8621 [4104-13,857], €9871 [7692-12,777], €16,550 [13,743-20,457], and €27,658 [22,275-35,777] for indirect costs respectively. Comorbidities contributed to the primary effect of COPD on direct costs only. An additional history of cancer or stroke had the largest effect on direct costs, but the effects were smaller than those of COPD grade 3/4. Conclusions: COPD is associated with substantially higher costs than previously reported.
Respiratory Medicine

Seidl, H.; Meisinger, C.; Kirchberger, I.; Burkhardt, K.; Kuch, B.; Holle, R.
Validity of self-reported hospital admissions in clinical trials depends on recall period length and individual characteristics.
J. Eval. Clin. Pract. 22, 446-454 (2016)
RATIONALE, AIMS AND OBJECTIVES: We investigated the validity of self-reported admission data compared to administrative records in a clinical trial. METHOD: In the randomized KORINNA study (ISRCTN02893746), hospital admission data were collected in telephone interviews with 273 elderly patients quarterly over a 1-year period and thereafter annually over a 2-year period. Data were compared with administrative records and discharge letters. Mixed models were used to investigate if recall period and individual characteristics influence validity. RESULTS: Specificity (>99%) and sensitivity (94%) of self-reported data did not differ for different recall periods (3 months vs. 12 months). The differences between self-reported and registered inpatient days were not statistically significant. Having regard to all the admissions within the time period of last interview and dropping out, the bias was up to 40% underestimation. The chance of disagreement was significantly smaller [odds ratio (OR) of misremember an admission = 0.596, P = 0.049, confidence interval (CI) = 0.355 to 1.00; OR of misremember length of stay = 0.521, P = 0.002, CI = 0.344 to 0.789] for 3-month periods, but this was primarily driven by number of admissions within the recall period. Individuals with better health and longer stays had a significantly smaller chance of disagreement. CONCLUSIONS: The bias within one year was not influenced by applying various recall periods, although the probability of correctly self-reported single hospital admission was higher using a recall period of three months. It can be recommended that lengthened recall periods of 12 months are appropriate for gathering self-reported hospital admission data in elderly people with myocardial infarction.
Journal of Evaluation in Clinical Practice

Yousri, N.A.; Kastenmüller, G.; AlHaq, W.G.; Holle, R.; Kääb, S.; Mohney, R.P.; Gieger, C.; Peters, A.; Adamski, J.; Suhre, K.; Arayssi, T.
Diagnostic and prognostic metabolites identified for joint symptoms in the KORA population.
J. Proteome Res. 15, 554-562 (2016)
This study aims at identifying metabolites that significantly associate with self-reported joint symptoms (diagnostic) and metabolites that can predict the change from a symptom-free status to the development of self-reported joint symptoms after a 7 years period (prognostic). More than 300 metabolites were analyzed for 2246 subjects from the longitudinal study of the KORA (Cooperative Health Research in the Region of Augsburg, Germany), specifically the fourth survey S4 and its 7-year follow-up study F4. Two types of self-reported symptoms, chronic joint inflammation and worn out joints, were used for the analyses. Diagnostic analysis identified dysregulated metabolites in cases with symptoms compared with controls. Prognostic analysis

identified metabolites that differentiate subjects in S4 who remained symptom-free after 7 years (F4) from those who developed any combination of symptoms. 48 metabolites were identified as nominally significantly ($p < 0.05$) associated with the self-reported symptoms in the diagnostic analysis, among which steroids show Bonferroni significance. 45 metabolites were identified as nominally significantly associated with developing symptoms after 7 years, among which hippurate showed Bonferroni significance. We show that metabolic profiles of self-reported joint symptoms are in line with metabolites known to associate with various forms of arthritis and suggest that future studies may benefit from that by investigating the possible use of self-reporting/questionnaire along with metabolic markers for the early referral of patients for further diagnostic workup and treatment of arthritis.
Journal of Proteome Research

Italia, S.; Brüske, I.; Heinrich, J.; Berdel, D.; von Berg, A.; Lehmann, I.; Standl, M.; Wolfenstetter, S.B.
A longitudinal comparison of drug use among 10-year-old children and 15-year-old adolescents from the German GINIplus and LISAplus birth cohorts.
Eur. J. Clin. Pharmacol. 72, 301-310 (2016)
PURPOSE: The purpose of this study was to compare longitudinal data on drug utilization between 10-year-old children and 15-year-old adolescents and to analyse the association of drug use at the age of 15 years with drug use at the age of 10 years. METHODS: Based on the German GINIplus (German infant study on the Influence of Nutrition Intervention plus environmental and genetic influences on allergy development) and LISAplus (Influence of lifestyle factors on the immune system and allergies in East and West Germany plus the influence of traffic emissions and genetics) birth cohorts, data on drug utilization (past 4 weeks) were collected using a self-administered questionnaire for 3642 children (10-year follow-up) and 4677 adolescents (15-year follow-up). The drugs were classified by therapeutic categories (conventional drugs, homeopathic drugs, etc.) and by codes according to the anatomical therapeutic chemical (ATC) classification system. Associations of adolescents' drug use with gender, study area, maternal education, parental income, presence of chronic conditions, and prior drug use at the age of 10 years were analysed using a logistic regression model. RESULTS: The 4-week prevalence rates of overall drug use were similar for adolescents (41.1 %) and children (42.3 %). However, adolescents used noticeably more anti-inflammatory drugs, analgesics, and systemic antihistamines. Exactly 3194 children/adolescents participated in both follow-ups. Adolescents' use of anti-inflammatory drugs was predicted (OR = 3.37) by use of anti-inflammatory drugs as a child. In summary, the strongest predictor of adolescents' use of specific therapeutic categories or ATC groups was the previous use of the same therapeutic drug category or ATC group as a 10-year-old child. CONCLUSIONS: Despite similar prevalence rates of overall drug utilization among both age groups, there is a noticeable difference concerning the use of drugs from specific ATC groups. Drug use as a child may partly determine what they use as an adolescent.
European Journal of Clinical Pharmacology

Butzke, B.; Oduncu, F.S.; Severin, F.; Pfeufer, A.; Heinemann, V.; Giessen-Jung, C.; Stollenwerk, B.; Rogowski, W.H.
The cost-effectiveness of UGT1A1 genotyping before colorectal cancer treatment with irinotecan from the perspective of the German statutory health insurance.
Acta Oncol. 55, 318-328 (2016)
BACKGROUND: The evidence concerning the cost-effectiveness of UGT1A1*28 genotyping is ambiguous and does not allow drawing valid conclusions for Germany. This study evaluates the cost-effectiveness of UGT1A1 genotyping in patients with metastatic colorectal cancer undergoing irinotecan-based chemotherapy compared to no testing from the perspective of the German statutory health insurance. MATERIAL AND METHODS: A decision-analytic Markov model with a life time horizon was developed. No testing was compared to two genotype-dependent therapy strategies: 1) dose reduction by 25%; and 2) administration of a prophylactic G-CSF growth factor analog for homozygous and heterozygous patients. Probability, quality of life and cost parameters used in this study were based on published literature. Deterministic and probabilistic sensitivity analyses were performed to account for parameter uncertainties. RESULTS: Strategy 1 dominated all remaining strategies. Compared to no testing, it resulted in only marginal QALY increases (0.0002) but a cost reduction of €580 per patient. Strategy 2 resulted in the same health gains but increased costs by €10 773. In the probabilistic analysis, genotyping and dose reduction was the optimal strategy in approximately 100% of simulations at a threshold of €50 000 per QALY. Deterministic sensitivity analysis shows that uncertainty for this strategy originated primarily from costs for irinotecan-based chemotherapy, from the prevalence of neutropenia among heterozygous patients, and from whether dose reduction is applied to both homozygotes and heterozygotes or only to the former. CONCLUSION: This model-based synthesis of the most recent evidence suggests that pharmacogenetic UGT1A1 testing prior to irinotecan-based chemotherapy dominates non-personalized colon cancer care in Germany. However, as structural uncertainty remains high, these results require validation in clinical practice, e.g. based on a managed-entry agreement.
Acta Oncologica

Shariful Islam, S.M.; Lechner, A.; Ferrari, U.; Seissler, J.; Holle, R.; Niessen, L.W.
Mobile phone use and willingness to pay for SMS for diabetes in Bangladesh.
J. Public Health 38, 163-169 (2016)
BACKGROUND: Mobile phone SMS is increasingly used as a means of communication between patients and their healthcare providers in many countries of the world. We investigated mobile phone use and factors associated with willingness-to-pay (WTP) for diabetes SMS among patients with type 2 diabetes in Bangladesh. METHODS: As part of a randomized controlled study, in 515 patients with type 2 diabetes, socioeconomic status, mobile phone use, WTP for diabetes SMS, anthropometry and HbA1c were measured. Multivariate regression was used to identify factors associated with WTP. RESULTS: The median (interquartile range [IQR]) of WTP for diabetes SMS was 20 (45) Bangladesh Taka (BDT) (1 BDT = 0.013 US$). WTP was significantly higher for males [OR 2.4, 95% CI (1.0-5.7)], patients with household income >50 000 BDT [4.6 (1.1-20.4)] and those with primary education [5.6 (1.2-26.6)] and secondary and higher education [5.2 (1.4-19.6)]. CONCLUSIONS: The high proportion of mobile phone use and

WTP for diabetes SMS are encouraging as possible strategy to use such technologies and deserve further evaluation.
Journal of Public Mental Health

Stollenwerk, B.; Welchowski, T.; Vogl, M.; Stock, S.
Cost-of-illness studies based on massive data: A prevalence-based, top-down regression approach.
Eur. J. Health Econ. 17, 235-244 (2016)
Despite the increasing availability of routine data, no analysis method has yet been presented for cost-of-illness (COI) studies based on massive data. We aim, first, to present such a method and, second, to assess the relevance of the associated gain in numerical efficiency. We propose a prevalence-based, top-down regression approach consisting of five steps: aggregating the data; fitting a generalized additive model (GAM); predicting costs via the fitted GAM; comparing predicted costs between prevalent and non-prevalent subjects; and quantifying the stochastic uncertainty via error propagation. To demonstrate the method, it was applied to aggregated data in the context of chronic lung disease to German sickness funds data (from 1999), covering over 7.3 million insured. To assess the gain in numerical efficiency, the computational time of the innovative approach has been compared with corresponding GAMs applied to simulated individual-level data. Furthermore, the probability of model failure was modeled via logistic regression. Applying the innovative method was reasonably fast (19 min). In contrast, regarding patient-level data, computational time increased disproportionately by sample size. Furthermore, using patient-level data was accompanied by a substantial risk of model failure (about 80 % for 6 million subjects). The gain in computational efficiency of the innovative COI method seems to be of practical relevance. Furthermore, it may yield more precise cost estimates.
The European journal of health economics

2015
Kilian, H.; Lehmann, F.; Richter-Kornweitz, A.; Kaba-Schönstein, L.; Mielck, A.
Gesundheitsförderung in den Lebenswelten gemeinsam stärken. Der Kopperationsverbund "Gesundheitliche Chancengleichheit".
Bundesgesundheitsbl.-Gesund. 59, 266-273 (2015)
BACKGROUND: In 2003, the German Federal Center for Health Education (BZgA) initiated a national Cooperation Network named "Equity in Health" to address scientific results, focusing on the association between social inequalities and health. The main goal is to support setting approaches aimed at reducing these health inequalities. RESULTS AND KEY ACTIVITIES: In the autumn of 2015 the Cooperation Network comprised a total of 65 (institutional) cooperation partners, e.g., from prevention and health promotion, from the medical profession, from the welfare associations, and from the municipal umbrella organziations. The website www.gesundheitliche-chancengleichheit.de was created to present the information available on all activities and structures. Further, Coordination Centers for Health Equity were established in all federal states of Germany to advise, coordinate and provide support for all those who are actively engaged in the key issues for each state. These Coordination Centers are sponsored by the statutory sickness funds and the Health Ministry of the respective states. They also support continuous quality improvement, based on the good practice criteria developed by the Cooperation Network. Since 2011, the local partner process "Health for All" (until November 2015 "Growing Up Healthily for All") has assisted the municipalities in developing their own integrated health strategies oriented toward the different stages in the life course ("prevention chains"). PERSPECTIVES: The results and structures that have emerged from the Cooperation Network form a good basis for the implementation of the new national Prevention Law passed by German Parliament in July 2015, to expand and develop further, on a country-wide basis and in the various states, living-space-oriented prevention and health promotion consolidating activities. The paper also discusses the present and future challenges of the Cooperation Network.
Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz

Kirsch, F.
A systematic review of Markov models evaluating multicomponent disease management programs in diabetes.
Expert Rev. Pharmacoecon. Outcomes Res. 15, 961-984 (2015)
Diabetes is the most expensive chronic disease; therefore, disease management programs (DMPs) were introduced. The aim of this review is to determine whether Markov models are adequate to evaluate the cost–effectiveness of complex interventions such as DMPs. Additionally, the quality of the models was evaluated using Philips and Caro quality appraisals. The five reviewed models incorporated the DMP into the model differently: two models integrated effectiveness rates derived from one clinical trial/meta-analysis and three models combined interventions from different sources into a DMP. The results range from cost savings and a QALY gain to costs of US$85,087 per QALY. The Spearman's rank coefficient assesses no correlation between the quality appraisals. With restrictions to the data selection process, Markov models are adequate to determine the cost–effectiveness of DMPs; however, to allow prioritization of medical services, more flexibility in the models is necessary to enable the evaluation of single additional interventions.
Expert Review of Pharmacoeconomics and Outcomes Research

Müller, D.; Gerber-Grote, A.; Stollenwerk, B.; Stock, S.; Auweiler, P.; Frey, S.; Adarkwah, C.C.; de Kinderen, R.; Hellmich, M.
Reporting health care decision models: A prospective reliability study of a multidimensional evaluation framework.
Expert Rev. Pharmacoecon. Outcomes Res. 16, 619-627 (2015)
© 2015 Taylor & Francis The aim of this study was to evaluate the inter-rater reliability of the Phillips-checklist, a proposed framework for the quality assessment of modeling studies. Six raters evaluated nine modeling studies from three different medical specialties. Intra-class correlation (ICC) and corresponding variance components were estimated from these studies. Raters were asked to comment on their experience with the framework. While overall the mean inter-rater reliability showed no significant rater-effect (ICC = 0.69, $p = 0.064$), there was – presumably as a result of a lower study variability – a significant rater effect for clopidogrel only ($p < 0.001$). The framework allowed a more structured methodological assessment but several items remained unclear. Regarding the quality assessment of modeling studies with the proposed framework, the rater variability is similar or even higher than variability because of studies or residual effects. Several scoring items can and should be improved to ease interpretation.
Expert Review of Pharmacoeconomics and Outcomes Research

Cheung, K.L.; Evers, S.M.; Hiligsmann, M.; Voko, Z.; Pokhrel, S.; Jones, T.; Muñoz, C.; Wolfenstetter, S.B.; Józwiak-Hagymásy, J.; de Vries, H.
Understanding the stakeholders' intention to use economic decision-support tools: A cross-sectional study with the tobacco return on investment tool.
Health Policy 120, 46-54 (2015)
Background: Despite an increased number of economic evaluations of tobacco control interventions, the uptake by stakeholders continues to be limited. Understanding the underlying mechanism in adopting such economic decision-support tools by stakeholders is therefore important. By applying the I-Change Model, this study aims to identify which factors determine potential uptake of an economic decision-support tool, i.e., the Return on Investment tool. Methods: Stakeholders (decision-makers, purchasers of services/pharma products, professionals/service providers, evidence generators and advocates of health promotion) were interviewed in five countries, using an I-Change based questionnaire. MANOVA's were conducted to assess differences between intenders and non-intenders regarding beliefs. A multiple regression analysis was conducted to identify the main explanatory variables of intention to use an economic decision-support tool. Findings: Ninety-three stakeholders participated. Significant differences in beliefs were found between non-intenders and intenders: risk perception, attitude, social support, and self-efficacy towards using the tool. Regression showed that demographics, pre-motivational, and motivational factors explained 69% of the variation in intention. Discussion: This study is the first to provide a theoretical framework to understand differences in beliefs between stakeholders who do or do not intend to use economic decision-support tools, and empirically corroborating the framework. This contributes to our understanding of the facilitators and barriers to the uptake of these studies.
Health Policy

Soellner, R.; Reder, M.; Machmer, A.; Holle, R.; Wilz, G.
The Tele.TAnDem intervention: Study protocol for a psychotherapeutic intervention for family caregivers of people with dementia.
BMC Nurs. 14, 11 (2015)
Background: Family caregivers are confronted with high demands creating a need for professional support and at the same time hindering its utilization. Telephone support allows easier access than face-to-face support because there is no need to leave the person with dementia alone or find an alternative carer. It is also independent of transport possibilities or mobility. The objectives are to evaluate whether telephone-based cognitive-behavioral therapy, which is implemented in established care provision structures, improves outcomes compared to usual care and whether it is as effective as face-to-face cognitive-behavioral therapy. Methods/Design: If participants live in the area of one of the study centers (Jena, Berlin, Munich) and indicate that attendance of a face-to-face therapy is possible, they will be assigned to the face-to-face group. The other participants will be randomized to receive either telephone-based cognitive-behavioral therapy or usual care. Data will be collected at baseline, post-intervention, and at a 6-month follow-up. The primary outcomes will be depressiveness, burden of care, health complaints, and problem-solving ability. The secondary outcomes will be anxiety, quality of life, violence in caregiving, utilization of professional assistance, and cost effectiveness. Discussion: This paper describes the evaluation design of our telephone-based cognitive-behavioral therapy in a randomized controlled trial. If this intervention proves to be an effective tool to improve outcomes, it will be made accessible to the public and the use of this support service will be recommended.
BMC Nursing

Holle, R.; Wacker, M.; Joerres, R.A.; Schulz, H.; Heinrich, J.; Peters, A.; Koch, A.; Leidl, R.; Vogelmeier, C.F.
Do comorbidities have a specific impact on generic Health-Related Quality of Life (HRQL) in COPD patients compared to controls? First results of the German COSYCONET cohort study.
Am. J. Respir. Crit. Care Med. 191:A6207 (2015)
American Journal of Respiratory and Critical Care Medicine
Meeting abstract

Wilke, S.; Watz, H.; Bals, R.; Franssen, F.; Holle, R.; Karch, A.; Koch, A.; Schulz, H.; Spruit, M.A.; Wacker, M.; Welte, T.; Wouters, E.F.M.; Joerres, R.A.; Vogelmeier, C.
Impact of peripheral artery disease on functional capacity and health status in patients with chronic obstructive pulmonary disease: Results of the COSYCONET study.
Am. J. Respir. Crit. Care Med. 191:A6204 (2015)
American Journal of Respiratory and Critical Care Medicine
Meeting abstract

Wacker, M.; Joerres, R.A.; Schulz, H.; Heinrich, J.; Peters, A.; Koch, A.; Leidl, R.; Vogelmeier, C.F.; Holle, R.
Work absenteeism and healthcare utilization in COPD: The clinical cohort COSYCONET compared with population-based controls.
Am. J. Respir. Crit. Care Med. 191:A2310 (2015)
American Journal of Respiratory and Critical Care Medicine
Meeting abstract

Korber, K.
Quality assessment of economic evaluations of health promotion programs for children and adolescents - a systematic review using the example of physical activity.
Health Econ. Rev. 5:35 (2015)
An increasing number of primary prevention programs aimed at promoting physical exercise in children and adolescents are being piloted. As resources are limited, it is important to ascertain the costs and benefits of such programs. The aim of this systematic review is to evaluate the currently available evidence on the cost-effectiveness of programs encouraging physical activity in children and adolescents and to assess their quality. A systematic review was conducted searching in well established literature databases considering all studies before February 2015. Citation tracking in Google Scholar and a manual search of the reference lists of included studies were used to consolidate this. The fundamental methodological elements of the included economic evaluations were extracted, and the quality of the included studies was evaluated using the Pediatric Quality Appraisal Questionnaire (PQAQ). In total, 14 studies were included. Considering the performance of the economic evaluation, the studies showed wide variation. Most of the studies used a societal perspective for their analyses and discounted costs and effects. The findings ranged from US$11.59 for a person to become more active (cheapest intervention) up to US$669,138 for a disability adjusted life year

(DALY) saved (most expensive intervention), with everything in between. Overall, the results of three studies are below a value of US$3061, with one of them even below US$200.00, for the achieved effects. For the other programs, the context-specific assessment of cost-effectiveness is problematic as there are different thresholds for cost-effectiveness in different countries or no clearly defined thresholds at all. There are multiple methodological difficulties involved in evaluating the cost-effectiveness of interventions aimed at increasing physical activity, which results in little consistency between different evaluations. The quality of the evaluations ranged from poor to excellent while a large majority of them was of very good methodological quality. Better comparability could be reached by greater standardization, especially regarding systematic consideration of implementation costs.
Health Economics Review

Bock, J.-O.; Brettschneider, C.; Seidl, H.; Bowles, D.; Holle, R.; Greiner, W.; König, H.-H.
Standardisierte Bewertungssätze aus gesellschaftlicher Perspektive für die gesundheitsökonomische Evaluation.
Baden-Baden: Nomos, 2015. 79 S.
Hoogendoorn, M.; Feenstra, T.; Asukai, Y.; Briggs, A.; Borg, S.; dal Negro, R.; Hansen, R.N.; Jansson, S.A.; Wacker, M.; Risebrough, N.; Samyshkin, Y.; Leidl, R.; Rutten van-Mölken, M.
Patient heterogeneity in cost-effectiveness models for Chronic Obstructive Pulmonary Disease (COPD): Are current models suitable to evaluate personalized medicine.
Value Health 18:A694 (2015)
Value in Health
Meeting abstract

Brandes, A.; Sinner, M.F.; Kääb, S.; Rogowski, W.H.
Early decision-analytic modeling - a case study on vascular closure devices.
BMC Health Serv. Res. 15:486 (2015)
BACKGROUND: As economic considerations become more important in healthcare reimbursement, decisions about the further development of medical innovations need to take into account not only medical need and potential clinical effectiveness, but also cost-effectiveness. Already early in the innovation process economic evaluations can support decisions on development in specific indications or patient groups by anticipating future reimbursement and implementation decisions. One potential concept for early assessment is value-based pricing. METHODS: The objective is to assess the feasibility of value-based pricing and product design for a hypothetical vascular closure device in the pre-clinical stage which aims at decreasing bleeding events. A deterministic decision-analytic model was developed to estimate the cost-effectiveness of established vascular closure devices from the perspective of the Statutory Health Insurance system. To identify early benchmarks for pricing and product design, three strategies of determining the product's value are explored: 1) savings from complications avoided by the new device; 2) valuation of the avoided complications based on an assumed willingness-to-pay-threshold (the efficiency frontier approach); 3) value associated with modifying the care pathways within which the device would be applied. RESULTS: Use of established vascular closure devices is dominated by manual compression. The hypothetical vascular closure device reduces overall complication rates at higher costs than manual compression. Maximum cost savings of only about €4 per catheterization could be realized by applying the hypothetical device. Extrapolation of an efficiency frontier is only possible for one subgroup where vascular closure devices are not a dominated strategy. Modifying care in terms of same-day discharge of patients treated with vascular closure devices could result in cost savings of €400-600 per catheterization. CONCLUSIONS: It was partially feasible to calculate value-based prices for the novel closure device which can be used to inform product design. However, modifying the care pathway may generate much more value from the payers' perspective than modifying the device per se. Manufacturers should thus explore the feasibility of combining reimbursement of their product with arrangements that make same-day discharge attractive also for hospitals. Due to the early nature of the product, the results are afflicted with substantial uncertainty.
BMC Health Services Research

Kreuter, M.; Herth, F.; Wacker, M.; Leidl, R.; Hellmann, A.; Pfeifer, M.; Behr, J.; Witt, S.; Kauschka, D.; Mall, M.; Günther, A.; Markart, P.
Exploring clinical and epidemiological characteristics of interstitial lung diseases: Rationale, aims, and design of a nationwide prospective registry - the EXCITING-ILD registry.
Biomed Res. Int. 2015:123876 (2015)
Despite a number of prospective registries conducted in past years, the current epidemiology of interstitial lung diseases (ILD) is still not well defined, particularly regarding the prevalence and incidence, their management, healthcare utilisation needs, and healthcare-associated costs. To address these issues in Germany, a new prospective ILD registry, "Exploring Clinical and Epidemiological Characteristics of Interstitial Lung Diseases" (EXCITING-ILD), is being conducted by the German Centre for Lung Research in association with ambulatory, inpatient, scientific pulmonology organisations and patient support groups. This multicentre, noninterventional, prospective, and observational ILD registry aims to collect comprehensive and validated data from all healthcare institutions on the incidence, prevalence, characteristics, management, and outcomes regarding all ILD presentations in the real-world setting. Specifically, this registry will collect demographic data, disease-related data such as ILD subtype, treatments, diagnostic procedures (e.g., HRCT, surgical lung biopsy), risk factors (e.g., familial ILD), significant comorbidities, ILD managements, and disease outcomes as well as healthcare resource consumption. The EXCITING-ILD registry will include in-patient and out-patient ILD healthcare facilities in more than 100 sites. In summary, this registry will document comprehensive and current epidemiological data as well as important health economic data for ILDs in Germany.
BioMed Research International

Strasser, B.; Arvandi, M.; Thorand, B.; Matteucci Gothe, R.; Siebert, U.; Volaklis, K.A.; Ladwig, K.-H.; Grill, E.; Horsch, A.; Laxy, M.; Peters, A.; Meisinger, C.
SUN-PP229: The role of nutritional status in the association between grip strength and risk of falling in the old age: Results from the Kora-Age study.
Clin. Nutr. 34, S108 (2015)
Clinical Nutrition
Meeting abstract

Laxy, M.; Hunger, M.; Stark, R.G.; Meisinger, C.; Kirchberger, I.; Heier, M.; von Scheidt, W.; Holle, R.
The burden of diabetes mellitus in patients with coronary heart disease: A methodological approach to assess quality-adjusted life-years based on individual-level longitudinal survey data.
Value Health 18, 969-976 (2015)
Background: Reliable burden of disease (BOD) estimates are needed to support decision making in health care. Objectives: The objective of this study was to introduce an analysis approach based on individual-level longitudinal survey data that estimates the burden of diabetes in patients with coronary heart disease in terms of quality-adjusted life-years (QALYs) lost. Methods: Data from two postal surveys (2006, N = 1022; 2010-2011, N = 716) of survivors from the KORA Myocardial Infarction Registry in Southern Germany were analyzed. Accumulated QALYs were calculated for each participant over a mean observation time of 4.1 years, considering the noninformative censoring structure of the follow-up study. Linear regression models were used to estimate the loss in (quality-unadjusted) life-years and QALYs between patients with and without diabetes, and generalized additive models were used to analyze the nonlinear association with age. The cross-sectional and longitudinal association with quality of life (QOL) and QOL change and the impact on mortality were analyzed to enhance the understanding of the observed results. Results: Diabetes was associated with a reduced QOL at baseline (cross-sectional: $\beta = -0.069$; $P < 0.001$), but not with a significant longitudinal QOL change. Mortality in patients with diabetes was increased (hazard ratio = 1.68; $P < 0.005$). This resulted in a loss of 0.14 life-years ($P = 0.003$) and 0.37 QALYs ($P < 0.001$). Results from generalized additive models indicated that the burden of diabetes is less pronounced in older subjects. Conclusions: The application of the proposed approach provides confounder-adjusted BOD estimates for the studied time horizon and can be used to compare the BOD across different chronic conditions. Curative efforts are needed to diminish the substantial diabetes-related QALY gap.
Value in Health

Laxy, M.; Stark, R.G.; Meisinger, C.; Kirchberger, I.; Heier, M.; von Scheidt, W.; Holle, R.
The effectiveness of German Disease Management Programs (DMPs) in patients with type 2 diabetes mellitus and coronary heart disease: Results from an observational longitudinal study.
Diabetol. Metab. Syndr. 7:77 (2015)
Background: Although the population-based German disease management programs (DMPs) for diabetes mellitus (DM) and coronary heart disease (CHD) are among the biggest worldwide, evidence on the effectiveness of these programs is still inconclusive or missing, particularly for high risk patients with comorbidities. The objective of this study was therefore to analyze the impact of DMPs on process and outcome parameters in patients with both, type 2 DM and CHD. Methods: Analyses are based on two postal surveys of patients from the KORA myocardial infarction registry (southern Germany) with type 2 DM and on two postal validation studies with patients' general physicians (2006, n = 312 and 2011, n = 212). The association between DMP enrollment (being enrolled in either DMP-DM or DMP-CHD) and guideline care (defined by several process indicators) at baseline (2006) and its development until follow-up (2011) was analyzed using logistic regression models accounting for the repeated measurements structure. The impact of DMP enrollment/guideline care on cumulated (quality-adjusted) life years ((QA)LYs) over a 4-year time horizon (2006-2010) was assessed using multiple linear regression methods. Logistic regression models were applied to analyze the association between DMP status and patient self-management at follow-up. Results: Being enrolled in a DMP was associated with better guideline care at baseline [OR = 2.3 (95 % CI 1.27-4.03)], but not at follow-up [OR = 0.80 (95 % CI 0.40-1.58); p value for time-interaction <0.01]. DMP enrollment was not significantly [+0.15 LYs (95 % CI -0.07, 0.37); +0.06 QALYs (95 % CI -0.15, 0.26)], but treatment according to guideline care significantly [+0.40 LYs (95 % CI 0.21-0.60); +0.28 QALYs (95 % CI 0.10-0.45)] associated with higher (quality-adjusted) survival over the 4-year follow-up period. DMP enrollees further reported a somewhat better self-management than patients not being enrolled into a DMP. Conclusions: The results of this study concerning the effectiveness of DMPs in patients with DM and CHD are mixed, but are weakly in favor of DMPs. However, we found a clear positive impact of guideline care on quality adjusted survival in this patient group. The development of the association between DMP enrollment and guideline care over the follow-up time indicates some external effects, which should be the subject of further investigations.
Diabetology & Metabolic Syndrome

Schwarzkopf, L.°; Wacker, M.°; Holle, R.°; Leidl, R.°; Günster, C.°; Adler, J.B.°; Huber, R.M.°
Cost-components of lung cancer care within the first three years after initial diagnosis in context of different treatment regimens.
Lung Cancer 90, 274-280 (2015)
Objectives: Although lung cancer is of high epidemiological relevance in Germany, evidence on its economic implications is scarce. Sound understanding of current care structures and associated expenditures is required to comprehensively judge the additional benefit of novel interventions in lung cancer care. Adopting a payer perspective, our study aims to analyze expenditures for individuals with incident lung cancer. Material and methods: Patients with an initial diagnosis of lung cancer (ICD-10 code C34) in 2009 were searched in a large, nationwide base of health insurance claims data and grouped according to initial treatment (Surgery, Chemotherapy/Radiotherapy, No specific treatment). All-cause SHI and lung cancer-related spending was assessed for a patient-individual three-year time frame after initial diagnosis. Expenditures per case and expenditures per year survived were calculated via Generalized Linear Gamma Models adjusted for age, gender, living region, baseline metastases, multiple tumors and initial treatment regimen using time under observation as a weighting factor. Results: 17,478 individuals were identified. Lung cancer-related expenditures peaked within the first six months after initial diagnosis. Following, they declined subsequently and so did their share in all-cause SHI spending. Lung cancer-related expenditures per case were estimated at €20,400 (53% of all-cause expenditures) with a huge variance according to initial treatment regimen [Surgery: €20,400, Chemotherapy/Radiotherapy: €26,300, No specific treatment: €4200]. Cost per year survived amounted to €15,500 (55% of all cause expenditures) [Surgery: €11,600, Chemotherapy/Radiotherapy: €20,200, No specific treatment: €7600]. Conclusion: Analyses of lung cancer-related expenditures need to take into account treatment strategies and survival. Our study is representative for a large share of the

population and provides detailed, patient-level information on costs of care and their compilation. Results render estimates available for the cost of lung cancer e.g. for budget impact analyses, cost-effectiveness analyses of screening and prevention schemes, or prognostic models of life-time expenditures per lung cancer case.
Lung Cancer

Meyer, C.W.; Reitmeir, P.; Tschöp, M.H.
Exploration of energy metabolism in the mouse using indirect calorimetry: Measurement of Daily Energy Expenditure (DEE) and Basal Metabolic Rate (BMR).
Curr. Protoc. Mouse Biol. 5, 205-222 (2015)
Current comprehensive mouse metabolic phenotyping involves studying energy balance in cohorts of mice via indirect calorimetry, which determines heat release from changes in respiratory air composition. Here, we describe the measurement of daily energy expenditure (DEE) and basal metabolic rate (BMR) in mice. These well-defined metabolic descriptors serve as meaningful first-line read-outs for metabolic phenotyping and should be reported when exploring energy expenditure in mice. For further guidance, the issue of appropriate sample sizes and the frequency of sampling of metabolic measurements is also discussed.
Current Protocols of Mouse Biology

Rückert, I.-M.; Baumert, J.J.; Schunk, M.; Holle, R.; Schipf, S.; Völzke, H.; Kluttig, A.; Greiser, K.H.; Tamayo, T.; Rathmann, W.; Meisinger, C.
Blood pressure control has improved in people with and without type 2 diabetes but remains suboptimal: A longitudinal study based on the German DIAB-CORE consortium.
PLoS ONE 10:e0133493 (2015)
BACKGROUND: Hypertension is a very common comorbidity and major risk factor for cardiovascular complications, especially in people with Type 2 Diabetes (T2D). Nevertheless, studies in the past have shown that blood pressure is often insufficiently controlled in medical practice. For the DIAB-CARE study, we used longitudinal data based on the German DIAB-CORE Consortium to assess whether health care regarding hypertension has improved during the last decade in our participants. METHODS: Data of the three regional population-based studies CARLA (baseline 2002-2006 and follow-up 2007-2010), KORA (baseline 1999-2001 and follow-up 2006-2008) and SHIP (baseline 1997-2001 and follow-up 2002-2006) were pooled. Stratified by T2D status we analysed changes in frequencies, degrees of awareness, treatment and control. Linear mixed models were conducted to assess the influence of sex, age, study, and T2D status on changes of systolic blood pressure between the baseline and follow-up examinations (mean observation time 5.7 years). We included 4,683 participants aged 45 to 74 years with complete data and accounted for 1,256 participants who were lost to follow-up by inverse probability weighting. RESULTS: Mean systolic blood pressure decreased in all groups from baseline to follow-up (e.g. - 8.5 mmHg in those with incident T2D). Pulse pressure (PP) was markedly higher in persons with T2D than in persons without T2D (64.14 mmHg in prevalent T2D compared to 52.87 mmHg in non-T2D at baseline) and did not change much between the two examinations. Awareness, treatment and control increased considerably in all subgroups however, the percentage of those with insufficiently controlled hypertension remained high (at about 50% of those with hypertension) especially in prevalent T2D. Particularly elderly people with T2D often had both, high blood pressure ≥140/90 mmHg and a PP of ≥60 mmHg. Blood pressure in men had improved more than in women at follow-up, however, men still had higher mean SBP than women at follow-up. CONCLUSION: Blood pressure management has developed positively during past years in Germany. While hypertension prevalence, awareness and treatment were substantially higher in participants with T2D than in those without T2D at follow-up, hypertension control was achieved only in about half the number of people in each T2D group leaving much room for further improvement.
PLoS ONE

Kurz, C.F.
Stochastic profiling of single-cell heterogeneities : A Bayesian extention.
München, Hochschule für angewandte Wissenschaften, Fakultät für Informatik und Mathematik, Master-Thesis, 2015, 69 S.
Vogt, S.; Zierer, A.; Laxy, M.; Koenig, W.; Linkohr, B.; Linseisen, J.; Peters, A.; Thorand, B.
Association of serum vitamin D with change in weight and total body fat in a German cohort of older adults.
Eur. J. Clin. Nutr. 70, 136-139 (2015)
We examined the association of baseline serum 25-hydroxyvitamin D (25(OH)D) with change in weight and total body fat in a cohort of community-dwelling older adults from Southern Germany. A total of 735 participants of the population-based KORA-Age Study (2009-2012), aged 65-90 years, were followed for 2.9±0.1 years. Body fat was assessed with bioelectrical impedance analysis. Linear and multinomial logistic models, adjusted for baseline covariables, were used to examine the association of 25(OH)D with percentage weight and body fat change during follow-up. 25(OH)D levels were not associated with overall weight change or body fat loss. Higher 25(OH)D levels were associated with a lower likelihood of having gained >3% of body fat in women but not in men. As we cannot exclude residual confounding by outdoor physical activity and diet, our results are not sufficient to support a causal role of 25(OH)D in the etiology of obesity in Caucasian older adults.
European Journal of Clinical Nutrition

Anlauf, M.; Hein, L.; Hense, H.W.; Köbberling, J.; Lasek, R.; Leidl, R.; Schöne-Seifert, B.
Complementary and alternative drug therapy versus science-oriented medicine.
GMS Ger. Med. Sci. 13:Doc05 (2015)
This opinion deals critically with the so-called complementary and alternative medical (CAM) therapy on the basis of current data. From the authors' perspective, CAM prescriptions and most notably the extensive current endeavours to the "integration" of CAM into conventional patient care is problematic in several respects. Thus, several CAM measures are used, although no specific effects of medicines can be proved in clinical studies. It is extensively explained that the methods used in this regard are those of evidence-based medicine, which is one of the indispensable pillars of science-oriented medicine. This standard of proof of efficacy is fundamentally independent of the requirement of being able to explain efficacy of a therapy in a manner compatible with the insights of the natural sciences, which is also essential for medical progress. Numerous CAM treatments can however never conceivably satisfy this

requirement; rather they are justified with pre-scientific or unscientific paradigms. The high attractiveness of CAM measures evidenced in patients and many doctors is based on a combination of positive expectations and experiences, among other things, which are at times unjustified, at times thoroughly justified, from a science-oriented view, but which are non-specific (context effects). With a view to the latter phenomenon, the authors consider the conscious use of CAM as unrevealed therapeutic placebos to be problematic. In addition, they advocate that academic medicine should again systematically endeavour to pay more attention to medical empathy and use context effects in the service of patients to the utmost. The subsequent opinion discusses the following after an introduction to medical history: the definition of CAM; the efficacy of most common CAM procedures; CAM utilisation and costs in Germany; characteristics of science-oriented medicine; awareness of placebo research; pro and contra arguments about the use of CAM, not least of all in terms of aspects related to medical ethics.
GMS German Medical Science

Italia, S.; Brand, H.; Heinrich, J.; Berdel, D.; von Berg, A.; Wolfenstetter, S.B.
Utilization of self-medication and prescription drugs among 15-year-old children from the German GINIplus birth cohort.
Pharmacoepidemiol. Drug Saf. 24, 1133–1143 (2015)
PURPOSE: The objective was to analyse paediatric drug utilization in relation to self-medication, prescription drugs, and the most reported therapeutic drug categories. METHODS: Data were collected for 3013 children on their utilization of drugs (4-week prevalence) from a German birth cohort study (GINIplus, 15-year follow-up) using a self-administered questionnaire. The drugs were grouped into over-the-counter drugs and prescription drugs, and were classified according to the anatomical therapeutic chemical classification system. Predictors were analysed using a logistic regression model with four independent variables (gender, study area, maternal education, and parental income). RESULTS: Some 69% of the reported 2489 drugs were over-the-counter drugs, and 31% were prescription drugs. The 4-week prevalence for using any type of drug was 41.0%. Drug categories with high prevalence rates of use were antiinflammatory drugs (10.3%), analgesics (7.1%), and antiallergics (5.0%). Factors associated with higher use of over-the-counter drugs were female gender (OR = 1.56, $p < 0.0001$) and higher maternal education (OR = 1.60, $p = 0.0021$; university degree vs. secondary high school). Maternal education was correlated with the use of prescribed or self-medicated antiallergics (positive association) and contraceptives (negative association). The use of antibiotics, methylphenidate, and drugs for thyroid therapy was associated with lower parental income. CONCLUSION: The use of over-the-counter drugs in 15-year-old children from the GINIplus birth cohort is very common and is predicted by socioeconomic factors such as maternal education. This has to be considered by health care managers when deciding about the exclusion of over-the-counter drugs (normally used for self-medication) from reimbursement or the deregulation of drug sales.
Pharmacoepidemiology and Drug Safety

Fischer, L.; Arnold, M.; Kirsch, F.; Leidl, R.
Wirtschaftlichkeit des 21 Gene Tests in der Behandlung von Patientinnen mit nodal-positivem Mammakarzinom.
Gesundheitswesen, DOI: 10.1055/s-0035-1549989 (2015)
Ziel der Studie: Brustkrebs ist die häufigste Krebserkrankung von Frauen. Die meisten Leitlinien empfehlen Patientinnen mit Lymphknoten-positivem (LN +) Brustkrebs im Frühstadium eine adjuvante Chemotherapie, um das Risiko eines Rezidivs zu vermeiden. Dadurch kann es zu einem häufigen, undifferenzierten Einsatz von Chemotherapie kommen, der mit hohen Kosten und beträchtlichen Nebenwirkungen verbunden ist. Der Oncotype DX, auch genannt 21 Gene Test, von Genomic Health ist ein diagnostischer Multigentest, der das Rezidivrisiko von Brustkrebs und damit eine zentrale Nutzendeterminante der Chemotherapie bestimmt. Für Patientinnen mit LN− Brustkrebs haben eine Reihe von Studien Hinweise auf die Kosten-Effektivität des 21 Gene Tests erbracht. Dieser Beitrag gibt eine Übersicht zum Einsatz dieses Tests bei Patientinnen mit LN+ Brustkrebs. Methodik: Auf Basis der Datenbanken Pubmed, Embase, Business Source Complete und EconLit wurde eine systematische Literaturrecherche durchgeführt und die gefundenen Studien nach Ansatz, Parametern und Unsicherheitsanalysen ausgewertet. Die Generalisierbarkeit und Übertragbarkeit der Studienergebnisse auf Deutschland wurden anhand einer Kriterienliste überprüft. Ergebnisse: Es wurden 7 relevante ökonomische Studien identifiziert. Die Kosten-Nutzwert-Relation bewegte sich zwischen Kosteneinsparungen in Höhe von € 3 548 pro Patientin bis zu zusätzlichen Kosten von € 9 113 pro gewonnenen QALY. Eine Übertragbarkeit der Ergebnisse auf Deutschland wird vor allem durch Studienunterschiede im Ansatz medizinischer Kosten, in absoluten und relativen Preisen im Gesundheitswesen und im untersuchten Behandlungsablauf eingeschränkt. Schlussfolgerung: Es gibt Hinweise, dass ein Einsatz des Tests bei Patientinnen mit LN+ Brustkrebs eine ähnliche Größenordnung der Wirtschaftlichkeit erreicht wie bei der LN– Form. Präzisere Ergebnisse für Deutschland würden valide Daten bezüglich der Rückfallrisiken und der Beschreibung und Bewertung der gesundheitsbezogenen Lebensqualität der Patientinnen erfordern.
Gesundheitswesen, Das

Herder, C.; Bongaerts, B.W.; Ouwens, D.M.; Rathmann, W.; Heier, M.; Carstensen-Kirberg, M.; Koenig, W.; Thorand, B.; Roden, M.; Meisinger, C.; Ziegler, D.; KORA Study Group (Gieger, C.; Grallert, H.; Heinrich, J.; Holle, R.; Leidl, R.; Peters, A.; Strauch, K.)
Low serum omentin levels in the elderly population with type 2 diabetes and polyneuropathy.
Diabetic Med. 32, 1479-1483 (2015)
AIMS: To investigate the hypothesis that high serum levels of omentin, an adipokine with anti-inflammatory, insulin-sensitizing and cardioprotective properties, may be related to a lower risk of diabetic sensorimotor polyneuropathy. METHODS: The association between serum omentin level and polyneuropathy was estimated in people aged 61-82 years with Type 2 diabetes (47 with and 168 without polyneuropathy) from the population-based KORA F4 study. The presence of clinical diabetic sensorimotor polyneuropathy was defined as bilateral impairment of foot vibration perception and/or foot pressure sensation. Omentin levels were determined by enzyme-linked immunosorbent assay. RESULTS: Serum omentin level was inversely associated with polyneuropathy after adjustment for age, sex, height, waist circumference, hypertension, total cholesterol, smoking, alcohol intake and physical activity [odds

ratio 0.45 (95% CI 0.21-0.98); P = 0.043]. Although omentin was positively correlated with adiponectin (r = 0.55, P < 0.0001) and inversely with tumour necrosis factor-α (r = -0.30, P = 0.019), additional adjustment for adiponectin and tumour necrosis factor-α had little impact on the association. CONCLUSIONS: Serum levels of omentin are reduced in people with Type 2 diabetes and diabetic sensorimotor polyneuropathy, independently of established risk factors of polyneuropathy. This association is only partially explained by biomarkers of subclinical inflammation.
Diabetic Medicine

Strobl, R.; Maier, W.; Ludyga, A.; Mielck, A.; Grill, E.
Relevance of community structures and neighbourhood characteristics for participation of older adults: A qualitative study.
Qual. Life Res. 25, 143-152 (2015)
PURPOSE: Community and neighbourhood structures contribute not only to the health and well-being, but also to the participation of older adults. The degree of participation depends on both the living environment and the individual's personal characteristics, preferences and perception. However, there is still limited empirical evidence on how community and neighbourhood structures are linked to participation and health in the aged population. METHODS: A qualitative exploratory approach was chosen with a series of problem-centred, semi-structured focus group discussions. Study participants were selected from within the city of Augsburg, Southern Germany, and from two municipalities in surrounding rural districts. The interviews took place in 2013. Structuring content analysis was used to identify key concepts. RESULTS: We conducted 11 focus group discussions with a total of 78 different study participants. The study participants (33 men and 45 women) had a mean age of 74 years (range 65-92 years). Only two study participants lived in an assisted living facility. Of all study participants, 77 % lived in urban and 23 % in rural areas. We extracted four metacodes ('Usual activities', 'Requirements for participation', 'Barriers to participation' and 'Facilitators for participation') and 15 subcodes. Health and poorly designed infrastructure were mentioned as important barriers to participation, and friendship and neighbourhood cohesion as important facilitators. CONCLUSIONS: This qualitative study revealed that poor design and accessibility of municipal infrastructure are major barriers to participation in old age in Germany. Community and neighbourhood structures can be part of the problem but also part of the solution when accessibility and social networks are taken into account.
Quality of Life Research

Schremser, K.; Rogowski, W.H.; Adler-Reichel, S.; Tufman, A.L.; Huber, R.M.; Stollenwerk, B.
Cost-effectiveness of an individualized first-line treatment strategy offering erlotinib based on EGFR mutation testing in advanced lung adenocarcinoma patients in Germany.
Pharmacoeconomics 33, 1215-1228 (2015)
BACKGROUND: Lung cancer is among the top causes of cancer-related deaths. Epidermal growth factor receptor (EGFR)-tyrosine kinase inhibitors can increase progression-free survival compared with standard chemotherapy in patients with EGFR mutation-positive advanced non-small cell lung cancer (NSCLC). OBJECTIVE: The aim of the study was to evaluate the cost-effectiveness of EGFR mutation analysis and first-line therapy with erlotinib for mutation-positive patients compared with non-individualized standard chemotherapy from the perspective of German statutory health insurance. METHODS: A state transition model was developed for a time horizon of 10 years (reference year 2014). Data sources were published data from the European Tarceva versus Chemotherapy (EURTAC) randomized trial for drug efficacy and safety and German cost data. We additionally performed deterministic, probabilistic and structural sensitivity analyses. RESULTS: The individualized strategy incurred 0.013 additional quality-adjusted life-years (QALYs) and additional costs of 200, yielding an incremental cost-effectiveness ratio (ICER) of 15,577/QALY. Results were most sensitive to uncertainty in survival curves and changes in utility values. Cross-validating health utility estimates with recent German data increased the ICER to about 58,000/QALY. The probabilistic sensitivity analysis indicated that the individualized strategy is cost-effective, with a probability exceeding 50 % for a range of possible willingness-to-pay thresholds. LIMITATIONS: The uncertainty of the predicted survival curves is substantial, particularly for overall survival, which was not a primary endpoint in the EURTAC study. Also, there is limited data on quality of life in metastatic lung cancer patients. CONCLUSIONS: Individualized therapy based on EGFR mutation status has the potential to provide a cost-effective alternative to non-individualized care for patients with advanced adenocarcinoma. Further clinical research is needed to confirm these results.
PharmacoEconomics

Peyrot, W.J.; Lee, S.H.; Milaneschi, Y.; Abdellaoui, A.; Byrne, E.M.; Esko, T.; de Geus, E.J.; Hemani, G.; Hottenga, J.J.; Kloiber, S.; Levinson, D.F.; Lucae, S.; Psychiatric GWAS Consortium Major Depressive Disorder Working Group (Wray, N.R.); Martin, N.G.; Medland, S.E.; Metspalu, A.; Milani, L.; Noethen, M.M.; Potash, J.B.; Rietschel, M.; Rietveld, C.A.; Ripke, S.; Shi, J.; Social Science Genetic Association Consortium (Gieger, C.; Holle, R.; Illig, T.; Lichtner, P.; Mielck, A.; Wichmann, H.-E.); Willemsen, G.; Zhu, Z.; Boomsma, D.I.; Penninx, B.
The association between lower educational attainment and depression owing to shared genetic effects? Results in ~25 000 subjects.
Mol. Psychiatry 20, 735-743 (2015)
An association between lower educational attainment (EA) and an increased risk for depression has been confirmed in various western countries. This study examines whether pleiotropic genetic effects contribute to this association. Therefore, data were analyzed from a total of 9662 major depressive disorder (MDD) cases and 14 949 controls (with no lifetime MDD diagnosis) from the Psychiatric Genomics Consortium with additional Dutch and Estonian data. The association of EA and MDD was assessed with logistic regression in 15 138 individuals indicating a significantly negative association in our sample with an odds ratio for MDD 0.78 (0.75-0.82) per standard deviation increase in EA. With data of 884 105 autosomal common single-nucleotide polymorphisms (SNPs), three methods were applied to test for pleiotropy between MDD and EA: (i) genetic profile risk scores (GPRS) derived from training data for EA (independent meta-analysis on ~120 000 subjects) and MDD (using a 10-fold leave-one-out procedure in the current sample), (ii) bivariate genomic-relationship-matrix restricted maximum likelihood (GREML) and (iii) SNP effect concordance analysis (SECA). With these methods, we found (i) that the EA-GPRS did not

predict MDD status, and MDD-GPRS did not predict EA, (ii) a weak negative genetic correlation with bivariate GREML analyses, but this correlation was not consistently significant, (iii) no evidence for concordance of MDD and EA SNP effects with SECA analysis. To conclude, our study confirms an association of lower EA and MDD risk, but this association was not because of measurable pleiotropic genetic effects, which suggests that environmental factors could be involved, for example, socioeconomic status.
Molecular Psychiatry

Bozorgmehr, K.; Maier, W.; Brenner, H.; Saum, K.U.; Stock, C.; Miksch, A.; Holleczek, B.; Szecsenyi, J.; Razum, O.
Social disparities in disease management programmes for coronary heart disease in Germany: A cross-classified multilevel analysis.
J. Epidemiol. Community Health 69, 1091-1101 (2015)
Background Disease Management Programmes (DMPs) aim to improve effectiveness and equity of care but may suffer from selective enrolment. We analysed social disparities in DMP enrolment among elderly patients with coronary heart disease (CHD) in Germany, taking into account contextual effects at municipality and primary care practice levels. Methods Cross-sectional analysis of effects of educational attainment and regional deprivation on physician-reported DMP enrolment in a subsample of a large population-based cohort study in Germany, adjusting for individual-level, practice-level and area-level variables. We calculated OR and their 95% CIs (95% CI) in cross-classified, multilevel logistic regression models. Results Among N=1280 individuals with CHD (37.3% women), DMP enrolment rates were 22.2% (women) and 35% (men). The odds of DMP enrolment were significantly higher for male patients (OR=1.98 (1.50 to 2.62)), even after adjustment for potential confounding by individual-level, practice-level and area-level variables (range: OR=1.60 (1.08 to 2.36) to 2.16 (1.57 to 2.98)). Educational attainment was not significantly associated with DMP enrolment. Compared to patients living in least-deprived municipalities, the adjusted propensity of DMP enrolment was statistically significantly lower for patients living in medium-deprived municipalities (OR=0.41 (0.24 to 0.71)), and it also tended to be lower for patients living in the most-deprived municipalities (OR=0.70 (0.40 to 1.21)). Models controlling for the social situation (instead of health-related behaviour) yielded comparable effect estimates (medium-deprived/most-deprived vs least-deprived areas: OR=0.45 (0.26 to 0.78)/OR=0.68 (0.33 to 1.19)). Controlling for differences in comorbidity attenuated the deprivation effect estimates. Conclusions We found evidence for marked gender, but not educational disparities in DMP enrolment among patients with CHD. Small-area deprivation was associated with DMP enrolment, but the effects were partly explained by differences in comorbidity. Future studies on DMPs should consider contextual effects when analysing programme effectiveness or impacts on equity and efficiency.
Journal of Epidemiology and Community Health

Vogl, M.; Leidl, R.
Informing management on the future structure of hospital care: An extrapolation of trends in demand and costs in lung diseases.
Eur. J. Health Econ., DOI: 10.1007/s10198-015-0699-4 (2015)
OBJECTIVE: The planning of health care management benefits from understanding future trends in demand and costs. In the case of lung diseases in the national German hospital market, we therefore analyze the current structure of care, and forecast future trends in key process indicators. METHODS: We use standardized, patient-level, activity-based costing from a national cost calculation data set of respiratory cases, representing 11.9-14.1 % of all cases in the major diagnostic category "respiratory system" from 2006 to 2012. To forecast hospital admissions, length of stay (LOS), and costs, the best adjusted models out of possible autoregressive integrated moving average models and exponential smoothing models are used. RESULTS: The number of cases is predicted to increase substantially, from 1.1 million in 2006 to 1.5 million in 2018 (+2.7 % each year). LOS is expected to decrease from 7.9 to 6.1 days, and overall costs to increase from 2.7 to 4.5 billion euros (+4.3 % each year). Except for lung cancer (-2.3 % each year), costs for all respiratory disease areas increase: surgical interventions +9.2 % each year, COPD +3.9 %, bronchitis and asthma +1.7 %, infections +2.0 %, respiratory failure +2.6 %, and other diagnoses +8.5 % each year. The share of costs of surgical interventions in all costs of respiratory cases increases from 17.8 % in 2006 to 30.8 % in 2018. CONCLUSIONS: Overall costs are expected to increase particularly because of an increasing share of expensive surgical interventions and rare diseases, and because of higher intensive care, operating room, and diagnostics and therapy costs.
The European journal of health economics

Wolf, K.; Schneider, A.E.; Breitner, S.; Meisinger, C.; Heier, M.; Cyrys, J.; Kuch, B.; von Scheidt, W.; Peters, A.; KORA Study Group (Gieger, C.; Grallert, H.; Heinrich, J.; Holle, R.; Leidl, R.; Strauch, K.)
Associations between short-term exposure to particulate matter and ultrafine particles and myocardial infarction in Augsburg, Germany.
Int. J. Hyg. Environ. Health 218, 535-542 (2015)
BACKGROUND: Short-term exposure to increased particulate matter (PM) concentration has been reported to trigger myocardial infarction (MI). However, the association with ultrafine particles remains unclear. OBJECTIVES: We aimed to assess the effects of short-term air pollution and especially ultrafine particles on registry-based MI events and coronary deaths in the area of Augsburg, Germany. METHODS: Between 1995 and 2009, the MONICA/KORA myocardial infarction registry recorded 15,417 cases of MI and coronary deaths. Concentrations of PM<10µm (PM10), PM<2.5µm (PM2.5), particle number concentration (PNC) as indicator for ultrafine particles, and meteorological parameters were measured in the study region. Quasi-Poisson regression adjusting for time trend, temperature, season, and weekday was used to estimate immediate, delayed and cumulative effects of air pollutants on the occurrence of MI. The daily numbers of total MI, nonfatal and fatal events as well as incident and recurrent events were analysed. RESULTS: We observed a 1.3% risk increase (95%-confidence interval: [-0.9%; 3.6%]) for all events and a 4.4% [-0.4%; 9.4%] risk increase for recurrent events per 24.3µg/m(3) increase in same day PM10 concentrations. Nonfatal events indicated a risk increase of 3.1% [-0.1%; 6.5%] with previous day PM10. No association was seen for PM2.5 which was only available from 1999 on. PNC showed a risk increase of 6.0% [0.6%; 11.7%] for recurrent events per 5529 particles/cm(3) increase in 5-day average PNC. CONCLUSIONS: Our results suggested an association between short-term PM10 concentration and numbers of MI, especially for nonfatal and recurrent events. For ultrafine particles, risk increases were

notably high for recurrent events. Thus, persons who already suffered a MI seemed to be more susceptible to air pollution.
International Journal of Hygiene and Environmental Health

Vogt, S.; Mielck, A.; Berger, U.; Grill, E.; Peters, A.; Döring, A.; Holle, R.; Strobl, R.; Zimmermann, A.-K.; Linkohr, B.; Wolf, K.; Kneißl, K.; Maier, W.
Neighborhood and healthy aging in a German city: Distances to green space and senior service centers and their associations with physical constitution, disability, and health-related quality of life.
Eur. J. Ageing 12, 273-283 (2015)
The composition of the residential environment may have an independent influence on health, especially in older adults. In this cross-sectional study, we examined the associations between proximity to two features of the residential environment (green space and senior service centers) and three aspects of healthy aging (self-rated physical constitution, disability, and health-related quality of life). We included 1711 inhabitants from the city of Augsburg, Germany, aged 65 years or older, who participated in the KORA-Age study conducted in 2008/2009. We calculated the Euclidian distances between each participant's residential address and the nearest green space or senior service center, using a geographic information system. Multilevel logistic regression models were fitted to analyze the associations, controlling for demographic and socioeconomic factors. Contrary to expectations, we did not find clear associations between the distances to the nearest green space or senior service center and any of the examined aspects of healthy aging. The importance of living close to green space may largely depend on the study location. The city of Augsburg is relatively small (about 267,000 inhabitants) and has a high proportion of greenness. Thus, proximity to green space may not be as important as in a densely populated metropolitan area. Moreover, an objectively defined measure of access such as Euclidian distance may not reflect the actual use. Future studies should try to assess the importance of resources of the residential environment not only objectively, but also from the resident's perspective.
European Journal of Ageing

Laxy, M.; Malecki, K.C.; Givens, M.L.; Walsh, M.C.; Nieto, F.J.
The association between neighborhood economic hardship, the retail food environment, fast food intake, and obesity: Findings from the Survey of the Health of Wisconsin.
BMC Public Health 15:237 (2015)
Background: Neighborhood-level characteristics such as economic hardship and the retail food environment are assumed to be correlated and to influence consumers' dietary behavior and health status, but few studies have investigated these different relationships comprehensively in a single study. This work aims to investigate the association between neighborhood-level economic hardship, the retail food environment, fast food consumption, and obesity prevalence. Methods: Linking data from the population-based Survey of the Health of Wisconsin (SHOW, n = 1,570, 2008-10) and a commercially available business database, the Wisconsin Retail Food Environment Index (WRFEI) was defined as the mean distance from each participating household to the three closest supermarkets divided by the mean distance to the three closest convenience stores or fast food restaurants. Based on US census data, neighborhood-level economic hardship was defined by the Economic Hardship Index (EHI). Relationships were analyzed using multivariate linear and logistic regression models. Results: SHOW residents living in neighborhoods with the highest economic hardship faced a less favorable retail food environment (WRFEI = 2.53) than residents from neighborhoods with the lowest economic hardship (WRFEI = 1.77; p-trend < 0.01). We found no consistent or significant associations between the WRFEI and obesity and only a weak borderline-significant association between access to fast food restaurants and self-reported fast food consumption (≥2 times/week, OR = 0.59-0.62, p = 0.05-0.09) in urban residents. Participants reporting higher frequency of fast food consumption (≥2 times vs. <2 times per week) were more likely to be obese (OR = 1.35, p = 0.06). Conclusion: This study indicates that neighborhood-level economic hardship is associated with an unfavorable retail food environment. However inconsistent or non-significant relationships between the retail food environment, fast food consumption, and obesity were observed. More research is needed to enhance methodological approaches to assess the retail food environment and to understand the complex relationship between neighborhood characteristics, health behaviors, and health outcomes.
BMC Public Health

Grau, H.; Berth, H.; Lauterberg, J.; Holle, R.; Gräßel, E.
„Zuhause geht es nicht mehr" – Gründe für den Wechsel ins Pflegeheim bei Demenz.
Gesundheitswesen 78, 510-513 (2015)
Aim: What are the reasons for institutionalising community-dwelling persons with dementia? Method: A written survey of family caregivers and general practitioners was undertaken. Results: Within 2 years 47 of 351 people with dementia (13%) were institutionalised. The person with dementia was involved in the decision in only 1/3 of the cases. The 3 most common reasons were: ensuring the best possible care, high expenditure of care-giving time at home, deterioration of the health of the care-receiver. Conclusions: From the ethical point of view the exclusion of the persons with dementia from the decision-making with regard to institutionalisation has to be examined critically. The often given reason of ensuring the best possible care through institutionalisation could be counteracted by the improvement of community-based care.
Gesundheitswesen, Das

Idler, N.; Teuner, C.M.; Hunger, M.; Holle, R.; Ortlieb, S.; Schulz, H.; Bauer, C.P.; Hoffmann, U.; Koletzko, S.; Lehmann, I.; von Berg, A.; Berdel, D.; Hoffmann, B.; Schaaf, B.; Heinrich, J.; Wolfenstetter, S.B.
The association between physical activity and healthcare costs in children - results from the GINIplus and LISAplus cohort studies.
BMC Public Health 15:437 (2015)
BACKGROUND: Physical inactivity in children is an important risk factor for the development of various morbidities and mortality in adulthood, physical activity already has preventive effects during childhood. The objective of this study is to estimate the association between physical activity, healthcare utilization and costs in children. METHODS: Cross-sectional data of 3356 children aged 9 to 12 years were taken from the 10-year follow-up of the birth cohort studies GINIplus and LISAplus, including information on healthcare utilization and physical activity given by parents via self-administered questionnaires. Using a bottom-up approach, direct costs due to healthcare

utilization and indirect costs resulting from parental work absence were estimated for the base year 2007. A two-step regression model compared effects on healthcare utilization and costs for a higher (≥7 h/week) versus a lower (<7 h/week) level of moderate-to-vigorous physical activity (MVPA) adjusted for age, gender, BMI, education and income of parents, single parenthood and study region. Recycled predictions estimated adjusted mean costs per child and activity group. RESULTS: The analyses for the association between physical activity, healthcare utilization and costs showed no statistically significant results. Different directions of estimates were noticeable throughout cost components in the first step as well as the second step of the regression model. For higher MVPA (≥7 h/week) compared with lower MVPA (<7 h/week) total direct costs accounted for 392 EUR (95% CI: 342-449 EUR) versus 398 EUR (95% CI: 309-480 EUR) and indirect costs accounted for 138 EUR (95% CI: 124-153 EUR) versus 127 EUR (95% CI: 111-146 EUR). CONCLUSIONS: The results indicate that childhood might be too early in life, to detect significant preventive effects of physical activity on healthcare utilization and costs, as diseases attributable to lacking physical activity might first occur later in life. This underpins the importance of clarifying the long-term effects of physical activity as it may strengthen the promotion of physical activity in children from a health economic perspective.
BMC Public Health

Huber, M.B.; Wacker, M.; Vogelmeier, C.F.; Leidl, R.
Excess costs of comorbidities in chronic obstructive pulmonary disease: A systematic review.
PLoS ONE 10:e0123292 (2015)
BACKGROUND: Chronic obstructive pulmonary disease (COPD) is a leading cause of morbidity and mortality worldwide. Comorbidities are often reported in patients with COPD and may influence the cost of care. Yet, the extent by which comorbidities affect costs remains to be determined. OBJECTIVES: To review, quantify and evaluate excess costs of comorbidities in COPD. METHODS: Using a systematic review approach, Pubmed and Embase were searched for studies analyzing excess costs of comorbidities in COPD. Resulting studies were evaluated according to study characteristics, comorbidity measurement and cost indicators. Mark-up factors were calculated for respective excess costs. Furthermore, a checklist of quality criteria was applied. RESULTS: Twelve studies were included. Nine evaluated comorbidity specific costs; three examined index-based results. Pneumonia, cardiovascular disease and diabetes were associated with the highest excess costs. The mark-up factors for respective excess costs ranged between 1.5 and 2.5 in the majority of cases. On average the factors constituted a doubling of respective costs in the comorbid case. The main cost driver, among all studies, was inpatient cost. Indirect costs were not accounted for by the majority of studies. Study heterogeneity was high. CONCLUSIONS: The reviewed studies clearly show that comorbidities are associated with significant excess costs in COPD. The inclusion of comorbid costs and effects in future health economic evaluations of preventive or therapeutic COPD interventions seems highly advisable.
PLoS ONE

Kirchberger, I.; Hunger, M.; Stollenwerk, B.; Seidl, H.; Burkhardt, K.; Kuch, B.; Meisinger, C.; Holle, R.
Effects of a 3-year nurse-based case management in aged patients with acute myocardial infarction on rehospitalisation, mortality, risk factors, physical functioning and mental health. A secondary analysis of the randomized controlled KORINNA study.
PLoS ONE 10:e0116693 (2015)
BACKGROUND: Home-based secondary prevention programs led by nurses have been proposed to facilitate patients' adjustment to acute myocardial infarction (AMI). The objective of this study was to conduct secondary analyses of the three-year follow-up of a nurse-based case management for elderly patients discharged from hospital after an AMI. METHODS: In a single-centre randomized two-armed parallel group trial of hospitalized patients with AMI ≥65 years, patients hospitalized between September 2008 and May 2010 in the Hospital of Augsburg, Germany, were randomly assigned to case management or usual care. The case-management intervention consisted of a nurse-based follow-up for three years including home visits and telephone calls. Study endpoints were time to first unplanned readmission or death, clinical parameters, functional status, depressive symptoms and malnutrition risk. Persons who assessed three-year outcomes and validated readmission data were blinded. The intention-to-treat approach was applied to the statistical analyses which included Cox Proportional Hazards models. RESULTS: Three hundred forty patients were allocated to receive case-management (n = 168) or usual care (n = 172). During three years, in the intervention group there were 80 first unplanned readmissions and 6 deaths, while the control group had 111first unplanned readmissions and 3 deaths. The intervention did not significantly affect time to first unplanned readmission or death (Hazard Ratio 0.89, 95% confidence interval (CI) 0.67-1.19; p = 0.439), blood pressure, cholesterol level, instrumental activities of daily life (IADL) (only for men), and depressive symptoms. However, patients in the intervention group had a significantly better functional status, as assessed by the HAQ Disability Index, IADL (only for women), and hand grip strength, and better SCREEN-II malnutrition risk scores than patients in the control group. CONCLUSIONS: A nurse-based management among elderly patients with AMI did not significantly affect time to unplanned readmissions or death during a three-year follow-up. However, the results indicate that functional status and malnutrition risk can be improved. TRIAL REGISTRATION: Current Controlled Trials ISRCTN02893746.
PLoS ONE

Dondorp, W.; de Wert, G.; Bombard, Y.; Bianchi, D.W.; Bergmann, C.; Borry, P.; Chitty, L.S.; Fellmann, F.; Forzano, F.; Hall, A.; Henneman, L.; Howard, H.C.; Lucassen, A.; Ormond, K.; Peterlin, B.; Radojkovic, D.; Rogowski, W.H.; Soller, M.; Tibben, A.; Tranebjærg, L.; van El, C.G.; Cornel, M.C.
Non-invasive prenatal testing for aneuploidy and beyond: Challenges of responsible innovation in prenatal screening. Summary and recommendations.
Eur. J. Hum. Genet., DOI: 10.1038/ejhg.2015.56 (2015)
European Journal of Human Genetics

Schwarzkopf, L.; Wacker, M.; Leidl, R.; Huber, R.M.; Holle, R.
Analyse der Versorgungssitutation von Lungenkrebspatienten anhand von GKV-Routinedaten.
Pneumologie 69, P88 (2015)
Hintergrund: Trotz der hohen epidemiologischen Relevanz von Lungenkrebs liegen kaum aktuelle Daten zur

Versorgungssituation der Betroffenen vor. Die vorliegende Studie nutzt Kassendaten, um die Versorgung von Lungenkrebspatienten und ihre Kosten im Zeitverlauf zu analysieren. Methoden: Über bundesweite, personenbezogene Leistungsdaten der AOK wurden 2009 17.641 Versicherte mit Erstdiagnose Lungenkrebs identifiziert und über 3 Jahre verfolgt. Dabei wurden sowohl relevante Therapieschemata anhand von GOPs, OPS- und ATC-Codes sowie DRGs nachvollzogen als auch die Kosten, die in den einzelnen Leistungsbereichen der GKV im Kontext von Lungenkrebs entstehen, quartalsbezogen ermittelt. Ergebnisse: Die Diagnose erfolgte im Mittel mit 68,5 Jahren, ca. 70% der Betroffenen waren Männer. 3.319 Patienten (ca. 19%) überlebten den dreijährigen Beobachtungszeitraum, wobei die Prognose im Fall einer Operation am günstigsten war. Im Zeitverlauf wurden nahezu alle Patienten stationär versorgt, doch nur eine – wenn auch größer werdende – Minderheit ambulant durch Pneumologen (ca. 29%) bzw. Onkologen (ca. 17%) betreut. Die lungenkrebsassoziierten Ausgaben waren im Diagnosequartal am höchsten und sanken sukzessive auf ca. 20% des Ausgangswerts. Maßgeblich hierfür war ein substantieller Rückgang der Kosten im stationären Bereich. Diskussion: Kassendaten erlauben bei geeigneter Operationalisierung eine umfassende Analyse der Versorgung von Lungenkrebspatienten innerhalb des GKV-Systems. Hierbei zeigt sich, dass die Betroffenen insbesondere in der Anfangsphase vorwiegend (teil)stationär versorgt werden. Die ambulante onkologische Betreuung spielt insgesamt eine eher untergeordnete Rolle, allerdings wächst ihre relative Bedeutung für die Lungenkrebstherapie im Zeitverlauf. Inwieweit diese Strukturen und die aus ihnen resultierenden Versorgungskosten medizinisch angemessen sind, ist in weiteren Studien zu erforschen.
Pneumologie
Meeting abstract

Italia, S.; Brand, H.; Heinrich, J.; Berdel, D.; von Berg, A.; Wolfenstetter, S.B.
Utilization of Complementary and Alternative Medicine (CAM) among children from a German birth cohort (GINIplus): Patterns, costs, and trends of use.
BMC Complement. Altern. Med. 15:569 (2015)
BACKGROUND: The use of complementary and alternative medicine (CAM) is widespread among children in Germany and other European countries. Only a few studies are available on trends in pediatric CAM use over time. The study's objective was to present updated results for prevalence, predictors, and costs of CAM use among German children and a comparison with findings from a previous follow-up of the same birth cohort. METHODS: Data were collected for 3013 children on their utilization of medicinal products (during the last 4 weeks) and consultation with CAM providers (in the preceding year) from a German birth cohort study (GINIplus, 15-year follow-up) using a self-administered questionnaire. The reported medicinal CAMs were classified into six categories (homeopathy, herbal drugs, nutritionals, minerals and trace elements, microorganisms, further CAM). Drug prices were traced using pharmaceutical identification numbers (PZNs), or otherwise conservatively estimated. Finally, the results were compared with data obtained from the 10-year follow-up of the same birth cohort study by adopting the identical methodology. RESULTS: In all, 26% of the reported 2489 drugs were medicinal CAM. The 4-week prevalence for homeopathy and herbal drug use was 7.5% and 5.6%, respectively. Some 13.9% of the children used at least one type of medicinal CAM in the preceding 4 weeks. The 1-year prevalence for consultation with CAM providers was 10.8%. From the drugs identified as CAM, 53.7% were homeopathic remedies, and 30.8% were herbal drugs. Factors associated with higher medicinal CAM use were female gender, residing in Munich, and higher maternal education. A homeopathy user utilized on average homeopathic remedies worth EUR 15.28. The corresponding figure for herbal drug users was EUR 16.02, and EUR 18.72 for overall medicinal CAM users. Compared with the 10-year follow-up, the prevalence of homeopathy use was more than halved (-52%) and dropped substantially for herbal drug use (-36%) and overall CAM use (-38%) as well. CONCLUSION: CAM use among 15-year-old children in the GINIplus cohort is popular, but decreased noticeably compared with children from the same cohort at the age of 10 years. This is possibly mainly because German health legislation normally covers CAM for children younger than 12 years only.
BMC Complementary and Alternative Medicine

Schunk, M.; Stark, R.G.; Reitmeir, P.; Meisinger, C.; Holle, R.
Towards patient-oriented diabetes care: Results from two KORA surveys in Southern Germany:
J. Diabetes Res. 2015:368570 (2015)
Objective. This study aims to examine the relationship of diabetes care processes and patient outcomes with an expanded set of indicators regarding patient-oriented care delivery, such as treatment satisfaction, the quality of patient-physician relationship, and a wider range of patient outcomes such as self-management, health behaviour, disease-related burden, and health-related quality of life (HRQL). Methods. The study population consisted of 486 participants with type 2 diabetes in two population-based follow-up surveys, conducted in 2003 to 2005 and 2006 to 2008 in Southern Germany. Data were self-reported and questionnaire-based, including the SF-12 for HRQL. Multiple regression models were used to identify associations between care processes and outcomes with adjustment for confounders. Results. Frequent medical examinations increased the likelihood of self-monitoring activities, such as foot care. A positive patient experienced relationship with their physician is associated with higher adherence to medical recommendations, such as medication intake, and the score of the SF-12 mental component. Participants with diabetes-related complications reported higher levels of medical examinations and multiprofessional care. Conclusions. Indicators of patient-oriented care should become an indispensable part of diabetes clinical practice guidelines with the aim of striving for more effective support of patients.
Journal of Diabetes Research

Müller, G.; Wellmann, J.; Hartwig, S.; Greiser, K.H.; Moebus, S.; Jöckel, K.-H.; Schipf, S.; Völzke, H.; Maier, W.; Meisinger, C.; Tamayo, T.; Rathmann, W.; Berger, K.
Association of neighbourhood unemployment rate with incident type 2 diabetes mellitus in five German regions.
Diabetic Med. 32, 1017-1022 (2015)
AIM: To analyse the association of neighbourhood unemployment with incident self-reported physician-diagnosed Type 2 diabetes in a population aged 45-74 years from five German regions. METHODS: Study participants were linked via their addresses at baseline to particular neighbourhoods. Individual-level data from five population-based studies were

pooled and combined with contextual data on neighbourhood unemployment. Type 2 diabetes was assessed according to a self-reported physician diagnosis of diabetes. We estimated proportional hazard models (Weibull distribution) in order to obtain hazard ratios and 95% CIs of Type 2 diabetes mellitus, taking into account interval-censoring and clustering. RESULTS: We included 7250 participants residing in 228 inner city neighbourhoods in five German regions in our analysis. The incidence rate was 12.6 per 1000 person-years (95% CI 11.4-13.8). The risk of Type 2 diabetes mellitus was higher in men [hazard ratio 1.79 (95% CI 1.47-2.18)] than in women and higher in people with a low education level [hazard ratio 1.55 (95% CI 1.18-2.02)] than in those with a high education level. Independently of individual-level characteristics, we found a higher risk of Type 2 diabetes mellitus in neighbourhoods with high levels of unemployment [quintile 5; hazard ratio 1.72 (95% CI 1.23-2.42)] than in neighbourhoods with low unemployment (quintile 1). CONCLUSIONS: Low education level and high neighbourhood unemployment were independently associated with an elevated risk of Type 2 diabetes mellitus. Studies examining the impact of the residential environment on Type 2 diabetes mellitus will provide knowledge that is essential for the identification of high-risk populations.
Diabetic Medicine

Dondorp, W.; de Wert, G.; Bombard, Y.; Bianchi, D.W.; Bergmann, C.; Borry, P.; Chitty, L.S.; Fellmann, F.; Forzano, F.; Hall, A.; Henneman, L.; Howard, H.C.; Lucassen, A.; Ormond, K.; Peterlin, B.; Radojkovic, D.; Rogowski, W.H.; Soller, M.; Tibben, A.; Tranebjærg, L.; van El, C.G.; Cornel, M.C.
Non-invasive prenatal testing for aneuploidy and beyond: Challenges of responsible innovation in prenatal screening.
Eur. J. Hum. Genet. 23, 1438-1450 (2015)
This paper contains a joint ESHG/ASHG position document with recommendations regarding responsible innovation in prenatal screening with non-invasive prenatal testing (NIPT). By virtue of its greater accuracy and safety with respect to prenatal screening for common autosomal aneuploidies, NIPT has the potential of helping the practice better achieve its aim of facilitating autonomous reproductive choices, provided that balanced pretest information and non-directive counseling are available as part of the screening offer. Depending on the health-care setting, different scenarios for NIPT-based screening for common autosomal aneuploidies are possible. The trade-offs involved in these scenarios should be assessed in light of the aim of screening, the balance of benefits and burdens for pregnant women and their partners and considerations of cost-effectiveness and justice. With improving screening technologies and decreasing costs of sequencing and analysis, it will become possible in the near future to significantly expand the scope of prenatal screening beyond common autosomal aneuploidies. Commercial providers have already begun expanding their tests to include sex-chromosomal abnormalities and microdeletions. However, multiple false positives may undermine the main achievement of NIPT in the context of prenatal screening: the significant reduction of the invasive testing rate. This document argues for a cautious expansion of the scope of prenatal screening to serious congenital and childhood disorders, only following sound validation studies and a comprehensive evaluation of all relevant aspects. A further core message of this document is that in countries where prenatal screening is offered as a public health programme, governments and public health authorities should adopt an active role to ensure the responsible innovation of prenatal screening on the basis of ethical principles. Crucial elements are the quality of the screening process as a whole (including non-laboratory aspects such as information and counseling), education of professionals, systematic evaluation of all aspects of prenatal screening, development of better evaluation tools in the light of the aim of the practice, accountability to all stakeholders including children born from screened pregnancies and persons living with the conditions targeted in prenatal screening and promotion of equity of access.
European Journal of Human Genetics

Bozorgmehr, K.; San Sebastian, M.; Brenner, H.; Razum, O.; Maier, W.; Saum, K.U.; Holleczek, B.; Miksch, A.; Szecsenyi, J.
Analysing horizontal equity in enrolment in Disease Management Programmes for coronary heart disease in Germany 2008–2010.
Int. J. Equity Health 14:28 (2015)
Background Disease Management Programmes (DMPs) have been introduced in Germany ten years ago with the aim to improve effectiveness and equity of care, but little is known about the degree to which enrolment in the programme meets the principles of equity in health care. We aimed to analyse horizontal equity in DMP enrolment among patients with coronary heart disease (CHD). Methods Cross-sectional analysis of horizontal inequities in physician-reported enrolment in the DMP for CHD in a large population-based cohort-study in Germany (2008–2010). We calculated horizontal inequity indices (HII) and their 95% confidence intervals [95%CI] for predicted need-standardised DMP enrolment across two measures of socio-economic status (SES) (educational attainment, regional deprivation) stratified by sex. Need-standardised DMP enrolment was predicted in multi-level logistic regression models. Results Among N = 1,280 individuals aged 55–84 years and diagnosed with CHD, DMP enrolment rates were 22.2% (women) and 35.0% (men). Education-related inequities in need-standardised DMP enrolment favoured groups with lower education, but HII estimates were not significant. Deprivation-related inequities among women significantly favoured groups with higher SES (HII = 0.086 [0.007; 0.165]. No such deprivation-related inequities were seen among men (HII = 0.014 [−0.048; 0.077]). Deprivation-related inequities across the whole population favoured groups with higher SES (HII estimates not significant). Conclusion Need-standardised DMP enrolment was fairly equitable across educational levels. Deprivation-related inequities in DMP enrolment favoured women living in less deprived areas relative to those living in areas with higher deprivation. Further research is needed to gain a better understanding of the mechanisms that contribute to deprivation-related horizontal inequities in DMP enrolment among women.
International Journal for Equity in Health

Pospiech, S.°; Rosenbrock, R.°; Mielck, A.°; Lehmann, F°
Priorität auf Zusammenarbeit und gute Qualität: Der bundesweite 'Kooperationsverbund Gesundheitliche Chancengleichheit'.
In: Walter, U.*; Koch, U.* [Eds.]: Prävention und Gesundheitsförderung in Deutschland - Konzepte, Strategien und Interventionsansätze der Bundeszentrale für gesundheitliche Aufklärung (BZgA). Köln: 2015. 108-117

Ziegler, D.; Voss, A.; Rathmann, W.; Strom, A.; Perz, S.; Roden, M.; Peters, A.; Meisinger, C.; KORA Study Group (Heinrich, J.; Gieger, C.; Grallert, H.; Holle, R.; Leidl, R.; Strauch, K.)
Increased prevalence of cardiac autonomic dysfunction at different degrees of glucose intolerance in the general population: The KORA S4 survey.
Diabetologia 58, 1118-1128 (2015)
Aims/hypothesis: Cardiac autonomic nervous dysfunction (CAND) raises the risk of mortality, but the glycaemic threshold at which it develops is unclear. We aimed to determine the prevalence of, risk factors for and impact of CAND in glucose intolerance and diabetes. Methods: Among 1,332 eligible participants aged 55–74 years in the population-based cross-sectional KORA S4 study, 130 had known diabetes mellitus (k-DM), and the remaining 1,202 underwent an OGTT. Heart rate variability (HRV) and QT variability were computed from supine 5 min ECGs. Results: In all, 565 individuals had normal glucose tolerance (NGT), 336 had isolated impaired fasting glucose (i-IFG), 72 had isolated impaired glucose tolerance (i-IGT), 151 had combined IFG–IGT (IFG–IGT) and 78 had newly detected diabetes mellitus (n-DM). Adjusted normal HRV limits were defined in the NGT population (5th and 95th percentiles). Three HRV measures were more frequently abnormal in those with k-DM, n-DM, IFG–IGT and i-IFG than in those with NGT ($p < 0.05$). The rates of CAND (≥2 of 4 HRV indices abnormal) were: NGT, 4.5%; i-IFG, 8.1%; i-IGT, 5.9%; IFG–IGT, 11.4%; n-DM, 11.7%; and k-DM, 17.5% ($p < 0.05$ vs NGT, except for i-IGT). Reduced HRV was associated with cardiovascular risk factors used to construct a simple screening score for CAND. Mortality was higher in participants with reduced HRV ($p < 0.05$ vs normal HRV). Conclusions/interpretation: In the general population aged 55–74 years, the prevalence of CAND is increased not only in individuals with diabetes, but also in those with IFG–IGT and, to a lesser degree, in those with i-IFG. It is associated with mortality and modifiable cardiovascular risk factors which may be used to screen for diminished HRV in clinical practice.
Diabetologia

Schott, K.; Hunger, M.; Lampert, T.; Spengler, S.; Mess, F.; Mielck, A.
Soziale Unterschiede in der körperlich-sportlichen Aktivität bei Jugendlichen: Analyse der MoMo-Daten mithilfe der metabolischen Äquivalente (MET).
Gesundheitswesen 78, 630-636 (2015)
Introduction: Energy consumption, i. e., the metabolic equivalent of task (MET), provides a precise assessment of physical activity (PA). Studies on social inequalities of PA have hardly used this possibility, however. Methods: The analyses are based on the 'Motorik-Modul (MoMo) of the KiGGS study (German Health Interview and Examination Survey for Children and Adolescents) conducted between 2003 and 2006 (n=1 757; age group 11-17 years). PA has been assessed in 3 settings (sport club in school, other sport club, leisure time). 3 dependent variables were distinguished by combining the following criteria: at least 21 MET-hours per week, intensity between 3 and 6 METs, at least 7 hours a week. The main independent variables are: type of school and socioeconomic status (SES) of the parents. 'Two part models' have been used to assess social difference in PA among those who are physically active. Results: PA is much more common in the higher SES groups. Looking at the MET-hours, though, there are just little differences among those who are physically active (regressions coefficient for low vs. high SES: 1.15; 95% conf. interv. 0.99-1.33). Conclusion: Social differences can be seen mainly for the proportion of adolescents being physically active, not for the extent of PA among those who are physically active. Therefore, the central request should be to increase the proportion of adolescents performing any PA in the low SES group.
Gesundheitswesen, Das

de Wit, G.A.; Over, E.A.; Schmid, B.V.; van Bergen, J.E.; van den Broek, I.V.; van der Sande, M.A.; Welte, R.; Op de Coul, E.L.; Kretzschmar, M.E.
Chlamydia screening is not cost-effective at low participation rates: Evidence from a repeated register-based implementation study in the Netherlands.
Sex. Transm. Dis. 91, 423-429 (2015)
OBJECTIVE: In three pilot regions of the Netherlands, all 16-29 year olds were invited to participate in three annual rounds of Chlamydia screening. The aim of the present study is to evaluate the cost-effectiveness of repeated Chlamydia screening, based on empirical data. METHODS: A mathematical model was employed to estimate the influence of repeated screening on prevalence and incidence of Chlamydial infection. A model simulating the natural history of Chlamydia was combined with cost and utility data to estimate the number of major outcomes and quality-adjusted life-years (QALYs) associated with Chlamydia. Six screening scenarios (16-29 years annually; 16-24 years annually; women only; biennial screening; biennial screening women only; screening every five years) were compared with no screening in two sexual networks, representing both lower ('national network') and higher ('urban network') baseline prevalence. Incremental cost-effectiveness ratios (ICERs) for the different screening scenarios were estimated. Uncertainty and sensitivity analyses were performed. RESULTS: In all scenarios and networks, cost per major outcome averted are above €5000. Cost per QALY are at least €50 000. The default scenario as piloted in the Netherlands was least cost-effective, with ICERs of €232 000 in the national and €145 000 in the urban sexual network. Results were robust in sensitivity analyses. CONCLUSIONS: It is unlikely that repeated rounds of Chlamydia screening will be cost-effective. Only at high levels of willingness to pay for a QALY (>€50 000) screening may be more cost-effective than no screening.
Sexually Transmitted Diseases

Hofmeister, C.; Maier, W.; Mielck, A.; Stahl, L.; Breckenkamp, J.; Razum, O.
Regionale Deprivation in Deutschland: Bundesweite Analyse des Zusammenhangs mit Mortalität unter Verwendung des ‚German Index of Multiple Deprivation (GIMD)‘.
Gesundheitswesen 78, 42-48 (2015)
Background: Deprivation indices are increasingly being used to assess the effects of contextual factors on health. In Germany, the recently developed 'German Index of Multiple Deprivation (GIMD)' integrates various dimensions of regional deprivation. We aim to assess the validity of the GIMD through a recalculation using more recent rural and urban district level data and by analysing its association with mortality at the national level. Methods: We calculated a new version of the GIMD based on data from 2007 to 2010 for all 412 rural and urban districts in Germany. Mortality was quantified using indirectly standardised mortality ratios (SMRs). Correlation analyses and Poisson regression analyses were used to assess the association

between the GIMD scores and total mortality, as well as premature mortality (< 65 years). Results: Correlation analyses showed a positive association between the GIMD and both total mortality (p<0.001) and premature mortality (p<0.001). In the Poisson regression analyses, rural and urban districts in the quintile with the highest deprivation showed a significantly elevated risk of total mortality (RR: 1.29; 95% CI: 1.28-1.30) as well as premature mortality (RR: 1.50; 95% CI: 1.47-1.53), compared to the districts in the lowest quintile. Conclusion: The association between regional deprivation and mortality has already been shown for the federal state of Bavaria. Using more recent data, this relationship could be confirmed here for Germany as a whole. The GIMD has been shown to be able to effectively assess regional deprivation. Concerning public health policy, the significant, positive and stable association between regional deprivation and mortality indicates an increased need for health care provision particularly in the most deprived districts. Further studies should examine, for example, whether and how the allocation of districts to quintiles of regional deprivation changes over time, and how this affects mortality.
Gesundheitswesen, Das

Lotty, E.Y.; Hämmerling, C.; Mielck, A.
Gesundheitszustand von Menschen ohne Krankenversicherung und von Menschen ohne legalen Aufenthaltsstatus: Analyse von Daten der Malteser Migranten Medizin (MMM) in München.
Gesundheitswesen 77, e143-e152 (2015)
Introduction: It is estimated that more than 100 000 persons are without health insurance in Germany. The number of undocumented migrants is roughly estimated to be about 40 000. There are hardly any empirical studies looking at health care provision for these population groups, it is even rarely stressed that more empirical studies are needed. There seems to be a major gap concerning perception and research. The present study aims at promoting this discussion by presenting analyses based on data from an institution providing health care for these population groups, i. e., the Malteser Migranten Medizin (MMM) in Munich. Methods: Data were available from all patients coming to MMM between January 2009 and October 2012 (i. e., from 2 352 visits altogether). The following information is available for each visit: date, sex, age group, country of origin, residence permit status (3 groups), diagnosis (ICD-10 chapter), type of health care (4 broad groups). Multivariate analyses have been conducted for simultaneous control of these variables. In order to compare these data with information from the general population, data from a large statutory sickness fund have been included as well. Results: Focusing first on the MMM patients, the analyses showed large differences concerning diagnoses by country of origin and by residence permit status. We were not able, however, to confirm the hypothesis that mental health problems are especially common among undocumented migrants. The comparison with the general population indicated, surprisingly, that MMM patients showed a very similar spectrum of diagnoses as compared with the general population. Conclusion: The data from MMM do not allow a precise assessment of health care need, they still indicate, though, how different the patients are who seek help. MMM offers a broad range of health care, but it is hardly possible to meet the manifold demands of all the patients; there is no psychotherapist, for example. The resources available at MMM will always just allow a very limited provision of health care. It would be important to promote the integration of persons without health insurance and for undocumented migrants into the general system of statutory sickness funds.
Gesundheitswesen, Das

Teuner, C.M.; John, J.; Wolfenstetter, S.B.; Holle, R.
An economic perspective on childhood obesity.
Pediatr. Adolesc. Med. 19, 148-159 (2015)
This review provides an overview on the latest literature on the costs of childhood and adolescent obesity and on the cost-effectiveness of interventions to prevent or manage this problem. Findings on the economic burden of childhood obesity are inconclusive, and the majority of the identified studies found excess healthcare costs for obese compared with normal-weight children by analysing different cost components and age groups. However, there are several limitations to these studies, e.g. short study periods and a strong focus on healthcare costs, disregarding other components of the economic burden of childhood obesity. Economic evaluation studies of childhood and adolescent obesity programmes indicate that cost-effective, in some cases even cost-saving, preventive and management interventions do exist. However, because of the strong variation in methodological aspects, it is difficult to compare preventive and treatment approaches in terms of their cost-effectiveness. To design effective public policies, a better understanding of these economic aspects of childhood and adolescent obesity is necessary. This understanding, however, depends on the collection of additional longitudinal data. Economic evaluation of childhood obesity interventions poses various methodological challenges that should be addressed in further research in order to support decision making.
Pediatric and Adolescent Medicine

Becker, C.; Holle, R.; Stollenwerk, B.
The excess health care costs of KardioPro, an integrated care program for coronary heart disease prevention.
Health Policy 119, 778-786 (2015)
Coronary heart disease (CHD) is a major cause of death and important driver of health care costs. Recent German health care reforms have promoted integrated care contracts allowing statutory health insurance providers more room to organize health care provision. One provider offers KardioPro, an integrated primary care-based CHD prevention program. As insurance providers should be aware of the financial consequences when developing optional programs, this study aims to analyze the costs associated with KardioPro participation. 13,264 KardioPro participants were compared with a propensity score-matched control group. Post-enrollment health care costs were calculated based on routine data over a follow-up period of up to 4 years. For those people who incurred costs, KardioPro participation was significantly associated with increased physician costs (by 33%), reduced hospital costs (by 19%), and reduced pharmaceutical costs (by 16%). Overall costs were increased by 4%, but this was not significant. Total excess costs per observation year were €131 per person (95% confidence interval: [€-36.5; €296]). Overall, KardioPro likely affected treatment as the program increased costs of physician services and reduced costs of hospital services. Further effects of substituting potential inpatient care with increased outpatient care might become fully apparent only over a longer time horizon.
Health Policy

Kirsch, F.
A systematic review of quality and cost-effectiveness derived from Markov models evaluating smoking cessation interventions in patients with chronic obstructive pulmonary disease.
Expert Rev. Pharmacoecon. Outcomes Res. 15, 301-316 (2015)
Smoking cessation is the only strategy that has shown a lasting reduction in the decline of lung function in patients with chronic obstructive pulmonary disease. This study aims to evaluate the cost-effectiveness of smoking cessation interventions in patients with chronic obstructive pulmonary disease, to assess the quality of the Markov models and to estimate the consequences of model structure and input data on cost-effectiveness. A systematic literature search was conducted in PubMed, Embase, BusinessSourceComplete and Econlit on June 11, 2014. Data were extracted, and costs were inflated. Model quality was evaluated by a quality appraisal, and results were interpreted. Ten studies met the inclusion criteria. The results varied widely from cost savings to additional costs of €17,004 per quality adjusted life year. The models scored best in the category structure, followed by data and consistency. The quality of the models seems to rise over time, and regarding the results there is no economic reason to refuse the reimbursement of any smoking cessation intervention.
Expert Review of Pharmacoeconomics and Outcomes Research

Stollenwerk, B.; Bartmus, T.; Klug, F.; Stock, S.; Müller, D.
Cost-effectiveness of hip protector use on a geriatric ward in Germany: A Markov model.
Osteoporos. Int. 26, 1367-1379 (2015)
In this study, we determined the cost-effectiveness of hip protector use compared with no hip protector on a geriatric ward in Germany. From both the societal and the statutory health insurance (SHI) perspectives, the cost-effectiveness ratios for the provision of hip protectors were below 12,000/quality-adjusted life year (QALY) even if unrelated costs in added life years were included. INTRODUCTION: The aim of this study is to determine the cost-effectiveness of the provision of hip protectors compared with no hip protectors on a geriatric ward in Germany. METHODS: A lifetime decision-analytic Markov model was developed. Costs were measured from the societal and from the statutory health insurance (SHI) perspectives and comprised direct medical, non-medical and unrelated costs in additional life years gained. Health outcomes were measured in terms of quality-adjusted life years (QALYs). To reflect several levels of uncertainty, first- and second-order Monte Carlo simulation (MCS) approaches were applied. RESULTS: Hip protector use compared with no hip protector results in savings (costs, -5.1/QALYs, 0.003) for the societal perspective. For the SHI perspective, the incremental cost-effectiveness ratio was 4416 /QALY (costs, +13.4). If unrelated costs in life years gained were included, the cost-effectiveness ratio increases to 9794/QALY for the societal perspective and to 11,426/QALY for the SHI perspective. In the MCS, for the societal perspective without unrelated costs, 47 % of simulations indicated hip protectors to be cost saving (i.e. lower costs and higher effects). CONCLUSION: Although the gain in QALYs due to the provision of providing hip protectors to patients on geriatric wards is small, all scenarios showed acceptable cost-effectiveness ratios or even savings.
Osteoporosis International

Severin, F.; Stollenwerk, B.; Holinski-Feder, E.; Meyer, E.; Heinemann, V.; Giessen-Jung, C.; Rogowski, W.H.
Economic evaluation of genetic screening for Lynch syndrome in Germany.
Genet. Med. 17, 765-773 (2015)
Purpose:Lynch syndrome (LS) screening among patients with newly diagnosed colorectal cancer can decrease mortality in their affected first-degree relatives. In Germany, it is not yet clinical practice and the cost-effectiveness of different testing strategies is unknown.Methods:We developed a decision-analytic model to analyze the cost-effectiveness of LS screening from the perspective of the German Statutory Health Insurance system. A total of 22 testing strategies considering family-history assessment, analysis of tumor samples (i.e., immunohistochemistry (IHC), microsatellite instability, and BRAF mutation testing) and genetic sequencing were analyzed. Life-years gained in relatives by closed-meshed colonoscopy and aspirin prophylaxis were estimated by Markov models. Uncertainty was assessed deterministically and probabilistically.Results:On average, detected mutation carriers gained 0.52 life-years (undiscounted: 1.34) by increased prevention. Most strategies were dominated, with three exceptions: family assessment by the Bethesda criteria followed by IHC and BRAF testing and genetic sequencing; IHC and BRAF testing and genetic sequencing; and direct sequencing of all index patients. Their incremental cost-effectiveness was [euro]77,268, [euro]253,258, and [euro]4,188,036 per life-year gained, respectively.Conclusion:The results were less favorable than those of previous models. Chemoprevention appears to provide comparably low additional benefit and improves cost-effectiveness only slightly.
Genetics in Medicine

Schunk, M.; Reitmeir, P.; Schipf, S.; Völzke, H.; Meisinger, C.; Ladwig, K.-H.; Kluttig, A.; Greiser, K.H.; Berger, K.U.; Müller, G.; Ellert, U.; Neuhauser, H.; Tamayo, T.; Rathmann, W.; Holle, R.
Health-related quality of life in women and men with type 2 diabetes: A comparison across treatment groups.
J. Diab. Complic. 29, 203-211 (2015)
Aim: This study compares health-related quality of life (HRQL) in patients with type 2 diabetes (T2DM) across treatment groups and explores gender differences. Methods: Four regional surveys (KORA, CARLA, SHIP, DHS) and a national survey (GNHIES98) were pooled at individual level. HRQL was assessed with the SF-12/-36v1. Linear regression models were used to assess the effect of T2DM by treatment type (no medication; oral; oral/insulin combination; insulin) on the physical (PCS-12) and mental summary score (MCS-12) and the SF-6D, controlling for age, sex, study and covariates. We also performed an explanatory analysis of single items. Results: PCS-12 scores and treatment type were associated (P-value 0.006), with lowest values for insulin treatment (-4.44 vs. oral; -4.41 vs. combination). MCS-12 scores were associated with treatment type and gender (P-value <. 0.012), with lower scores for women undergoing oral (-4.25 vs. men) and combination treatment (-6.99 vs. men). Similar results were observed for SF-6D utilities and single items, related to mental health, social functioning, vitality and role limitation (emotional). Comorbidities were predictors of lower PCS-12 and SF-6D scores. Conclusions: T2DM treatment impacts differently on physical and mental HRQL and on women and men. Further studies of gender-specific perceptions of T2DM treatment regimens are needed.

Journal of Diabetes and its Complications

Rogowski, W.H.°; Schleidgen, S.°
Using needs-based frameworks for evaluating new technologies: An application to genetic tests.
Health Policy 119, 147-155 (2015)
Given the multitude of newly available genetic tests in the face of limited healthcare budgets, the European Society of Human Genetics assessed how genetic services can be prioritized fairly. Using (health) benefit maximizing frameworks for this purpose has been criticized on the grounds that rather than maximization, fairness requires meeting claims (e.g. based on medical need) equitably. This study develops a prioritization score for genetic tests to facilitate equitable allocation based on need-based claims. It includes attributes representing health need associated with hereditary conditions (severity and progression), a genetic service's suitability to alleviate need (evidence of benefit and likelihood of positive result) and costs to meet the needs. A case study for measuring the attributes is provided and a suggestion is made how need-based claims can be quantified in a priority function. Attribute weights can be informed by data from discrete-choice experiments. Further work is needed to measure the attributes across the multitude of genetic tests and to determine appropriate weights. The priority score is most likely to be considered acceptable if developed within a decision process which meets criteria of procedural fairness and if the priority score is interpreted as "strength of recommendation" rather than a fixed cut-off value.
Health Policy

Hollederer, A.; Braun, G.E.; Dahlhoff, G.; Drexler, H.; Engel, J.; Gräßel, E.; Häusler, E.; Heide, H.; Heuschmann, P.U.; Hörl, G.; Imhof, H.; Kaplan, M.; Kasperbauer, R.; Klemperer, D.; Kolominsky-Rabas, P.; Kuhn, J.; Lang, M.; Langejürgen, R.; Lankes, A.; Leidl, R.; Liebl, B.; Loss, J.; Ludewig, K.; Mansmann, U.; Melcop, N.; Nagels, K.; Nowak, D.; Pfundner, H.; Reuschenbach, B.; Schneider, A.; Schneider, W.; Schöffski, O.; Schreiber, W.; Voigtländer, S.; Wildner, M.; Zapf, A.; Zellner, A.
Memorandum „Weiterentwicklung der Gesundheitsversorgungsforschung in Bayern aus Sicht der Landesarbeitsgemeinschaft Gesundheitsversorgungsforschung: Status quo – Entwicklungspotenziale – Strategien“.
Gesundheitswesen 77, 180-185 (2015)
The aim of the memorandum on the development of health services research (HSR) in Bavaria is to operationalise the global objectives of the State Working Group "Health Services Research" (LAGeV) and to collectively define future topics, specific implementation steps, methods as well as ways of working for the future course of the LAGeV. The LAGeV is an expert committee that integrates and links the competencies of different actors from science, politics and health care regarding HSR and facilitates their cooperation. The memorandum is based on an explorative survey among the LAGeV members, which identified the status quo of health services research in Bavaria, potential for development, important constraints, promoting factors, specific recommendations as well as future topics for the further development of HSR in Bavaria. From the perspective of the LAGeV members, the 12 most important future topics are: 1) Interface and networking research, 2) Innovative health care concepts, 3) Health care for multimorbid patients, 4)Health care for chronically ill patients, 5) Evaluation of innovations, processes and technologies, 6) Patient orientation and user focus, 7) Social and regional inequalities in health care, 8) Health care for mentally ill patients, 9) Indicators of health care quality, 10) Regional needs planning, 11) Practical effectiveness of HSR and 12) Scientific use of routine data. Potential for development of HSR in Bavaria lies a) in the promotion of networking and sustainable structures, b) the establishment of an HSR information platform that bundles information and results in regard to current topics and aims to facilitate cooperation as well as c) in the initiation of measures and projects. The latter ought to pinpoint health care challenges and make recommendations regarding the improvement of health care and its quality. The cooperation and networking structures that were established with the LAGeV should be continuously expanded and be used to work on priority topics in order to achieve the global objectives of the LAGeV.
Gesundheitswesen, Das

Mensch, A.; Stock, S.; Stollenwerk, B.; Müller, D.
Cost effectiveness of rivaroxaban for stroke prevention in German patients with atrial fibrillation.
Pharmacoeconomics 33, 271-283 (2015)
OBJECTIVE: The aim of this study was to assess the cost effectiveness of the novel fixed-dose anticoagulant rivaroxaban compared with the current standard of care, warfarin, for the prevention of stroke in patients with atrial fibrillation (AF). METHODS: A Markov model was constructed to model the costs and health outcomes of both treatments, potential adverse events, and resulting health states over 35 years. Analyses were based on a hypothetical cohort of 65-year-old patients with non-valvular AF at moderate to high risk of stroke. The main outcome measure was cost per quality-adjusted life-year (QALY) gained over the lifetime, and was assessed from the German Statutory Health Insurance (SHI) perspective. Costs and utility data were drawn from public data and the literature, while event probabilities were derived from both the literature and rivaroxaban's pivotal ROCKET AF trial. RESULTS: Stroke prophylaxis with rivaroxaban offers health improvements over warfarin treatment at additional cost. From the SHI perspective, at baseline the incremental cost-effectiveness ratio of rivaroxaban was 15,207 per QALY gained in 2014. The results were robust to changes in the majority of variables; however, they were sensitive to the price of rivaroxaban, the hazard ratios for stroke and intracranial hemorrhage, the time horizon, and the discount rate. CONCLUSIONS: Our results showed that the substantially higher medication costs of rivaroxaban were offset by mitigating the shortcomings of warfarin, most notably frequent dose regulation and bleeding risk. Future health economic studies on novel oral anticoagulants should evaluate the cost effectiveness for secondary stroke prevention and, as clinical data from direct head-to-head comparisons become available, new anticoagulation therapies should be compared against each other.
PharmacoEconomics

Siegel, M.; Mielck, A.; Maier, W.
Individual income, area deprivation, and health: Do income-related health equalities vary by small area deprivation?
Health Econ. 24, 1523-1530 (2015)
This paper aims to explore potential associations between health inequalities related to socioeconomic deprivation at the individual and the small area level. We use German cross-sectional survey data for the years 2002 and 2006, and measure small area

deprivation via the German Index of Multiple Deprivation. We test the differences between concentration indices of income-related and small area deprivation related inequalities in obesity, hypertension, and diabetes. Our results suggest that small area deprivation and individual income both yield inequalities in health favoring the better-off, where individual income-related inequalities are significantly more pronounced than those related to small area deprivation. We then apply a semiparametric extension of Wagstaff's corrected concentration index to explore how individual-level health inequalities vary with the degree of regional deprivation. We find that the concentration of obesity, hypertension, and diabetes among lower income groups also exists at the small area level. The degree of deprivation-specific income-related inequalities in the three health outcomes exhibits only little variations across different levels of multiple deprivation for both sexes.
Health Economics

Rogowski, W.H.; Payne, K.; Schnell-Inderst, P.; Manca, A.; Rochau, U.; Jahn, B.; Alagoz, O.; Leidl, R.; Siebert, U.
Concepts of 'personalization' in personalized medicine: Implications for economic evaluation.
Pharmacoeconomics 33, 49-59 (2015)
CONTEXT: This study assesses if, and how, existing methods for economic evaluation are applicable to the evaluation of personalized medicine (PM) and, if not, where extension to methods may be required. METHODS: A structured workshop was held with a predefined group of experts (n = 47), and was run using a modified nominal group technique. Workshop findings were recorded using extensive note taking, and summarized using thematic data analysis. The workshop was complemented by structured literature searches. RESULTS: The key finding emerging from the workshop, using an economic perspective, was that two distinct, but linked, interpretations of the concept of PM exist (personalization by 'physiology' or 'preferences'). These interpretations involve specific challenges for the design and conduct of economic evaluations. Existing evaluative (extra-welfarist) frameworks were generally considered appropriate for evaluating PM. When 'personalization' is viewed as using physiological biomarkers, challenges include representing complex care pathways; representing spillover effects; meeting data requirements such as evidence on heterogeneity; and choosing appropriate time horizons for the value of further research in uncertainty analysis. When viewed as tailoring medicine to patient preferences, further work is needed regarding revealed preferences, e.g. treatment (non)adherence; stated preferences, e.g. risk interpretation and attitude; consideration of heterogeneity in preferences; and the appropriate framework (welfarism vs. extra-welfarism) to incorporate non-health benefits. CONCLUSIONS: Ideally, economic evaluations should take account of both interpretations of PM and consider physiology and preferences. It is important for decision makers to be cognizant of the issues involved with the economic evaluation of PM to appropriately interpret the evidence and target future research funding.
PharmacoEconomics

Vogl, M.; Leidl, R.; Plötz, W.; Gutacker, N.
Comparison of pre- and post-operative health-related quality of life and length of stay after primary total hip replacement in matched English and German patient cohorts.
Qual. Life Res. 24, 513-520 (2015)
PURPOSE: We compare pre- and post-operative health-related quality of life (HRQoL) and length of stay after total hip replacement (THR) in matched German and English patient cohorts to test for differences in admission thresholds, clinical effectiveness and resource utilisation between the healthcare systems. METHODS: German data (n = 271) were collected in a large orthopaedic hospital in Munich, Germany; English data (n = 26,254) were collected as part of the national patient-reported outcome measures programme. HRQoL was measured using the EuroQoL-5D instrument. Propensity score matching was used to construct two patient cohorts that are comparable in terms of preoperative patient characteristics. RESULTS: Before matching, patients in England showed lower preoperative EQ-5D scores (0.35 vs 0.52, $p < 0.001$) and experienced a larger improvement in HRQoL (0.43 vs 0.33, $p < 0.001$) than German patients. Patients in the German cohort were more likely to report no or only moderate problems with mobility and pain preoperatively than their English counterparts. After matching, improvements in HRQoL were comparable (0.32 vs 0.33, $p = 0.638$); post-operative scores were slightly higher in the German cohort (0.82 vs 0.85, $p = 0.585$). Length of stay was substantially lower in England than in Germany (4.5 vs 9.0 days, $p < 0.001$). CONCLUSIONS: Our results highlight differences in preoperative health status between countries, which may arise due to different admission thresholds and access to surgery. In terms of quality of life, THR surgery is equally effective in both countries when performed on similar patients, but hospital stay is shorter in England.
Quality of Life Research

Seidl, H.; Hunger, M.; Leidl, R.; Meisinger, C.; Wende, R.; Kuch, B.; Holle, R.
Cost-effectiveness of nurse-based case management versus usual care for elderly patients with myocardial infarction: Results from the KORINNA study.
Eur. J. Health Econ. 16, 671-681 (2015)
Objectives We assessed the cost-effectiveness of a case management intervention by trained nurses in elderly (≥65 years) patients with myocardial infarction from a societal perspective. Methods The intervention and observation period spanned 1 year and 329 participants were enrolled. The intervention consisted of at least one home visit and quarterly telephone calls. Data on resource use and quality of life were collected quarterly. The primary measurements of effect were quality-adjusted life years (QALYs), based on the EuroQol five-dimensional questionnaire (EQ-5D-3L) health utilities from the German time trade-off. The secondary measurements were EQ-5D-3L utility values and patients' self-rated health states according to the visual analogue scale (VAS) among survivors. To estimate mean differences, a linear regression model was used for QALYs and a gamma model for costs. Health states among the survivors were analysed using linear mixed models. To assess the impact of different health state valuation methods, VAS-adjusted life years were constructed. Results The mean difference in QALYs was small and not significant (-0.0163; CI -0.0681-0.0354, p value: 0.536, n = 297). Among survivors, EQ-5D-3L utilities showed significant improvements within 6 months in the intervention group (0.051; CI 0.0028-0.0989; p value: 0.0379, n = 280) but returned towards baseline levels by month 12. The mean improvement in self-rated health (VAS) within 1 year was significantly larger in the intervention group (+9.2, CI 4.665-13.766, p value: <0.0001, n = 266). The overall cost

difference was -€17.61 (CI - €2,601-€2,615; p value: 0.9856, n = 297). The difference in VAS-adjusted life years was 0.0378 (CI - 0.0040-0.0796, p value: 0.0759, n = 297). Conclusions This study could not provide evidence to conclude that the case management intervention was an effective and cost-effective alternative to usual care within a time horizon of 1 year.
The European journal of health economics

Bock, J.O.; Brettschneider, C.; Seidl, H.; Bowles, D.; Holle, R.; Greiner, W.; König, H.H.
Ermittlung standardisierter Bewertungssätze aus gesellschaftlicher Perspektive für die gesundheitsökonomische Evaluation.
Gesundheitswesen 77, 53-61 (2015)
Purpose: Due to demographic aging, economic evaluation of health care technologies for the elderly becomes more important. A standardised questionnaire to measure the health-related resource utilisation has been designed. The monetary valuation of the resource use documented by the questionnaire is a central step towards the determination of the corresponding costs. The aim of this paper is to provide unit costs for the resources in the questionnaire from a societal perspective. Methods: The unit costs are calculated pragmatically based on regularly published sources. Thus, an easy update is possible. Results: This paper presents the calculated unit costs for outpatient medical care, inpatient care, informal and formal nursing care and pharmaceuticals from a societal perspective. Conclusion: The calculated unit costs can serve as a reference case in health economic evaluations and hence help to increase their comparability.
Gesundheitswesen, Das

Hofmann, M.; Mielck, A.
Gesundheitliche Chancengleichheit und Kosten-Effektivität: Was sagen wichtige gesundheitspolitische Akteure zu diesem potentiellen Zielkonflikt?
Gesundheitswesen 77, 81-85 (2015)
The German statutory health-care system is based on the principle of solidarity and thus it is committed to the objective of 'equal chances'. From an economic perspective it is also important to emphasise that scarcity of resources continuously pushes the services towards cost control and towards increasing cost-effect-iveness. There could be conflicts between the 2 objectives 'equal chances' and 'cost-effectiveness', of course, for example if measures for increasing cost-effectiveness lead to increased financial burdens of the insured. To date it has not been studied if and how this potential conflict is discussed in Germany.In a first step we searched for German publications discussing this potential conflict focusing on 3 major public health journals (Das Gesundheitswesen, Bundesgesundheitsblatt, Ethik in der Medizin) and on the internet portal "gerechte-gesundheit.de". For the main part of the paper, we looked for publications from 4 major health policy actors (Bundesärztekammer, Zentrale Ethikkommission bei der Bundesärztekammer, Deutscher Ethikrat, Sachverständigenrat zur Begutachtung der Entwicklung im Gesundheitswesen). All papers published since the year 2000 were included in the system-atic qualitative analysis.The analyses show that the potential conflict between 'equal chances' and 'cost-effectiveness' is rarely discussed in any detail, at most in an implicit way. It would be important, though, to have an explicit discussion, supported by scientifically based analyses and recommendations. One step towards this objective could be, for example, a closer cooperation between social-epidemiologists and health--economists.
Gesundheitswesen, Das

Müller, D.J.; Stock, S.; Stollenwerk, B.
Cost-effectiveness of a multifactorial fracture prevention program for elderly people admitted to nursing homes.
Eur. J. Health Econ. 16, 517-527 (2015)
Background Fractures are one of the most costly consequences of falls in elderly patients in nursing homes. Objectives To compare the cost-effectiveness of a 'multifactorial fracture prevention program' provided by a multidisciplinary team with 'no prevention' in newly admitted nursing home residents. Methods We performed a cost-utility analysis using a Markov-based simulation model to establish the effectiveness of a multifaceted fall prevention program from the perspective of statutory health insurance (SHI) and long-term care insurance (LCI). The rate of falls was used to estimate the clinical and economic consequences resulting from hip and upper limb fractures. Robustness of the results was assessed using deterministic and probabilistic sensitivity analyses. Results Compared to no prevention a multifactorial prevention program for nursing home residents resulted in a cost-effectiveness ratio of €21,353 per quality-adjusted life-year. The total costs for SHI/LCI would result in €1.7 million per year. Results proved to be robust following deterministic and probabilistic sensitivity analyses. Conclusion Multifactorial fracture prevention appears to be cost-effective in preventing fractures in nursing home residents. Since the results were based on the number of falls further research is required to confirm the results.
The European journal of health economics

Severin, F.; Hess, W.; Schmidtke, J.; Mühlbacher, A.; Rogowski, W.H.
Value judgments for priority setting criteria in genetic testing: A discrete choice experiment.
Health Policy 119, 164-173 (2015)
As our understanding of genetics has increased, so has the number of genetic tests that have entered clinical practice. Given the need of many European health care systems to contain costs, the question of how to prioritise genetic tests fairly has become an emerging concern. This study uses a discrete-choice experiment to assess the value judgements of clinical geneticists, patient representatives and other stakeholders regarding the prioritisation of genetic tests. The respondents chose between two hypothetical scenarios that differed in severity of the disease, risk of the disease, aim of the test, medical benefit of the test, and costs of the test. Standard logit models and mixed effects models were used to estimate the weights different stakeholders attached to attribute levels. Responses from 594 participants were analysed. The most highly valued attribute levels were a proven medical benefit of the test, high risk of having the disease and low costs of the test. Results also showed that rankings differ between clinical geneticists and other stakeholders. The priority weights determined within this study can inform the policy debate and improve the consistency of prioritisation in genetics. Further stakeholder deliberation is needed to explore their most appropriate use in decision practice.
Health Policy

Seidl, H.; Bowles, D.; Bock, J.O.; Brettschneider, C.; Greiner, W.; König, H.H.; Holle, R.
FIMA – Fragebogen zur Erhebung von Gesundheitsleistungen im Alter: Entwicklung und Pilotstudie.
Gesundheitswesen 77, 46-52 (2015)
Durch den demografischen Wandel wird der Anteil der älteren Bevölkerung und folglich die Inanspruchnahme von Gesundheitsleistungen ansteigen. Die damit verbundenen Kosten können über die Routinedaten der Kranken- und Pflegeversicherung (Sekundärdaten) oder durch Patientenbefragungen (Primärdaten) erhoben bzw. geschätzt werden. Die Erhebung der Inanspruchnahme über Patientenfragebogen spielt dabei eine große Rolle, da eine Verknüpfung mit anderen sozialen und medizinischen Patientendaten möglich ist und der von den Patienten geleistete Eigenanteil in Kassendaten nicht abgebildet ist. Deshalb wurde ein geeignetes Instrument zur Erhebung des gesundheitsbezogenen Ressourcenverbrauchs von älteren Menschen entwickelt. Die Entwicklung des FIMA (Fragebogen zur Inanspruchnahme medizinischer und nicht-medizinischer Versorgungsleistungen im Alter) erfolgte in 6 Schritten. Hierzu gehörte die Bestimmung der Fragebogeninhalte auf Basis einer Literaturrecherche und der Analyse bestehender Fragebögen. Es folgte die sprachliche Gestaltung und die Festlegung des Layouts. Anschließend wurde der Fragebogen im Rahmen einer altersspezifischen Pilotstudie erprobt und modifiziert. Alle direkten medizinischen und nicht-medizinischen Ressourcenverbräuche außer Transport- und Zeitkosten wurden erfasst. Produktivitätsverluste wurden nicht mit eingeschlossen. Die abgefragten Zeiträume (7 Tage, 3 Monate, 12 Monate) wurden auf die Ressourcenkategorien abgestimmt. Für die Pilotstudie wurden 63 Fragebögen ausgewertet. Die Rücklaufquote betrug 69%, die mittlere Ausfüllzeit 21 min. Drei Viertel der Teilnehmer füllten den Fragebogen alleine aus und 90% stuften den Schwierigkeitsgrad als einfach bis sehr einfach ein. Erste Anhaltspunkte für die Validität der Eigenangaben lieferte der Phi-Koeffizient zwischen der Lebensqualität und den beanspruchten Ressourcen im Bereich der pflegerischen und hauswirtschaftlichen Versorgung. Dieser lag zwischen 0,52 („Für sich selbst sorgen") und 0,58 („Beweglichkeit" und „Allgemeine Tätigkeiten"). Der FIMA ist ein generischer Fragebogen, um innerhalb der älteren Bevölkerungsgruppe den gesundheitsbezogenen Ressourcenverbrauch erheben zu können.
Gesundheitswesen, Das

Maron, J.; Mielck, A.
Nimmt die gesundheitliche Ungleichheit zu? Ergebnisse eines Literaturreviews und Empfehlungen für die weitere Forschung.
Gesundheitswesen 77, 137-147 (2015)
Es ist häufig gezeigt worden, dass der sozio-ökonomische Status eng mit dem Gesundheitszustand zusammenhängt. Die weiterführende Frage, ob sich das Ausmaß dieser ‚gesundheitlichen Ungleichheit' mit der Zeit vergrößert hat, ist von großer gesundheitspolitischer Relevanz. Bisher wird darüber in Deutschland jedoch kaum diskutiert – es fehlt auch eine Überblicksarbeit zu den vorhandenen empirischen Arbeiten. Die hier vorgestellten Ergebnisse einer systematischen Literaturrecherche beziehen sich auf 4 Themenbereiche: Zeitliche Veränderungen im Ausmaß der gesundheitlichen Ungleichheit bei Mortalität/Lebenserwartung, selbst-eingeschätztem Gesundheitszustand (Self-Rated Health), Rauchen, Adipositas. Eingeschlossen wurden alle Arbeiten aus Deutschland und Publikationen aus dem europäischen Ausland aus dem Zeitraum 2008 bis 2012. In einem mehrstufigen Verfahren wurden anhand vorher festgelegter Kriterien 44 Studien (davon 5 aus Deutschland) für die detailliertere Darstellung der Ergebnisse und Methoden ausgewählt. Die stark anwachsende Zahl der Publikationen zeigt deutlich, wie sehr das Interesse an zeitlichen Trends im Ausmaß dieser gesundheitlichen Ungleichheit in den letzten Jahren zugenommen hat. Die empirischen Ergebnisse der 44 Studien lassen sich wie folgt zusammenfassen: Insgesamt werden 184 einzelne Ergebnisse zu zeitlichen Veränderungen im Ausmaß der gesundheitlichen Ungleichheit berichtet – davon weisen 112 auf eine Zunahme und nur 13 auf eine Verringerung der gesundheitlichen Ungleichheit hin. Auch die aus Deutschland vorliegenden Studien zeigen in die gleiche Richtung. Deutlich wird auch eine große methodische Heterogenität: In einigen Studien werden Unterschiede nach individuellem Status untersucht (z. B. Schulbildung), in anderen nach regionaler Deprivation. Zum Teil fehlt eine explizite Berechnung der zeitlichen Veränderung im Ausmaß der gesundheitlichen Ungleichheit, manchmal wird nur die absolute oder nur die relative gesundheitliche Ungleichheit analysiert. Die in Deutschland verfügbaren Datensätze sollten mehr als bisher für Analysen zu zeitlichen Veränderungen im Ausmaß der gesundheitlichen Ungleichheit verwendet werden. Die Studien sollten dabei nach Möglichkeit individuelle und regionale Ungleichheiten einbeziehen, absolute und relative gesundheitliche Ungleichheiten analysieren (getrennt für Männer und Frauen, mit Signifikanztests für die zeitlichen Veränderungen), möglichst viele Zeitpunkte betrachten und die Zusammenhänge mit gesellschaftlichen Veränderungen untersuchen.
Gesundheitswesen, Das

Hunger, M.; Kirchberger, I.; Holle, R.; Seidl, H.; Kuch, B.; Wende, R.; Meisinger, C.
Does nurse-based case management for aged myocardial infarction patients improve risk factors, physical functioning and mental health? The KORINNA trial.
Eur. J. Prev. Cardiol. 22, 442-450 (2015)
BACKGROUND: Older patients with acute myocardial infarction (MI) are often lacking optimal support to continue rehabilitation after discharge from hospital. The objective of the study was to examine whether a home-based case management programme led by nurses can improve atherogenic risk factors, physical functioning, and mental health in the first year following discharge. METHODS: The KORINNA study is a randomized two-armed parallel group trial including 329 patients (aged 65-92 years) from the Augsburg Hospital in southern Germany. The intervention consisted of an individualized follow-up programme with a duration of 1 year, including home visits and telephone calls. The control group received usual care. Secondary outcome measures included clinical parameters (blood pressure, lipid parameters), functional status measures, cognitive status, depressive symptoms, and nutrition risk. RESULTS: At 1-year follow up, patients in the intervention group (n = 116) had significantly better low-density lipoprotein cholesterol levels (-8.4 mg/dl, 95% CI -16.4 to -0.4), hand grip strength (+2.53 kg, 95% CI 0.56 to 4.50), and SCREEN-II nutrition risk scores (+2.03, 95% CI 0.58 to 3.48) than patients in the control group (n = 136). The intervention group also had better mean scores

with regard to self-reported disability, activities in daily living, and mental health, but differences were not always significant and meaningful. CONCLUSIONS: The results of the KORINNA study indicate that nurse-based case management can improve blood lipid levels, functional status, and nutrition risk of aged patients with MI.
European Journal of Preventive Cardiology

Perna, L.; Mielck, A.; Lacruz, M.E.; Emeny, R.T.; von Eisenhart Rothe, A.; Meisinger, C.; Ladwig, K.-H.
The association between resilience and diabetic neuropathy by socioeconomic position: Cross-sectional findings from the KORA-Age study.
J. Health Psychol. 20, 1222-1228 (2015)
We investigated whether older adults with diabetes mellitus and lower resilience have an increased risk of diabetic neuropathy as compared to older adults with higher resilience, and whether this association varies by socioeconomic position. In total, 3942 individuals took part in a health survey in Augsburg, Germany, in 2008-2010 (KORA-Age study). We found that among participants with low socioeconomic position, those with higher resilience had a lower probability of suffering from neuropathy as compared to participants with lower resilience (absolute risk reduction = 10%). Adjusted odds ratio with 95% confidence intervals for the outcome diabetic neuropathy also showed that lower resilience scores had an independent effect in increasing the risk of diabetic neuropathy among elderly individuals with a low socioeconomic position (odds ratio: 1.83; confidence interval: 1.09-3.08). Health-promoting strategies focussing on resilience should be further explored.
Journal of Health Psychology

2014

Laxy, M.; Hunger, M.; Thorand, B.; Meisinger, C.; Kirchberger, I.; Holle, R.
The intermediate burden of diabetes mellitus in patients with cardiovascular disease (CVD): A quality adjusted life year (QALY) - analysis based on primary longitudinal data.
Value Health 17, A494 (2014)
Value in Health
Meeting abstract

Rochau, U.; Kuhner, F.; Jahn, B.; Kurzthaler, C.; Ramos, C.; Chhatwal, J.; Stollenwerk, B.; Goldhaber-Fiebert, J.D.; Siebert, U.
Prioritization of future outcomes research studies in chronic myeloid leukemia: Value of information analysis.
Value Health 17, A639 (2014)
Value in Health
Meeting abstract

Butzke, B.; Oduncu, F.; Heinemann, V.; Pfeufer, A.; Giessen, C.; Stollenwerk, B.; Rogowski, W.H.
Cost-effectiveness analysis of ugt1a1 genotyping before colorectal cancer treatment with irinotecan.
Value Health 17, A643 (2014)
Value in Health
Meeting abstract

Brandes, A.; Koerber, F.; Schwarzkopf, L.; Hunger, M.; Waidelich, R.; Rogowski, W.H.
Cost-effectiveness of radical prostatectomy, radiation therapy and active surveillance for the treatment of localized prostate cancer - a claims data analysis.
Value Health 17, A636-A637 (2014)
Value in Health
Meeting abstract

Islam, S.; Lechner, A.; Ferrari, U.; Froeschl, G.; Alam, D.; Holle, R.; Seissler, J.; Niessen, L.W.
Mobile phone intervention for increasing adherence to treatment for type 2 diabetes in an urban area of Bangladesh: Protocol for a randomized controlled trial.
BMC Health Serv. Res. 14:586 (2014)
BackgroundMobile phone technologies including SMS (short message service) have been used to improve the delivery of health services in many countries. However, data on the effects of mobile health technology on patient outcomes in resource-limited settings are limited. The aim of this study therefore is to measure the impact of a mobile phone SMS service on treatment success of newly diagnosed type 2 diabetes in an urban area of Bangladesh.Methods/designThis is a single-centred randomized controlled intervention trial (prospective) comparing standard-of-care with standard-of-care plus a mobile phone-based SMS intervention for 6 months. A total of 216 participants with newly diagnosed type 2 diabetes will be recruited. Data will be collected at the outpatient department of Bangladesh Institute of Health Science (BIHS) hospital at baseline and after 6 months. The primary outcome measure will be change in HbA1c between baseline and 6 months. The secondary outcome measures are self-reported medication adherence, clinic attendance, self-reported adoption of healthy behaviours, diabetes knowledge, quality of life and cost effectiveness of the SMS intervention. The inclusion criteria will be as follows: diagnosed as patients with type 2 diabetes by the BIHS physician, using oral medication therapy, living in Dhaka city, registered with the BIHS hospital, using a mobile phone, willing to return for follow up after 6 months and providing written informed consent. Participants will be allocated to control and intervention arms after recruitment using a randomization software. Data will be collected on Socio-demographic and economic information, mobile phone use and habits, knowledge of prevention, management and complications of diabetes, self-perceived quality of life assessment, self-reported diseases, medical history, family history of diseases, medication history, medication adherence, health seeking behaviour, tobacco use, physical activity, diet, mental health status, life events and disability, anthropometric measurements of weight, height, blood pressure and blood tests for HbA1c.DiscussionMobile phone SMS services have the potential to communicate with diabetes patients and to build awareness about the disease, improve self-management and avoid complications also in resource-limited setting. If this intervention proves to be efficient and cost-effective in the current trial, large-scale implementation could be undertaken.Trial registration DRKS00005188.
BMC Health Services Research

Grundmann, N.°; Mielck, A.°; Siegel, M.°; Maier, W.°
Area deprivation and the prevalence of type 2 diabetes and obesity: Analysis at the municipality level in Germany.
BMC Public Health 14:1264 (2014)
Background The objective of this study was to analyse the association between area deprivation at municipality level and

the prevalence of type 2 diabetes (T2D) and obesity across Germany, controlling for individual socioeconomic status (SES). Methods The analyses are based on a large survey conducted in 2006. Information was included from 39,908 adults aged 20 years or above. Area deprivation was assessed using the German Index of Multiple Deprivation (GIMD) at municipality level. About 4,700 municipalities could be included and assigned to a deprivation quintile. Individual SES was assessed by income and educational level. Multilevel logistic models were used to control for individual SES and other potential confounders such as age, sex and physical activity. Results We found a positive association of area deprivation with T2D and obesity. Controlling for all individual-level variables, the odds ratios for municipalities in the most deprived quintile were significantly increased for T2D (OR 1.35; 95% CI 1.12-1.64) as well as for obesity (OR 1.14; 95% CI 1.02-1.26). Further analyses showed that these associations were relatively similar for both men and women. Conclusions Based on a nationwide dataset, we were able to show that area deprivation at municipality level is significantly associated with the prevalence of T2D and obesity. It will be important to focus preventive efforts on very deprived municipalities.
BMC Public Health

Stollenwerk, B.; Waldeyer, R.; Klein-Meding, C.; Müller, D.; Stock, S.
Cost effectiveness of external hip protectors in the hospital setting: A modeling study.
Nurs. Econ. 32, 89-98 (2014)
Chronic illnesses, for which many patients are admitted to hospitals, substantially increase the risk of falling, and hence the likelihood of incurring a hip fracture. Hip fractures not only have devastating consequences on an individual's quality of life but may also affect a hospital's reputation in the community. In addition, hospitals may face litigation claims and increased costs for patients who fall and suffer a major injury as a consequence. External hip protectors are comparable to padded undergarments and shield the trochanter, reducing the detrimental effects and force impacting the bone during a fall. Screening for patients at high risk of falling and providing high-risk patients with hip protectors as a preventive measure to avoid hip fractures, not only improves public health, but can also save hospitals care and litigation costs.
Nursing Economics

Witt, S.; Leidl, R.; Becker, C.; Holle, R.; Block, M.; Brachmann, J.; Silber, S.; Stollenwerk, B.
The effectiveness of the cardiovascular disease prevention programme 'KardioPro' initiated by a German sickness fund: A time-to-event analysis of routine data.
PLoS ONE 9:e114720 (2014)
BACKGROUND: Cardiovascular disease is the leading cause of morbidity and mortality in the developed world. To reduce this burden of disease, a German sickness fund ('Siemens-Betriebskrankenkasse', SBK) initiated the prevention programme 'KardioPro' including primary (risk factor reduction) and secondary (screening) prevention and guideline-based treatment. The aim of this study was to assess the effectiveness of 'KardioPro' as it is implemented in the real world. METHODS: The study is based on sickness fund routine data. The control group was selected from non-participants via propensity score matching. Study analysis was based on time-to-event analysis via Cox proportional hazards regression with the endpoint 'all-cause mortality, acute myocardial infarction (MI) and ischemic stroke (1)', 'all-cause mortality (2)' and 'non-fatal acute MI and ischemic stroke (3)'. RESULTS: A total of 26,202 insurants were included, 13,101 participants and 13,101 control subjects. 'KardioPro' enrolment was associated with risk reductions of 23.5% (95% confidence interval (CI) 13.0-32.7%) (1), 41.7% (95% CI 30.2-51.2%) (2) and 3.5% (hazard ratio 0.965, 95% CI 0.811-1.148) (3). This corresponds to an absolute risk reduction of 0.29% (1), 0.31% (2) and 0.03% (3) per year. CONCLUSION: The prevention programme initiated by a German statutory sickness fund appears to be effective with regard to all-cause mortality. The non-significant reduction in non-fatal events might result from a shift from fatal to non-fatal events.
PLoS ONE

Pokhrel, S.; Evers, S.; Leidl, R.; Trapero-Bertran, M.; Kalo, Z.; Vries, H.d.; Crossfield, A.; Andrews, F.; Rutter, A.; Coyle, K.; Lester-George, A.; West, R.; Owen, L.; Jones, T.; Vogl, M.; Radu-Loghin, C.; Voko, Z.; Huic, M.; Coyle, D.
EQUIPT: Protocol of a comparative effectiveness research study evaluating cross-context transferability of economic evidence on tobacco control.
BMJ Open 4:e006945 (2014)
INTRODUCTION: Tobacco smoking claims 700 000 lives every year in Europe and the cost of tobacco smoking in the EU is estimated between €98 and €130 billion annually; direct medical care costs and indirect costs such as workday losses each represent half of this amount. Policymakers all across Europe are in need of bespoke information on the economic and wider returns of investing in evidence-based tobacco control, including smoking cessation agendas. EQUIPT is designed to test the transferability of one such economic evidence base-the English Tobacco Return on Investment (ROI) tool-to other EU member states. METHODS AND ANALYSIS: EQUIPT is a multicentre, interdisciplinary comparative effectiveness research study in public health. The Tobacco ROI tool already developed in England by the National Institute for Health and Care Excellence (NICE) will be adapted to meet the needs of European decision-makers, following transferability criteria. Stakeholders' needs and intention to use ROI tools in sample countries (Germany, Hungary, Spain and the Netherlands) will be analysed through interviews and surveys and complemented by secondary analysis of the contextual and other factors. Informed by this contextual analysis, the next phase will develop country-specific ROI tools in sample countries using a mix of economic modelling and Visual Basic programming. The results from the country-specific ROI models will then be compared to derive policy proposals that are transferable to other EU states, from which a centralised web tool will be developed. This will then be made available to stakeholders to cater for different decision-making contexts across Europe. ETHICS AND DISSEMINATION: The Brunel University Ethics Committee and relevant authorities in each of the participating countries approved the protocol. EQUIPT has a dedicated work package on dissemination, focusing on stakeholders' communication needs. Results will be disseminated via peer-reviewed publications, e-learning resources and policy briefs.
BMJ Open

Donath, C.°; Ulbrecht, G.°; Grau, H,°; Graessel, E.°; Schwarzkopf, L.°; Menn, P.°; Kunz, S.°; Holle, R.°

Health services utilization by community-dwelling dementia patients and their family caregivers.
In: Janssen, C.*; Swart, E.*; von Lengerke, T.* [Eds.]: Health Care Utilization in Germany : Theory, Methodology, and Results. New York: Springer, 2014. 193-219
Background In research as well as in the practice of home-living persons with dementia and their family caregivers, influencing the probability of institutionalization is considered an important characteristic of home care. Two presented studies implementing the behavioral model of Andersen provide information on predictors of utilization of care and support services, the utilization of nondrug therapies, and the utilization of health insurance and long-term care insurance benefits. Methods One study examined the awareness, utilization, need, and accessibility of ten specific services. It aims to clarify which of the three types of factors from the Andersen model is predictive of utilization (predisposing, enabling, and need factors). Binary-logistic regression analyses were conducted. The second study investigated the predictor of utilization in terms of mild or moderate dementia. Results Not all predisposing factors were as much conspicuous and for all services consistently predictive, as in case of the “need factor” (“need a service”). All types of services presented in the first study were used more often when the family caregiver subjectively believed he was in need of a service. In the second of our described studies, a factor in the evaluated need category (diagnosis of mild versus moderate dementia) was a significant predictor of the utilization of certain types of non-pharmacological treatments. The reasons for utilizing health insurance and long-term care insurance benefits were largely comparable between the two groups of diagnosis of mild versus moderate dementia. Conclusion To increase the utilization of care and support services, family caregivers should be made aware of the service or the available services; the advantages of using these services should be pointed out to them. Every family caregiver should be informed about the location and accessibility of the nearest support services that are not provided at the patient’s home.

Grintsova, O.; Maier, W.; Mielck, A.
Inequalities in health care among patients with type 2 diabetes by individual Socio-Economic Status (SES) and regional deprivation: A systematic literature review.
Int. J. Equity Health 13:43 (2014)
Introduction Quality of care could be influenced by individual socio-economic status (SES) and by residential area deprivation. The objective is to synthesize the current evidence regarding inequalities in health care for patients with Type 2 diabetes mellitus (Type 2 DM). Methods The systematic review focuses on inequalities concerning process (e.g. measurement of HbA1c, i.e. glycolised haemoglobin) and intermediate outcome indicators (e.g. HbA1c level) of Type 2 diabetes care. In total, of n = 886 publications screened, n = 21 met the inclusion criteria. Results A wide variety of definitions for ‘good quality diabetes care’, regional deprivation and individual SES was observed. Despite differences in research approaches, there is a trend towards worse health care for patients with low SES, concerning both process of care and intermediate outcome indicators. Patients living in deprived areas less often achieve glycaemic control targets, tend to have higher blood pressure (BP) and worse lipid profile control. Conclusion The available evidence clearly points to the fact that socio-economic inequalities in diabetes care do exist. Low individual SES and residential area deprivation are often associated with worse process indicators and worse intermediate outcomes, resulting in higher risks of microvascular and macrovascular complications. These inequalities exist across different health care systems. Recommendations for further research are provided.
International Journal for Equity in Health

von Lengerke, T.°; Menn, P.°; Holle, R.°; Mielck, A.°; Meisinger, C.°; Wolfenstetter, S.B.°
Utilization of primary care physicians by obese men and women: Review for Germany and results from the MONICA/KORA cohorts S3/F3 and S4/F4.
In: Janssen, C.*; Swart, E.*; von Lengerke, T. [Eds.]: Health Care Utilization in Germany : Theory, Methodology, and Results. New York: Springer, 2014. 221-236
Objectives To provide a review on the obesity-associated utilization of outpatient primary care physicians (PCPs) by adults in Germany, analyze associations between moderate and severe obesity and the utilization of outpatient PCP care, and systematize the results using the behavioral model of health services use. Methods For the review, a literature search was conducted in PubMed for the print publication period of January 1, 1998 to December 31, 2012, and adults as the target group. The first author assessed these publicationsby screening titles, abstracts, and, if necessary, full texts. For the empirical study, self-reported PCP data were collected within twopopulation-based cohorts (baseline surveys: Monitoring of Trends and Determinants in Cardiovascular Disease (MONICA)-S3 1994/95 and Cooperative Health Research in the Region of Augsburg (KORA)-S4 1999/2001; follow-ups: KORA-F3 2004/05 andKORA-F4 2006/08) in the region of Augsburg, Germany, and were pooled for present purposes. Adults (N = 5,171)aged 25–64 years at baseline participated. Thenumber of visits to PCPat follow-up was compared across four groups defined by body mass index (BMI) at baseline. Body weight and height were measured anthropometrically. Hierarchical generalized linear negative binomial regressions adjusted for age at baseline, school education, survey cohort, and diabetes status were conducted. Results First, the review of population-based studies on obesity-associated PCP utilization found significantly higher use in obese than in nonobese groups as measured by the number of visits per annum. Second, the analysis of data from the MONICA/KORA cohorts S3/F3 and S4/F4 showed that women had almost one-third (31.3%) more PCP visits than men, and PCP visits linearly increased with the BMI group, with the highest mean number of PCP visits in severely obese individuals (4.7 vs. 2.8 in normal weight). Third, among women, all overweight groups had more PCP visits than the normal-weight group (4.3, 4.5, and 5.0, vs. 3.1). Among men, those with severe obesity reported higher utilization than the other three BMIgroups (4.4 vs. 2.6 in the normal-weight group, 2.8 in the preobesity group, and 3.1 given moderate obesity). Conclusion In population-based studies in Germany, obesity is associated with excess utilization of PCPs in terms of number of visits, holding especially for severe obesity. Excess PCP utilization is associated only with severe obesity among men, but with all three degrees of overweight among women. This pattern parallels obesity-associated reduction in physical health-related quality of life. Future studies should replicate these findings and examine the roles of enabling and contextual factors in this context, for instance, income as an effect modifier and the gender-specific impact of regional PCP density.

Tamayo, T.; Schipf, S.; Meisinger, C.; Schunk, M.; Maier, W.; Herder, C.; Roden, M.; Nauck, M.; Peters, A.; Völzke, H.; Rathmann, W.
Regional differences of undiagnosed type 2 diabetes and prediabetes prevalence are not explained by known risk factors.
PLoS ONE 9:e113154 (2014)
BACKGROUND: We have previously found regional differences in the prevalence of known type 2 diabetes between northeastern and southern Germany. We aim to also provide prevalence estimates for prediabetes (isolated impaired fasting glucose (i-IFG), isolated glucose intolerance (i-IGT), combined IFG and IGT) and unknown type 2 diabetes for both regions. METHODS: Prevalence (95%CI) of prediabetes (i-IFG: fasting glucose 5.6-6.9 mmol/l; i-IGT: 2 h postchallenge gluose 7.8-11.0 mmol/l, oral glucose tolerance test (OGTT), ≥8 h overnight fasting) and unknown diabetes were analyzed in two regional population-based surveys (age group 35-79 years): SHIP-TREND (Study of Health in Pomerania (northeast), 2008-2012) and KORA F4 (Cooperative Health Research in the region of Augsburg (south), 2006-2008). Both studies used similar methods, questionnaires, and identical protocols for OGTT. Overall, 1,980 participants from SHIP-TREND and 2,617 participants from KORA F4 were included. RESULTS: Age-sex-standardized prevalence estimates (95%CI) of prediabetes and unknown diabetes were considerably higher in the northeast (SHIP-TREND: 43.1%; 40.9-45.3% and 7.1%; 5.9-8.2%) than in the south of Germany (KORA F4: 30.1%; 28.4-31.7% and 3.9%; 3.2-4.6%), respectively. In particular, i-IFG (26.4%; 24.5-28.3% vs. 17.2%; 15.7-18.6%) and IFG+IGT (11.2%; 9.8-12.6% vs. 6.6%; 5.7-7.5%) were more frequent in SHIP-TREND than in KORA. In comparison to normal glucose tolerance, the odds of having unknown diabetes (OR, 95%CI: 2.59; 1.84-3.65) or prediabetes (1.98; 1.70-2.31) was higher in the northeast than in the south after adjustment for known risk factors (obesity, lifestyle). CONCLUSIONS: The regional differences of prediabetes and unknown diabetes are in line with the geographical pattern of known diabetes in Germany. The higher prevalences in the northeast were not explained by traditional risk factors.
PLoS ONE

Malzahn, D.; Müller-Nurasyid, M.; Heid, I.M.; Wichmann, H.-E.; Bickeböller, H.; KORA Study Group (Gieger, C.; Grallert, H.; Heinrich, J.; Holle, R.; Leidl, R.; Meisinger, C.; Peters, A.; Strauch, K.)
Controversial association results for INSIG2 on body mass index may be explained by interactions with age and with MC4R.
Eur. J. Hum. Genet. 22, 1217-1224 (2014)
Among the single-nucleotide polymorphisms (SNPs) previously reported to be associated with body Mass index (BMI) and obesity, we focus on a common risk variant rs7566605 upstream of the insulin-induced gene 2 (INSIG2) gene and a rare protective variant rs2229616 on the melanocortin-4 receptor (MC4R) gene. INSIG2 is involved in adipogenesis and MC4R effects hormonal appetite control in response to the amount of adipose tissue. The influence of rs2229616 (MC4R) on BMI and obesity has been confirmed repeatedly and insight into the underlying mechanism provided. However, a main effect of rs7566605 (INSIG2) is under debate because of inconsistent replications of association. Interaction of rs7566605 with age may offer an explanation. SNP-age and SNP-SNP interaction models were tested on independent individuals from three population-based longitudinal cohorts, restricting the analysis to an observed age of 25-74 years. KORA S3/F3, KORA S4/F4 (Augsburg, Germany, 1994-2005, 1999-2008), and Framingham-Offspring data (Framingham, USA, 1971-2001) were analysed, with a total sample size of N=6926 in the joint analysis. The effect of interaction between rs7566605 and age on BMI and obesity status is significant and consistent across studies. This new evidence for rs7566605 (INSIG2) complements previous research. In addition, the interaction effect of rs7566605 with the MC4R variant rs2229616 on BMI was observed. This effect size was three times larger than that in a previously reported single-locus main effect of rs2229616. This leads to the conclusion that SNP-age or SNP-SNP interactions can mask genetic effects for complex diseases if left unaccounted for.
European Journal of Human Genetics

Schwarzkopf, L.; Hao, Y.; Holle, R.; Graessel, E.
Health care service utilization of dementia patients before and after institutionalization: A claims data analysis.
Dement. Geriatr. Cogn. Disord. 4, 195-208 (2014)
BACKGROUND: Community-based and institutional dementia care has been compared in cross-sectional studies, but longitudinal information on the effect of institutionalization on health care service utilization is sparse. METHODS: We analyzed claims data from 651 dementia patients via Generalized Estimation Equations to assess health care service utilization profiles and corresponding expenditures from four quarters before to four quarters after institutionalization. RESULTS: In all domains, utilization increased in the quarter of institutionalization. Afterwards, the use of drugs, medical aids, and non-physician services (e.g., occupational therapy and physiotherapy) remained elevated, but use of in- and outpatient treatment decreased. Cost of care showed corresponding profiles. CONCLUSION: Institutional dementia care seems to be associated with an increased demand for supportive services but not necessarily for specialized medical care.
Dementia and Geriatric Cognitive Disorders

Italia, S.; Wolfenstetter, S.B.; Teuner, C.M.
Patterns of Complementary and Alternative Medicine (CAM) use in children: A systematic review.
Eur. J. Pediatr. 173, 1413-1428 (2014)
UNLABELLED: Utilization of Complementary and Alternative Medicine (CAM) among children/adolescents is popular. This review summarizes the international findings for prevalence and predictors of CAM use among children/adolescents. We therefore systematically searched four electronic databases (PubMed, Embase, PsycINFO, AMED; last update in 07/2013) and reference lists of existing reviews and all included studies. Publications without language restriction reporting patterns of CAM utilization among children/adolescents without chronic conditions were selected for inclusion. The prevalence rates for overall CAM use, homeopathy, and herbal drug use were extracted with a focus on country and recall period (lifetime, 1 year, current use). As predictors, we extracted socioeconomic factors, child's age, and gender. The database search and citation tracking yielded 58 eligible studies from 19 countries. There was strong variation regarding study quality. Prevalence rates for overall CAM use ranged from 10.9-87.6 % for lifetime use and from 8-48.5 % for current use. The respective percentages for homeopathy (highest in Germany, United Kingdom, and Canada) ranged from 0.8-39 % (lifetime) and from

1-14.3 % (current). Herbal drug use (highest in Germany, Turkey, and Brazil) was reported for 0.8-85.5 % (lifetime) and 2.2-8.9 % (current) of the children/adolescents. Studies provided a relatively uniform picture of the predictors of overall CAM use (higher parental income and education, older children), but only a few studies analyzed predictors for single CAM modalities. CONCLUSION: CAM use is widespread among children/adolescents. Prevalence rates vary widely regarding CAM modality, country, and reported recall period.
European Journal of Pediatrics

Mielck, A.
Wer möchte schon gerne 'Zielgruppe' sein?
Impulse 84, 2-3 (2014)
Impulse
Editorial
Editorial

Mueller, M.; Strobl, R.; Jahn, K.; Linkohr, B.; Ladwig, K.-H.; Mielck, A.; Grill, E.
Impact of vertigo and dizziness on self-perceived participation and autonomy in older adults: Results from the KORA-Age study.
Qual. Life Res. 23, 2301-2308 (2014)
The impact of vertigo and dizziness on healthy ageing, and especially on participation, is not fully understood. The objective of this study was to investigate the association of vertigo and dizziness with self-perceived participation and autonomy in older non-institutionalised individuals, adjusted for the presence of other health conditions. Specifically, we wanted to investigate the different effects of vertigo and dizziness on specific components of participation, i.e. restrictions in indoor and outdoor autonomy, family role, social life and relationships, and work and education. Data originate from the second wave of the German KORA-Age cohort study collected in 2012. Participation and autonomy was investigated with the Impact on Participation and Autonomy Questionnaire. We used robust regression to analyse the association of vertigo and dizziness with self-perceived participation and autonomy adjusted for covariates. A total of 822 participants (49.6 % female) had a mean age of 78.1 years (SD 6.39). Participation and autonomy were significantly lower in participants with vertigo and dizziness across all domains. Adjusted for age, sex, and chronic conditions, vertigo and dizziness were significantly associated with participation restrictions in all domains except social life and relationships. The results of our study indicate that vertigo and dizziness contribute to restrictions in participation and autonomy in individuals of older age. Recognising vertigo and dizziness as independent contributors to loss of autonomy and decreased chances for independent living may create new options for patient care and population health, such as the designing of complex interventions to maintain participation and autonomy.
Quality of Life Research

Korber, K.
Potential transferability of economic evaluations of programs encouraging physical activity in children and adolescents across different countries - a systematic review.
Int. J. Environ. Res. Public Health 11, 10606-10621 (2014)
Physical inactivity is an increasing problem. Owing to limited financial resources, one method of getting information on the cost-effectiveness of different types of prevention programs is to examine existing programs and their results. The aim of this paper is to give an overview of the transferability of cost-effectiveness results of physical activity programs for children and adolescents to other contexts. Based on a systematic review of the literature, the transferability of the studies found was assessed using a sub-checklist of the European Network of Health Economic Evaluation Databases (EURONHEED). Thirteen studies of different physical activity interventions were found and analyzed. The results for transferability ranged from "low" to "very high". A number of different factors influence a program's cost-effectiveness (i.e., discount rate, time horizon, etc.). Therefore, transparency with regard to these factors is one fundamental element in the transferability of the results. A major point of criticism is that transferability is often limited because of lack of transparency. This paper is the first to provide both an overview and an assessment of transferability of economic evaluations of existing programs encouraging physical activity in children and adolescents. This allows decision makers to gain an impression on whether the findings are transferable to their decision contexts, which may lead to time and cost savings.
International Journal of Environmental Research and Public Health

Weidenhammer, W.; Lacruz, M.E.; Emeny, R.T.; Linde, K.; Peters, A.; Thorand, B.; Mielck, A.; Ladwig, K.-H.
Prevalence of use and level of awareness of CAM in older people - results from the KORA-Age study.
Forsch. Komplementmed. 21, 294-301 (2014)
Forschende Komplementärmedizin

Osterwald, B.; Günter, M.; Mielck, A.
"Der Ton redet mit mir. Verstehst Du, was er sagt?" Die Arbeit am Tonfeld mit Kindern.
Diskurs Kindheit. Jugendforsch. 9, 245-250 (2014)
Diskurs Kindheits- und Jugendforschung

International League Against Epilepsy Consortium on Complex Epilepsies (Gieger, C.; Grallert, H.; Heinrich, J.; Holle, R.; Leidl, R.; Meisinger, C.; Peters, A.; Strauch, K.)
Genetic determinants of common epilepsies: A meta-analysis of genome-wide association studies.
Lancet Neurol. 13, 893-903 (2014)
Background The epilepsies are a clinically heterogeneous group of neurological disorders. Despite strong evidence for heritability, genome-wide association studies have had little success in identification of risk loci associated with epilepsy, probably because of relatively small sample sizes and insufficient power. We aimed to identify risk loci through meta-analyses of genome-wide association studies for all epilepsy and the two largest clinical subtypes (genetic generalised epilepsy and focal epilepsy). Methods We combined genome-wide association data from 12 cohorts of individuals with epilepsy and controls from population-based datasets. Controls were ethnically matched with cases. We phenotyped individuals with epilepsy into categories of genetic generalised epilepsy, focal epilepsy, or unclassified epilepsy. After standardised filtering for quality control and imputation to account for different genotyping platforms across sites, investigators at each site conducted a linear mixed-model association analysis for each dataset. Combining summary statistics, we conducted fixed-effects meta-analyses of all epilepsy, focal epilepsy, and genetic generalised epilepsy. We set the genome-wide significance threshold at $p<1.66 \times 10^{-8}$. Findings We included 8696 cases and 26157

controls in our analysis. Meta-analysis of the all-epilepsy cohort identified loci at 2q24.3 (p=8.71 x 10(-10), implicating SCN1A, and at 4p15.1 (p=5.44 x 10(-9)), harbouring PCDH7, which encodes a protocadherin molecule not previously implicated in epilepsy. For the cohort of genetic generalised epilepsy, we noted a single signal at 2p16.1 (p=9.99 x 10(-9)), implicating VRK2 or FANCL. No single nucleotide polymorphism achieved genome-wide significance for focal epilepsy. Interpretation This meta-analysis describes a new locus not previously implicated in epilepsy and provides further evidence about the genetic architecture of these disorders, with the ultimate aim of assisting in disease classification and prognosis. The data suggest that specific loci can act pleiotropically raising risk for epilepsy broadly, or can have effects limited to a specific epilepsy subtype. Future genetic analyses might benefit from both lumping (ie, grouping of epilepsy types together) or splitting (ie, analysis of specific clinical subtypes).
Lancet Neurology, The

Vogl, M.; Wilkesmann, R.; Lausmann, C.; Hunger, M.; Ploetz, W.
The impact of preoperative patient characteristics on health states after total hip replacement and related satisfaction thresholds: A cohort study.
Health Qual. Life Outcomes 12:108 (2014)
Background The aim of the study was to analyze the effect of preoperative patient characteristics on health outcomes 6 months after total hip replacement (THR), to support patient's decision making in daily practice with predicted health states and satisfaction thresholds. By giving incremental effects for different patient subgroups, we support comparative effectiveness research (CER) on osteoarthritis interventions. Methods In 2012, 321 patients participated in health state evaluation before and 6 months after THR. Health-related quality of life (HRQoL) was measured with the EQ-5D questionnaire. Hip-specific pain, function, and mobility were measured with the WOMAC in a prospective observation of a cohort. The predictive capability of preoperative patient characteristics – classified according to socio-demographic factors, medical factors, and health state variables – for changes in health outcomes is tested by correlation analysis and multivariate linear regressions. Related satisfaction thresholds were calculated with the patient acceptable symptom state (PASS) concept. Results The mean WOMAC and EQ-5D scores before operation were 52 and 60 respectively (0 worst, 100 best). At the 6-month follow-up, scores improved by 35 and 19 units. On average, patients reported satisfaction with the operation if postoperative (change) WOMAC scores were higher than 85 (32) and postoperative (change) EQ-5D scores were higher than 79 (14). Conclusions Changes in WOMAC and EQ-5D scores can mainly be explained by preoperative scores. The lower the preoperative WOMAC or EQ-5D scores, the higher the change in the scores. Very good or very poor preoperative scores lower the probability of patient satisfaction with THR. Shared decision making using a personalized risk assessment approach provides predicted health states and satisfaction thresholds.
Health and Quality of Life Outcomes

Severin, F.; Borry, P.; Cornel, M.C.; Daniels, N.; Fellmann, F.; Hodgson, S.V.; Howard, H.C.; John, J.; Kääriäinen, H.; Kayserili, H.; Kent, A.; Koerber, F.; Kristoffersson, U.; Kroese, M.; Lewis, C.M.; Marckmann, G.; Meyer, P.; Pfeufer, A.; Schmidtke, J.; Skirton, H.; Tranebjærg, L.; Rogowski, W.H.; EuroGentest Consortium (); ESHG/PPPC Priority Consortium ()
Points to consider for prioritizing clinical genetic testing services: European consensus process oriented at accountability for reasonableness.
Eur. J. Hum. Genet. 23, 729-735 (2014)
Given the cost constraints of the European health-care systems, criteria are needed to decide which genetic services to fund from the public budgets, if not all can be covered. To ensure that high-priority services are available equitably within and across the European countries, a shared set of prioritization criteria would be desirable. A decision process following the accountability for reasonableness framework was undertaken, including a multidisciplinary EuroGentest/PPPC-ESHG workshop to develop shared prioritization criteria. Resources are currently too limited to fund all the beneficial genetic testing services available in the next decade. Ethically and economically reflected prioritization criteria are needed. Prioritization should be based on considerations of medical benefit, health need and costs. Medical benefit includes evidence of benefit in terms of clinical benefit, benefit of information for important life decisions, benefit for other people apart from the person tested and the patient-specific likelihood of being affected by the condition tested for. It may be subject to a finite time window. Health need includes the severity of the condition tested for and its progression at the time of testing. Further discussion and better evidence is needed before clearly defined recommendations can be made or a prioritization algorithm proposed. To our knowledge, this is the first time a clinical society has initiated a decision process about health-care prioritization on a European level, following the principles of accountability for reasonableness. We provide points to consider to stimulate this debate across the EU and to serve as a reference for improving patient management.
European Journal of Human Genetics

Rogowski, W.H.
Public and Professional Policy Committee der ESHG: Aktivitäten zur Priorisierung genetischer Tests.
Med. Genet. 26, 48 (2014)
Medizinische Genetik
Sonstiges: Nachrichtenmeldung
Other: News Item
Vogl, M.; Wilkesmann, R.; Lausmann, C.; Plötz, W.
The impact of preoperative patient characteristics on the cost-effectiveness of total hip replacement: A cohort study.
BMC Health Serv. Res. 14:342 (2014)
BACKGROUND: To facilitate the discussion on the increasing number of total hip replacements (THR) and their effectiveness, we apply a joint evaluation of hospital case costs and health outcomes at the patient level to enable comparative effectiveness research (CER) based on the preoperative health state. METHODS: In 2012, 292 patients from a German orthopedic hospital participated in health state evaluation before and 6 months after THR, where health-related quality of life (HRQoL) and disease specific pain and dysfunction were analyzed using EQ-5D and WOMAC scores. Costs were measured with a patient-based DRG costing scheme in a prospective observation of a cohort. Costs per quality-adjusted life year (QALY) were calculated based on the preoperative WOMAC score, as preoperative health states were found to be the best predictors of QALY gains in multivariate linear regressions. RESULTS: Mean inpatient costs of THR were 6,310

Euros for primary replacement and 7,730 Euros for inpatient lifetime costs including revisions. QALYs gained using the U.K. population preference-weighted index were 5.95. Lifetime costs per QALY were 1,300 Euros. CONCLUSIONS: The WOMAC score and the EQ-5D score before operation were the most important predictors of QALY gains. The poorer the WOMAC score or the EQ-5D score before operation, the higher the patient benefit. Costs per QALY were far below common thresholds in all preoperative utility score groups and with all underlying calculation methodologies.
BMC Health Services Research

Wacker, M.; Hunger, M.; Karrasch, S.; Heinrich, J.; Peters, A.; Schulz, H.; Holle, R.
Health-related quality of life and chronic obstructive pulmonary disease in early stages - longitudinal results from the population-based KORA cohort in a working age population.
BMC Pulm. Med. 14:134 (2014)
BACKGROUND: It is widely recognized that health-related quality of life (HRQL) is impaired in patients with Chronic Obstructive Pulmonary Disease (COPD), but there is a lack of research on longitudinal associations of COPD and HRQL. This study examined the effects of COPD in early stages of disease on HRQL over ten years in a working-age general population setting in Southern Germany while considering the influence of common comorbidities. METHODS: In the population-based KORA F4 study (2006-08) 1,321 participants aged 41-61 years performed spirometry and reported information on HRQL (measured by the generic SF-12) and comorbidities. For the same participants, HRQL information was available seven years before and three years after the lung function test from the previous S4 (1999-2001) and the F4L follow-up study (2010). Using linear mixed models, the physical and mental component summary scores (PCS-12 / MCS-12) of the SF-12 were compared over time between COPD groups. RESULTS: 7.8% of participants were classified as having COPD (according to the LLN definition and the Global Lungs Initiative), 59.4% of them in grade 1. Regression models showed a negative cross-sectional association of COPD grade 2+ with PCS-12 which persisted when comorbidities were considered. Adjusted mean PCS-12 scores for the COPD grade 2+ group were reduced (-3.5 (p = 0.008) in F4, -3.3 (p = 0.014) in S4 and -4.7 (p = 0.003) in F4L) compared to the group without airflow limitation. The size of the COPD effect in grade 2+ was similar to the effect of myocardial infarction and cancer. Over ten years, a small decline in PCS-12 was observed in all groups. This decline was larger in participants with COPD grade 2+, but insignificant. Regarding MCS-12, no significant cross-sectional or longitudinal associations with COPD were found. CONCLUSION: Despite small HRQL differences between COPD patients in early disease stages and controls and small changes over ten years, our results indicate that it is important to prevent subjects with airflow limitation from progression to higher grades. Awareness of HRQL impairments in early stages is important for offering early interventions in order to maintain high HRQL in COPD patients.
BMC Pulmonary Medicine

Hoogendoorn, M.; Feenstra, T.L.; Asukai, Y.; Borg, S.; Hansen, R.N.; Jansson, S.A.; Samyshkin, Y.; Wacker, M.; Briggs, A.H.; Lloyd, A.; Sullivan, S.D.; Rutten-van Mölken, M.P.
Cost-effectiveness models for chronic obstructive pulmonary disease: Cross-model comparison of hypothetical treatment scenarios.
Value Health 17, 525-536 (2014)
OBJECTIVES: To compare different chronic obstructive pulmonary disease (COPD) cost-effectiveness models with respect to structure and input parameters and to cross-validate the models by running the same hypothetical treatment scenarios. METHODS: COPD modeling groups simulated four hypothetical interventions with their model and compared the results with a reference scenario of no intervention. The four interventions modeled assumed 1) 20% reduction in decline in lung function, 2) 25% reduction in exacerbation frequency, 3) 10% reduction in all-cause mortality, and 4) all these effects combined. The interventions were simulated for a 5-year and lifetime horizon with standardization, if possible, for sex, age, COPD severity, smoking status, exacerbation frequencies, mortality due to other causes, utilities, costs, and discount rates. Furthermore, uncertainty around the outcomes of intervention four was compared. RESULTS: Seven out of nine contacted COPD modeling groups agreed to participate. The 5-year incremental cost-effectiveness ratios (ICERs) for the most comprehensive intervention, intervention four, was €17,000/quality-adjusted life-year (QALY) for two models, €25,000 to €28,000/QALY for three models, and €47,000/QALY for the remaining two models. Differences in the ICERs could mainly be explained by differences in input values for disease progression, exacerbation-related mortality, and all-cause mortality, with high input values resulting in low ICERs and vice versa. Lifetime results were mainly affected by the input values for mortality. The probability of intervention four to be cost-effective at a willingness-to-pay value of €50,000/QALY was 90% to 100% for five models and about 70% and 50% for the other two models, respectively. CONCLUSIONS: Mortality was the most important factor determining the differences in cost-effectiveness outcomes between models.
Value in Health

Richter, K.; Breitner, S.; Webb, A.R.; Huth, C.; Thorand, B.; Kift, R.; Linseisen, J.; Schuh, A.; Kratzsch, J.; Mielck, A.; Weidinger, S.; Peters, A.; Schneider, A.E.
Influence of external, intrinsic and individual behaviour variables on serum 25(OH)D in a German survey.
J. Photochem. Photobiol. B-Biol. 140, 120-129 (2014)
The objective of the present study was to identify external, intrinsic or behavioural factors that significantly influenced serum 25-hydroxyvitamin D (25(OH)D) concentrations in a German survey. Data from 3061 participants in the Cooperative Health Research in the Region of Augsburg, Germany (KORA) F4 survey were used to relate potential determinants to measured mean serum 25(OH)D concentrations using multivariable regression models. The factors significantly associated with hypovitaminosis D (defined as 25(OH)D<25nmolL(-1)) were season (winter, spring and autumn), urban environment and high body mass index. In contrast, times spent in sunny regions, hours per day spent outdoors in the summer as well as additional oral intake were associated with higher 25(OH)D concentrations. These results suggest that mainly ambient UV exposure but also individual behaviour are the most important determinants for personal 25(OH)D concentrations. The analyses further showed that in winter 43% of subjects were vitamin D deficient and 42% insufficient. Even in summer over

half the population has insufficient vitamin D status with 8% deficient and 47% insufficient. Therefore measures to mitigate widespread vitamin D insufficiency such as regular short-term sun exposure and/or improved dietary intake/supplementation recommendations by public health bodies need to be considered.
Journal of Photochemistry and Photobiology B-Biology

Strobl, R.; Maier, W.; Mielck, A.; Fuchs, J.; Richter-Kornweitz, A.; Gostomzyk, J.G.; Grill, E.
Wohnumfeld - Stolperstein oder Weg zum gesunden Altern? : Ergebnisse der Augsburger Regionalkonferenz "Wohnumfeld, Alter und Gesundheit".
Bundesgesundheitsbl.-Gesund. 57, 1120-1126 (2014)
Neben einer guten medizinischen Versorgung ist die Struktur des Wohnumfeldes von zentraler Bedeutung, um soziale Teilhabe älterer Menschen zu fördern. Für die Kommunen bedeutet dies, dass sie der altersgerechten Gestaltung des direkten Wohnumfelds hohe Priorität einräumen sollten. Am 1. Oktober 2013 wurden auf der Regionalkonferenz „Wohnumfeld, Alter und Gesundheit" im Augsburger Rathaus verschiedene Ergebnisse der KORA-Age-Studie zum Thema Teilhabe und Wohnumfeld vorgestellt und mit politischen Entscheidungsträgern aus Augsburg und Seniorenvertretern aus der Region diskutiert. Die Studie untersuchte den Zusammenhang zwischen Wohnumfeld und Teilhabe mittels zweier unterschiedlicher Ansätze: qualitative Ergebnisse aus Fokusgruppendiskussionen und quantitative Ergebnisse basierend auf Telefoninterviews und der Verwendung eines Geoinformationssystems. Die Ergebnisse wurden durch Beiträge aus regionaler und überregionaler Sicht ergänzt. In der Diskussion ergab sich, dass nur mit einem breiten Spektrum an Maßnahmen ein seniorenfreundliches Wohnumfeld geschaffen werden kann, sodass einerseits physische Barrieren abgebaut und andererseits das Gemeinschaftsgefühl, der nachbarschaftliche Zusammenhalt und das Miteinander gefördert werden.
Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz

Schipf, S.; Ittermann, T.; Tamayo, T.; Holle, R.; Schunk, M.; Maier, W.; Meisinger, C.; Thorand, B.; Kluttig, A.; Greiser, K.H.; Berger, K.; Müller, G.; Moebus, S.; Slomiany, U.; Icks, A.; Rathmann, W.; Völzke, H.
Regional differences in the incidence of self-reported type 2 diabetes in Germany: Results from five population-based studies in Germany (DIAB-CORE Consortium)
J. Epidemiol. Community Health 68, 1088-1095 (2014)
Background Population-based data are paramount to investigate the long-term course of diabetes, for planning in healthcare and to evaluate the cost-effectiveness of primary prevention. We analysed regional differences in the incidence of self-reported type 2 diabetes mellitus in Germany. Methods Data of participants (baseline age 45–74 years) from five regional population-based studies conducted between 1997 and 2010 were included (mean follow-up 2.2–7.1 years). The incidence of self-reported type 2 diabetes mellitus at follow-up was compared. The incidence rates per 1000 person-years (95% CI) and the cumulative incidence (95% CI) from regional studies were directly standardised to the German population (31 December 2007) and weighted by inverse probability weights for losses to follow-up. Results Of 8787 participants, 521 (5.9%) developed type 2 diabetes mellitus corresponding to an incidence rate of 11.8/1000 person-years (95% CI 10.8 to 12.9). The regional incidence was highest in the East and lowest in the South of Germany with 16.9 (95% CI 13.3 to 21.8) vs 9.3 (95% CI 7.4 to 11.1)/1000 person-years, respectively. The incidence increased with age and was higher in men than in women. Conclusions The incidence of self-reported type 2 diabetes mellitus shows regional differences within Germany. Prevention measures need to consider sex-specific differences and probably can be more efficiently introduced toward those regions in need.
Journal of Epidemiology and Community Health

Becker, C.
Cost-of-illness studies of atrial fibrillation: Methodological considerations.
Expert Rev. Pharmacoecon. Outcomes Res. 14, 661-684 (2014)
Atrial fibrillation (AF) is the most common heart rhythm arrhythmia, which has considerable economic consequences. This study aims to identify the current cost-of-illness estimates of AF; a focus was put on describing the studies' methodology. A literature review was conducted. Twenty-eight cost-of-illness studies were identified. Cost-of-illness estimates exist for health insurance members, hospital and primary care populations. In addition, the cost of stroke in AF patients and the costs of post-operative AF were calculated. The methods used were heterogeneous, mostly studies calculated excess costs. The identified annual excess costs varied, even among studies from the USA (∼US$1900 to ∼US$19,000). While pointing toward considerable costs, the cost-of-illness studies' relevance could be improved by focusing on subpopulations and treatment mixes. As possible starting points for subsequent economic studies, the methodology of cost-of-illness studies should be taken into account using methods, allowing stakeholders to find suitable studies and validate estimates.
Expert Review of Pharmacoeconomics and Outcomes Research

Maier, W.°; Mielck, A.°; Strobl, R.°; Grill, E.°
Verbesserung der sozialen Teilhabe älterer Menschen in den Kommunen.
Impulse 83:21 (2014)
Impulse

Aljutaili, M.; Becker, C.; Witt, S.; Holle, R.; Leidl, R.; Block, M.; Brachmann, J.; Silber, S.; Bestehorn, K.; Stollenwerk, B.
Should health insurers target prevention of cardiovascular disease? A cost-effectiveness analysis of an individualised programme in Germany based on routine data.
BMC Health Serv. Res. 14:263 (2014)
BACKGROUND: Cardiovascular diseases are the main cause of death worldwide, making their prevention a major health care challenge. In 2006, a German statutory health insurance company presented a novel individualised prevention programme (KardioPro), which focused on coronary heart disease (CHD) screening, risk factor assessment, early detection and secondary prevention. This study evaluates KardioPro in CHD risk subgroups, and analyses the cost-effectiveness of different individualised prevention strategies. METHODS: The CHD risk subgroups were assembled based on routine data from the statutory health insurance company, making use of a quasi-beta regression model for risk prediction. The control group was selected via propensity score matching based on logistic regression and an approximate nearest neighbour approach.

The main outcome was cost-effectiveness. Effectiveness was measured as event-free time, and events were defined as myocardial infarction, stroke and death. Incremental cost-effectiveness ratios comparing participants with non-participants were calculated for each subgroup. To assess the uncertainty of results, a bootstrapping approach was applied. RESULTS: The cost-effectiveness of KardioPro in the group at high risk of CHD was [euro sign]20,901 per event-free year; in the medium-risk group, [euro sign]52,323 per event-free year; in the low-risk group, [euro sign]186,074 per event-free year; and in the group with known CHD, [euro sign]26,456 per event-free year. KardioPro was associated with a significant health gain but also a significant cost increase. However, statistical significance could not be shown for all subgroups. CONCLUSION: The cost-effectiveness of KardioPro differs substantially according to the group being targeted. Depending on the willingness-to-pay, it may be reasonable to only offer KardioPro to patients at high risk of further cardiovascular events. This high-risk group could be identified from routine statutory health insurance data. However, the long-term consequences of KardioPro still need to be evaluated.
BMC Health Services Research

Al-Khadra, S.; Meisinger, C.; Amann, U.; Holle, R.; Kuch, B.; Seidl, H.; Kirchberger, I.
Secondary prevention medication after myocardial infarction: Persistence in elderly people over the course of 1 year.
Drugs Aging 31, 513-525 (2014)
AIMS: Persistent use of guideline-recommended drugs after acute myocardial infarction (AMI) is frequently reported to be inadequate in the elderly and scarce knowledge exists about factors that influence persistence in outpatient care. Our aim was to evaluate drug use and its predictors in survivors of AMI above 64 years from hospital discharge to 1-year post-AMI. METHODS: In a single-centre randomised controlled trial, discharge medication of 259 patients with AMI was obtained from medical records at hospital stay. Follow-up drug use and use of the healthcare system were self-reported to study nurses over 1 year in 3-month intervals. Predictors for persistence were modelled with multivariate logistic regression analysis considering demographics, co-morbidities and treatment characteristics. RESULTS: At discharge, 99.2 % of the patients used anti-platelets, 86.5 % beta blockers, 95.0 % statins and 90.4 % angiotensin-converting enzyme inhibitors or angiotensin receptor blockers. Use of the combination of all four drug classes decreased from discharge to 1 year post-AMI from 74.1 to 37.8 % and was significantly reduced by age ≥75 years (odds ratio [OR] 0.49; 95 % confidence interval [CI] 0.29-0.85) and ten or more visits with general practitioners (GPs) over 1 year (OR 0.29; 95 % CI 0.17-0.51). Persistence from month 3 to 12 was significantly associated with drug use at discharge for the single drug classes, but not for the drug combination. CONCLUSION: Older age and frequent GP visits are associated with decreased use of the guideline-recommended drug combination after AMI. Further research is needed to specify underlying reasons and develop measures to improve persistence.
Drugs & Aging

Rottenkolber, M.; Rottenkolber, D.; Fischer, R.; Ibáñez, L.; Fortuny, J.; Ballarin, E.; Sabaté, M.; Ferrer, P.; Thürmann, P.; Hasford, J.; Schmiedl, S.
Inhaled beta-2-agonists/muscarinic antagonists and acute myocardial infarction in COPD patients.
Respir. Med. 108, 1075-1090 (2014)
OBJECTIVE: Empirical results indicate an increased risk for cardiovascular (CV) adverse drug events (ADE) in chronic obstructive pulmonary disease (COPD) patients treated with beta-2-agonists (B2A) and muscarinic antagonists (MA). A systematic review (including a meta-analysis for drug classes with sufficient sample size) was conducted assessing the association between B2A or MA and acute myocardial infarctions (MI) in COPD patients. METHODS: Comprehensive literature search in electronic databases (MEDLINE, Cochrane database) was performed (January 1, 1946-April 1, 2013). Results were presented by narrative synthesis including a comprehensive quality assessment. In the meta-analysis, a random effects model was used for estimating relative risk estimates for acute MI. RESULTS: Eight studies (two systematic reviews, two randomized controlled trials, and four observational studies) were comprised. Most studies comparing tiotropium vs. placebo showed a decreased MI risk for tiotropium, whereas for studies with active control arms no clear tendency was revealed. For short-acting B2A, an increased MI risk was shown after first treatment initiation. For all studies, a good quality was found despite some shortcomings in ADE-specific criteria. A meta-analysis could be conducted for tiotropium vs. placebo only, showing a relative risk reduction of MI (0.74 [0.61-0.90]) with no evidence of statistical heterogeneity among the included trials (I(2) = 0%; p = 0.8090). CONCLUSIONS: An MI-protective effect of tiotropium compared to placebo was found, which might be attributable to an effective COPD treatment leading to a decrease in COPD-related cardiovascular events. Further studies with effective control arms and minimal CV risk are required determining precisely tiotropium's cardiovascular risk.
Respiratory Medicine

Tamayo, T.; Claessen, H.; Rückert, I.-M.; Maier, W.; Schunk, M.; Meisinger, C.; Mielck, A.; Holle, R.; Thorand, B.; Narres, M.; Moebus, S.; Mahabadi, A.A.; Pundt, N.; Krone, B.; Slomiany, U.; Erbel, R.; Jöckel, K.-H.; Rathmann, W.; Icks, A.
Treatment pattern of type 2 diabetes differs in two German regions and with patients' socioeconomic position.
PLoS ONE 9:e99773 (2014)
BACKGROUND: Diabetes treatment may differ by region and patients' socioeconomic position. This may be particularly true for newer drugs. However, data are highly limited. METHODS: We examined pooled individual data of two population-based German studies, KORA F4 (Cooperative Health Research in the Region of Augsburg, south), and the HNR (Heinz Nixdorf Recall study, west) both carried out 2006 to 2008. To ascertain the association between region and educational level with anti-hyperglycemic medication we fitted poisson regression models with robust error variance for any and newer anti-hyperglycemic medication, adjusting for age, sex, diabetes duration, BMI, cardiovascular disease, lifestyle, and insurance status. RESULTS: The examined sample comprised 662 participants with self-reported type 2 diabetes (KORA F4: 83 women, 111 men; HNR: 183 women, 285 men). The probability to receive any anti-hyperglycemic drug as well as to be treated with newer anti-hyperglycemic drugs such as insulin analogues, thiazolidinediones, or glinides was significantly increased in southern compared to western Germany (prevalence ratio (PR); 95% CI: 1.12; 1.02-1.22, 1.52;1.10-2.11 respectively). Individuals

with lower educational level tended to receive anti-hyperglycemic drugs more likely than their better educated counterparts (PR; 95% CI univariable: 1.10; 0.99-1.22; fully adjusted: 1.10; 0.98-1.23). In contrast, lower education was associated with a lower estimated probability to receive newer drugs among those with any anti-hyperglycemic drugs (PR low vs. high education: 0.66; 0.48-0.91; fully adjusted: 0.68; 0.47-0.996). CONCLUSIONS: We found regional and individual social disparities in overall and newer anti-hyperglycemic medication which were not explained by other confounders. Further research is needed.
PLoS ONE

Laxy, M.; Holle, R.
Selbstmanagement der Patienten: Intensive Einbindung lohnt.
Dtsch. Ärztebl. 111, 20-22 (2014)
Daten einer deutschen bevölkerungsbasierten Langzeitstudie zeigen, dass Diabetespatienten mit gutem Selbstmanagement ein verringertes Sterblichkeitsrisiko aufweisen. Die Ergebnisse unterstreichen den Effekt des Patientenverhaltens auf den Krankheitsverlauf.
Deutsches Ärzteblatt

Eickholz, P.; Röllke, L.; Schacher, B.; Wohlfeil, M.; Dannewitz, B.; Kaltschmitt, J.; Krieger, J.K.; Krigar, D.M.; Reitmeir, P.; Kim, T.
Enamel matrix derivative in propylene glycol alginate for treatment of infrabony defects with or without systemic doxycycline: 12- and 24-month results.
J. Periodontol. 85, 669-675 (2014)
Background: This aim of this study is to compare regenerative therapy of infrabony defects with and without administration of post-surgical systemic doxycycline (DOXY) 12 and 24 months after therapy. Methods: In each of 57 patients, one infrabony defect (depth >= 4 mm) was treated regeneratively using enamel matrix derivative at two centers (Frankfurt am Main and Heidelberg). By random assignment, patients received either 200 mg DOXY per day or placebo (PLAC) for 7 days after surgery. Twelve and 24 months after surgery, clinical parameters (probing depths [PDs] and vertical clinical attachment level [CAL-V]) and standardized radiographs were obtained. Missing data were managed according to the last observation carried forward. Results: Data of 57 patients (DOXY: 28; PLAC: 29) were analyzed (26 males and 31 females; mean age: 52 +/- 10.2 years; 13 smokers). In both groups, significant (P < 0.01) PD reduction (DOXY: 3.7 +/- 2.2 mm; PLAC: 3.4 +/- 1.7 mm), CAL-V gain (DOXY: 2.7 +/- 1.9 mm; PLAC: 3.0 +/- 1.9 mm), and bone fill (DOXY: 1.6 +/- 2.7 mm; PLAC: 1.8 +/- 3.0 mm) were observed 24 months after surgery. However, the differences between both groups failed to be statistically significant (PD: P = 0.574; CAL-V: P = 0.696; bone fill: P = 0.318). Conclusions: Systemic DOXY, 200 mg/day for 7 days, after regenerative therapy of infrabony defects did not result in better PD reduction, CAL-V gain, or radiographic bone fill compared with PLAC 12 and 24 months after surgery, which may be attributable to low power and, thus, random chance.
Journal of Periodontology

Voigtländer, S.; Vogt, V.; Mielck, A.; Razum, O.
Explanatory models concerning the effects of small-area characteristics on individual health.
Int. J. Public Health 59, 427-438 (2014)
OBJECTIVES: Material and social living conditions at the small-area level are assumed to have an effect on individual health. We review existing explanatory models concerning the effects of small-area characteristics on health and describe the gaps future research should try to fill. METHODS: Systematic literature search for, and analysis of, studies that propose an explanatory model of the relationship between small-area characteristics and health. RESULTS: Fourteen studies met our inclusion criteria. Using various theoretical approaches, almost all of the models are based on a three-tier structure linking social inequalities (posited at the macro-level), small-area characteristics (posited at the meso-level) and individual health (micro-level). No study explicitly defines the geographical borders of the small-area context. The health impact of the small-area characteristics is explained by specific pathways involving mediating factors (psychological, behavioural, biological). These pathways tend to be seen as uni-directional; often, causality is implied. They may be modified by individual factors. CONCLUSIONS: A number of issues need more attention in research on explanatory models concerning small-area effects on health. Among them are the (geographical) definition of the small-area context; the systematic description of pathways comprising small-area contextual as well as compositional factors; questions of direction of association and causality; and the integration of a time dimension.
International Journal of Public Health

Rüger, A.; Maier, W.; Voigtländer, S.; Mielck, A.
Regionale Unterschiede in der Ärztedichte : Analyse zur ambulanten Versorgung in Bayern.
GGW 14, 7-17 (2014)
Gesundheit und Gesellschaft - Wissenschaft

Hess, W.; Schwarzkopf, L.; Hunger, M.; Holle, R.
Competing-risks duration models with correlated random effects: An application to dementia patients' transition histories.
Stat. Med. 33, 3919-3931 (2014)
Multi-state transition models are widely applied tools to analyze individual event histories in the medical or social sciences. In this paper, we propose the use of (discrete-time) competing-risks duration models to analyze multi-transition data. Unlike conventional Markov transition models, these models allow the estimated transition probabilities to depend on the time spent in the current state. Moreover, the models can be readily extended to allow for correlated transition probabilities. A further virtue of these models is that they can be estimated using conventional regression tools for discrete-response data, such as the multinomial logit model. The latter is implemented in many statistical software packages and can be readily applied by empirical researchers. Moreover, model estimation is feasible, even when dealing with very large data sets, and simultaneously allowing for a flexible form of duration dependence and correlation between transition probabilities. We derive the likelihood function for a model with three competing target states and discuss a feasible and readily applicable estimation method. We also present the results from a simulation study, which indicate adequate performance of the proposed approach. In an empirical application, we analyze dementia patients' transition probabilities from the domestic setting, taking into account several, partly duration-dependent covariates.
Statistics in Medicine

Mielck, A.; Vogelmann, M.; Leidl, R.
Health-related quality of life and socioeconomic status: Inequalities among adults with a chronic disease.
Health Qual. Life Outcomes 12:58 (2014)
Background: A number of studies have shown an association between health-related quality of life (HRQL) and socioeconomic status (SES). Indicators of SES usually serve as potential confounders; associations between SES and HRQL are rarely discussed in their own right. Also, few studies assess the association between HRQL and SES among those with a chronic disease. The study focuses on the question of whether people with the same state of health judge their HRQL differently according to their SES, and whether a bias could be introduced by ignoring these differences.Methods: The analyses were based on a representative sample of the adult population in Germany (n = 11,177). HRQL was assessed by the EQ-5D-3 L, i.e. the five domains (e.g. 'moderate or severe problems' concerning mobility) and the Visual Analog Scale (VAS). SES was primarily assessed by educational level; age, sex and family status were included as potential confounders. Six chronic diseases were selected, each having a prevalence of at least 1% (e.g. diabetes mellitus). Multivariate analyses were conducted by logistic and linear regression.Results: Among adults with a chronic disease, most 'moderate or severe problems' are reported more often in the low (compared with the high) educational group. The same social differences are seen for VAS values, also in subgroups characterized by 'moderate or severe problems'. Gender-specific analyses show that for women the associations with VAS values can just be seen in the total sample. For men, however, they are also present in subgroups defined by 'moderate or severe problems' or by the presence of a chronic disease; some of these differences exceed 10 points on the VAS scale.Conclusions: Low SES groups seem to be faced with a double burden: first, increased levels of health impairments and, second, lower levels of valuated HRQL once health is impaired. These associations should be analysed and discussed in their own right, based on interdisciplinary co-operation. Social epidemiologists could include measures of HRQL in their studies more often, for example, and health economists could consider assessing whether recommendations based on HRQL scales might include a social bias.
Health and Quality of Life Outcomes

Fischer, K.E.; Rogowski, W.H.
Funding decisions for newborn screening: A comparative review of 22 decision processes in Europe.
Int. J. Environ. Res. Public Health 11, 5403-5430 (2014)
Decision-makers need to make choices to improve public health. Population-based newborn screening (NBS) is considered as one strategy to prevent adverse health outcomes and address rare disease patients' needs. The aim of this study was to describe key characteristics of decisions for funding new NBS programmes in Europe. We analysed past decisions using a conceptual framework. It incorporates indicators that capture the steps of decision processes by health care payers. Based on an internet survey, we compared 22 decisions for which answers among two respondents were validated for each observation. The frequencies of indicators were calculated to elicit key characteristics. All decisions resulted in positive, mostly unrestricted funding. Stakeholder participation was diverse focusing on information provision or voting. Often, decisions were not fully transparent. Assessment of NBS technologies concentrated on expert opinion, literature review and rough cost estimates. Most important appraisal criteria were effectiveness (i.e., health gain from testing for the children being screened), disease severity and availability of treatments. Some common and diverging key characteristics were identified. Although no evidence of explicit healthcare rationing was found, processes may be improved in respect of transparency and scientific rigour of assessment.
International Journal of Environmental Research and Public Health

Little, M.H.R.; Reitmeir, P.; Peters, A.; Leidl, R.
The impact of differences between patient and general population EQ-5D-3L values on the mean tariff scores of different patient groups.
Value Health 17, 364-371 (2014)
Background: Health states can be valued by those who currently experience a health state (experienced health states [EHS]) or by the general public, who value a set of given health states (GHS) described to them. There has been debate over which method is more appropriate when making resource allocation decisions. Objective: This article informs this debate by assessing whether differences between these methods have an effect on the mean EQ-5D-3L tariff scores of different patient groups. Methods: The European tariff based on GHS valuations was compared with a German EHS tariff. Comparison was made in the context of EQ-5D-3L health states describing a number of diagnosed chronic diseases (stroke, diabetes, myocardial infarction, and cancer) taken from the Cooperative Health Research in the Augsburg Region population surveys. Comparison was made of both the difference in weighting of the dimensions of the EQ-5D-3L and differences in mean tariff scores for patient groups. Results: Weighting of the dimensions of the EQ-5D-3L were found to be systematically different. The EHS tariff gave significantly lower mean scores for most, but not all, patient groups despite tariff scores being lower for 213 of 243 EQ-5D-3L health states using the GHS tariff. Differences were found to vary between groups, with the largest change in difference being 5.45 in the multiple stoke group. Conclusions: The two tariffs have systematic differences that in certain patient groups could drive the results of an economic evaluation. Therefore, the choice as to which is used may be critical when making resource allocation decisions.
Value in Health

de Jong, T.M.; Jochens, A.; Jockel-Schneider, Y.; Harks, I.; Dommisch, H.; Graetz, C.; Flachsbart, F.; Staufenbiel, I.; Eberhard, J.; Folwaczny, M.; Noack, B.; Meyle, J.; Eickholz, P.; Gieger, C.; Grallert, H.; Lieb, W.; Franke, A.; Nebel, A.; Schreiber, S.; Doerfer, C.; Jepsen, S.; Bruckmann, C.; van der Velden, U.; Loos, B.G.; Schäfer, A.S.; KORA Study Group (Holle, R.; Illig, T.; John, J.; Meisinger, C.; Peters, A.; Wichmann, H.-E.)
SLC23A1 polymorphism rs6596473 in the vitamin C transporter SVCT1 is associated with aggressive periodontitis.
J. Clin. Periodontol. 41, 531-540 (2014)
AIM: Identification of variants within genes SLC23A1 and SLC23A2 coding for vitamin C transporter proteins associated with aggressive (AgP) and chronic periodontitis (CP). MATERIALS AND METHODS: Employment of three independent case-control samples of AgP (I. 283 cases, 979 controls; II. 417 cases, 1,912 controls; III. 164 cases, 357

controls) and one sample of CP (1,359 cases, 1,296 controls). RESULTS: Stage 1: Among the tested SNPs, the rare allele (RA) of rs6596473 in SLC23A1 showed nominal significant association with AgP (p = 0.026, odds ratio [OR] 1.26, and a highly similar minor allele frequency between different control panels. Stage 2: rs6596473 showed no significant association with AgP in the replication with the German and Dutch case-control samples. After pooling the German AgP populations (674 cases, 2,891 controls) to significantly increase the statistical power (SP = 0.81), rs6596473 RA showed significant association with AgP prior to and upon adjustment with the covariates smoking and gender with padj = 0.005, OR = 1.35. Stage 3: RA of rs6596473 showed no significant association with severe CP. CONCLUSION: SNP rs6596473 of SLC23A1 is suggested to be associated with AgP. These results add to previous reports that vitamin C plays a role in the pathogenesis of periodontitis.
Journal of Clinical Periodontology

Mielck, A.
Kunsttherapie als Ansatzpunkt zur Verringerung der gesundheitlichen Ungleichheit: Vorschläge aus Sicht eines Sozial-Epidemiologen.
In: Junker, J.*; Elbing, U.*; Bader, R.* [Eds.]: Zeitsprünge - Vergangenheit, Gegenwart und Zukunft der Kunsttherapie. Nürtingen: Hochschule für Kunsttherapie Nürtingen, Eigenverlag, 2014. 14-23
Koerber, F.; Waidelich, R.; Stollenwerk, B.; Rogowski, W.H.
The cost-utility of open prostatectomy compared with active surveillance in early localised prostate cancer.
BMC Health Serv. Res. 14:163 (2014)
BACKGROUND: There is an on-going debate about whether to perform surgery on early stage localised prostate cancer and risk the common long term side effects such as urinary incontinence and erectile dysfunction. Alternatively these patients could be closely monitored and treated only in case of disease progression (active surveillance). The aim of this paper is to develop a decision-analytic model comparing the cost-utility of active surveillance (AS) and radical prostatectomy (PE) for a cohort of 65 year old men with newly diagnosed low risk prostate cancer. METHODS: A Markov model comparing PE and AS over a lifetime horizon was programmed in TreeAge from a societal perspective. Comparative disease specific mortality was obtained from the Scandinavian Prostate Cancer Group trial. Direct costs were identified via national treatment guidelines and expert interviews covering in-patient, out-patient, medication, aids and remedies as well as out of pocket payments. Utility values were used as factor weights for age specific quality of life values of the German population. Uncertainty was assessed deterministically and probabilistically. RESULTS: With quality adjustment, AS was the dominant strategy compared with initial treatment. In the base case, it was associated with an additional 0.04 quality adjusted life years (7.60 QALYs vs. 7.56 QALYs) and a cost reduction of [euro sign]6,883 per patient (2011 prices). Considering only life-years gained, PE was more effective with an incremental cost-effectiveness ratio of [euro sign]96,420/life year gained. Sensitivity analysis showed that the probability of developing metastases under AS, utility weights under AS are a major sources of uncertainty. A Monte Carlo simulation revealed that AS was more likely to be cost-effective even under very high willingness to pay thresholds. CONCLUSION: AS is likely to be a cost-saving treatment strategy for some patients with early stage localised prostate cancer. However, cost-effectiveness is dependent on patients' valuation of health states. Better predictability of tumour progression and modified reimbursement practice would support widespread use of AS in the context of the German health care system. More research is necessary in order to reliably quantify the health benefits compared with initial treatment and account for patient preferences.
BMC Health Services Research

Hunger, M.; Holle, R.; Meisinger, C.; Rathmann, W.; Peters, A.; Schunk, M.
Longitudinal changes in health-related quality of life in normal glucose tolerance, prediabetes and type 2 diabetes: Results from the KORA S4/F4 cohort study.
Qual. Life Res. 23, 2515-2520 (2014)
PURPOSE: The aim of this study was to examine how transition between normal glucose tolerance, prediabetes and diabetes over a 7 year period is associated with change in health-related quality of life (HRQL) in an elder German population-based cohort. METHODS: We used data from 1,046 participants of the KORA S4/F4 cohort study aged 55-74 years at baseline. Based on an oral glucose tolerance test, prediabetes was defined as impaired fasting glucose and/or impaired glucose tolerance. HRQL was assessed with the SF-12 questionnaire. Using linear regression, we estimated mean change in HRQL over time, depending on glucose status at baseline and follow-up, adjusted by demographic and lifestyle variables. RESULTS: Individuals progressing to prediabetes or diabetes experienced a greater loss in the physical component score than patients with persistent normal glucose tolerance (-2.31 and -7.44 vs. -1.08), but the difference was only significant for subjects converting to diabetes. Subjects with prediabetes at baseline and diabetes at follow-up had a significant loss in mental health compared to subjects with persistent prediabetes. CONCLUSIONS: There is first evidence that worsening of glucose metabolism over time is associated with deteriorating HRQL, however, further and larger longitudinal studies are needed to confirm these findings.
Quality of Life Research

Jansen, L.; Eberle, A.; Emrich, K.; Gondos, A.; Holleczek, B.; Kajueter, H.; Maier, W.; Nennecke, A.; Pritzkuleit, R.; Brenner, H.
Socio-economic deprivation and cancer survival in Germany.
Oncol. Res. Treat. 37, 34 (2014)
Oncology Research and Treatment
Meeting abstract

Laxy, M.; Mielck, A.; Hunger, M.; Schunk, M.; Meisinger, C.; Rückert, I.-M.; Rathmann, W.; Holle, R.
The association between patient-reported self-management behavior, intermediate clinical outcomes, and mortality in patients with type 2 diabetes: Results from the KORA-A study.
Diabetes Care 37, 1604-1612 (2014)
OBJECTIVELittle is known about the impact of diabetes self-management behavior (SMB) on long-term outcomes. We aimed to examine the association among patient-reported SMB, intermediate clinical outcomes, and mortality in patients with type 2 diabetes.RESEARCH DESIGN AND METHODSData were collected from 340 patients with type 2 diabetes of the KORA-A study (1997/1998) who were recruited from two previous population-based surveys (n = 161) and a myocardial infarction registry (n = 179) in southern Germany. Based on previous methodological work, a high level of SMB was defined as being

compliant with at least four of six different self-care dimensions, comprising physical exercise, foot care, blood glucose self-monitoring, weight monitoring, having a diet plan, and keeping a diabetes diary. The vital status of the participants was observed until 2009. Multivariable linear, logistic, and Cox regression models were applied to assess the association with intermediate clinical outcomes at baseline and to predict mortality over the follow-up period, adjusted for sociodemographic, behavioral, and disease-related factors.RESULTSIn the cross-sectional perspective, a high level of SMB was weakly associated with a lower glycated hemoglobin A1c level (-0.44% [-4.8 mmol/mol] [95% CI -0.88-0.00]), but not with low-density lipoprotein cholesterol, systolic blood pressure, or the presence of microalbuminuria, peripheral arterial disease, or polyneuropathy. During a mean follow-up time of 11.6 years, 189 patients died. SMB was a preventive factor for all-cause (hazard ratio 0.61 [95% CI 0.40-0.91]) and cardiovascular mortality (0.65 [95% CI 0.41-1.03]).CONCLUSIONSAlthough measuring SMB is difficult and the used operationalization might be limited, our results give some indication that a high level of SMB is associated with prolonged life expectancy in patients with type 2 diabetes and highlight the potential impact of the patients' active contribution on the long-term trajectory of the disease. We assume that the used proxy for SMB is associated with unmeasured, but important, dimensions of health behavior.
Diabetes Care

Maron, J.; Hunger, M.; Kirchberger, I.; Peters, A.; Mielck, A.; KORA Study Group (Heinrich, J.; Holle, R.; Leidl, R.; Meisinger, C.; Strauch, K.)
Nimmt die gesundheitliche Ungleichheit zu?
Bundesgesundheitsbl.-Gesund. 57, 431-444 (2014)
The analyses focused on time trends in health inequalities in the 25 to 64-year-old population of Augsburg. The analyses are based on four independent cross-sectional surveys from the MONICA/KORA study covering 15 years: 1984/1985 (n = 4,022), 1989/1990 (n = 3,966), 1994/1995 (n = 3,916) and 1999/2000 (n = 3,492). Socioeconomic status (SES) was assessed by educational level and per capita household income with separate analyses for each of these two variables. Both absolute and relative health inequalities were calculated. The results showed that inequalities in self-rated health did not change very much (with some indications for increasing inequalities). However, concerning smoking the results clearly pointed towards increasing health inequalities (for example concerning relative inequalities among women by educational level: significant increase from survey to survey of about 20 %). The prevalence of obesity was increased in all SES groups but the inequalities did not change very much. These time trends show that the efforts aimed at reducing health inequalities should be intensified.
Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz

Quinones, P.A.; Seidl, H.; Holle, R.; Kuch, B.; Meisinger, C.; Hunger, M.; Kirchberger, I.
New potential determinants of disability in aged persons with myocardial infarction: Results from the KORINNA-study.
BMC Geriatr. 14:34 (2014)
BACKGROUND: Elderly individuals with coronary heart disease are a population particularly burdened by disability. However, to date many predictors of disability established in general populations have not been considered in studies examining disability in elderly acute myocardial infarction (AMI) survivors. Our study explores factors associated with the ability to perform basic activities of daily living in elderly patients with AMI. METHODS: Baseline data from 333 AMI-survivors older than 64 years included within the randomized controlled KORINNA-study were utilized to examine disability assessed by the Stanford Health Assessment Questionare Disability Index (HAQ-DI). Numerous potential determinants including demographic characteristics, clinical parameters, co-morbidities, interventions, lifestyle, behavioral and personal factors were measured.Disability was defined as a HAQ-DI ≥ 0.5. After bi-variate testing the probability of disability was modeled with logistic regression. Missing covariate values were imputed using a Markov Chain Monte Carlo method. RESULTS: Disability was significantly more frequent in older individuals (Odds Ratio (OR): 1.10, 95% Confidence Interval (CI): 1.05-1.16), patients with deficient nutrition (OR: 3.38, 95% CI: 1.60-7.15), coronary artery bypass graft (CABG) (OR: 3.26, 95% CI: 1.29-8.25), hearing loss in both ears (OR: 2.85, 95% CI: 1.41-5.74), diabetes mellitus (OR: 2.56, 95% CI: 1.39-4.72), and heart failure (OR: 3.32, 95% CI: 1.79-6.16). It was reduced in patients with percutaneous transluminal coronary angioplasty (PTCA) (OR: 0.41, 95% CI: 0.21-0.80) and male sex (OR: 0.48, 95% CI: 0.27-0.85). CONCLUSIONS: Effects of nutrition, hearing loss, and diametrical effects of PTCA and CABG on disability were identified as relevant for examination of causality in longitudinal trials. TRIAL REGISTRATION: ISRCTN02893746.
BMC Geriatrics

Stollenwerk, B.; Lhachimi, S.K.; Briggs, A.; Fenwick, E.; Caro, J.J.; Siebert, U.; Danner, M.; Gerber-Grote, A.
Communicating the parameter uncertainty in the IQWIG efficiency frontier to decision-makers.
Health Econ. 24, 481-490 (2014)
The Institute for Quality and Efficiency in Health Care (IQWiG) developed-in a consultation process with an international expert panel-the efficiency frontier (EF) approach to satisfy a range of legal requirements for economic evaluation in Germany's statutory health insurance system. The EF approach is distinctly different from other health economic approaches. Here, we evaluate established tools for assessing and communicating parameter uncertainty in terms of their applicability to the EF approach. Among these are tools that perform the following: (i) graphically display overall uncertainty within the IQWiG EF (scatter plots, confidence bands, and contour plots) and (ii) communicate the uncertainty around the reimbursable price. We found that, within the EF approach, most established plots were not always easy to interpret. Hence, we propose the use of price reimbursement acceptability curves-a modification of the well-known cost-effectiveness acceptability curves. Furthermore, it emerges that the net monetary benefit allows an intuitive interpretation of parameter uncertainty within the EF approach. This research closes a gap for handling uncertainty in the economic evaluation approach of the IQWiG methods when using the EF. However, the precise consequences of uncertainty when determining prices are yet to be defined.
Health Economics

Kirchberger, I.; Meisinger, C.; Golüke, H.; Heier, M.; Kuch, B.; Peters, A.; Quinones, P.A.; von Scheidt, W.; Mielck, A.

Long-term survival among older patients with myocardial infarction differs by educational level: Results from the MONICA/KORA myocardial infarction registry.
Int. J. Equity Health 13:19 (2014)
BACKGROUND: Socioeconomic disparities in survival after acute myocardial infarction (AMI) have been found in many countries. However, population-based results from Germany are lacking so far. Thus, the objective of this study was to examine the association between educational status and long-term mortality in a population-based sample of people with AMI. METHODS: The sample consisted of 2,575 men and 844 women, aged 28-74 years, hospitalized with a first-time AMI between 1 January 2000 and 31 December 2008, recruited from a population-based AMI registry. Patients were followed up until December 2011. Data on education, risk factors and co-morbidities were collected by individual interviews; data on clinical characteristics and AMI treatment by chart review. Cox proportional hazards models were used to assess the relationship between educational status and long-term mortality. RESULTS: During follow-up, 19.1% of the patients with poor education died compared with 13.1% with higher education. After adjustment for covariates, no effect of education on mortality was found for the total sample and for patients aged below 65 years. In older people, however, low education level was significantly associated with increased mortality (hazard ratio (HR) 1.44, 95% confidence interval (CI) 1.05-1.98, p = 0.023). Stratified analyses showed that women older than 64 years with poor education were significantly more likely to die than women in the same age group with higher education (HR 1.57, 95% CI 1.02-2.41, p = 0.039). CONCLUSIONS: Elderly, poorly educated patients with AMI, and particularly women, have poorer long-term survival than their better educated peers. Further research is required to illuminate the reasons for this finding.
International Journal for Equity in Health

Bauer, K.; Schwarzkopf, L.; Graessel, E.; Holle, R.
A claims data-based comparison of comorbidity in individuals with and without dementia.
BMC Geriatr. 14:10 (2014)
BACKGROUND: Multimorbidity is common in advanced age, and is usually associated with negative - yet to some extent preventable - health outcomes. Detecting comorbid conditions is especially difficult in individuals with dementia, as they might not always be able to sufficiently express discomfort. This study compares relevant comorbidity complexes in elderly people with and without dementia, with a particular look at gender- and living environment-specific differences. Moreover, associations between selected comorbid conditions and dementia are reviewed more closely. METHODS: Using 2006 claims data from a large German Statutory Health Insurance fund, 9,139 individuals with dementia and 28,614 age- and gender-matched control subjects aged 65 years and older were identified. A total of 30 comorbidity complexes were defined based on ICD-10 codes. Corresponding prevalence rates were calculated, and the association between a distinct condition and dementia was evaluated via logistic regression in the overall sample as well as in analyses stratified by gender and living environment. RESULTS: Individuals with dementia were more likely to be diagnosed with 15 comorbidity complexes, including Parkinson's, stroke, diabetes, atherosclerosis (supposed dementia risk factors) or fluids and electrolyte disorders, insomnia, incontinence, pneumonia, fractures and injuries (supposed sequelae). In contrast, they were less likely to be diagnosed with 11 other conditions, which included vision and hearing problems, diseases of the musculoskeletal system, lipoprotein disorders and hypertension. In a gender-stratified analysis, the patterns remained largely the same, but a bigger comorbidity gap between cases and control subjects emerged in the male population. Restricting the analysis to community-living individuals did not lead to any substantial changes. CONCLUSION: Besides strengthening the evidence on accepted dementia risk factors and sequelae, the analyses point to particular conditions that are likely to remain untreated or even undiagnosed. This issue seems to affect male and female individuals with dementia to varying degrees. Raising awareness of these conditions is important to possibly preventing comorbidity-associated complications and disease progression in dementia patients. To more comprehensively understand the mutual interactions between dementia and comorbidity, further research on diagnostic and treatment attitudes regarding comorbidity in dementia patients and on their gender-specific health-seeking behaviour seems to be required.
BMC Geriatrics

Quinones, P.A.; Kirchberger, I.; Heier, M.; Kuch, B.; Trentinaglia, I.; Mielck, A.; Peters, A.; von Scheidt, W.; Meisinger, C.
Marital status shows a strong protective effect on long-term mortality among first acute myocardial infarction-survivors with diagnosed hyperlipidemia - findings from the MONICA/KORA Myocardial Infarction Registry.
BMC Public Health 14:98 (2014)
BACKGROUND: Reduction of long term mortality by marital status is well established in general populations. However, effects have been shown to change over time and differ considerably by cause of death. This study examined the effects of marital status on long term mortality after the first acute myocardial infarction. METHODS: Data were retrieved from the population-based MONICA (Monitoring trends and determinants on cardiovascular diseases)/KORA (Cooperative Health Research in the Region of Augsburg)-myocardial infarction registry which assesses cases from the city of Augsburg and 2 adjacent districts located in southern Bavaria, Germany. A total of 3,766 men and women aged 28 to 74 years who were alive 28 days after their first myocardial infarction were included. Hazard ratios (HR) for the effects of marital status on mortality after one to 10 years of follow-up are presented. RESULTS: The study population included 2,854 (75.8%) married individuals. During a median follow-up of 5.3 years, with an inter-quartile range of 3.3 to 7.6 years, 533 (14.15%) deaths occurred. Among married and unmarried individuals 388 (13.6%) and 145 (15.9%) deaths occurred, respectively. Overall marital status showed an insignificant protective HR of 0.76 (95% confidence interval (CI) 0.47-1.22). Stratified analyses revealed strong protective effects only among men and women younger than 60 who were diagnosed with hyperlipidemia. HRs ranged from 0.27 (95% CI 0.13-0.59) for a two-year survival to 0.43 (95% CI 0.27-0.68) for a 10-year survival. Substitution of marital status with co-habitation status confirmed the strata-specific effect [HR: 0.52 (95% CI 0.31-0.86)]. CONCLUSIONS: Marital status has a strong protective effect among first myocardial infarction survivors with diagnosed hyperlipidemia, which diminishes with increasing age. Treatments, recommended lifestyle changes or other attributes specific to hyperlipidema may be underlying

factors, mediated by the social support of spouses. Underlying causes should be examined in further studies.
BMC Public Health

Hatz, M.H.M.°; Schremser, K.; Rogowski, W.H.°
Is individualized medicine more cost-effective? A systematic review.
Pharmacoeconomics 32, 443-455 (2014)
Background: Individualized medicine (IM) is a rapidly evolving field that is associated with both visions of more effective care at lower costs and fears of highly priced, low-value interventions. It is unclear which view is supported by the current evidence. Objective: Our objective was to systematically review the health economic evidence related to IM and to derive general statements on its cost-effectiveness. Data sources: A literature search of MEDLINE database for English- and German-language studies was conducted. Study appraisal and synthesis method: Cost-effectiveness and cost-utility studies for technologies meeting the MEDLINE medical subject headings (MeSH) definition of IM (genetically targeted interventions) were reviewed. This was followed by a standardized extraction of general study characteristics and cost-effectiveness results. Results: Most of the 84 studies included in the synthesis were from the USA (n = 43, 51 %), cost-utility studies (n = 66, 79 %), and published since 2005 (n = 60, 71 %). The results ranged from dominant to dominated. The median value (cost-utility studies) was calculated to be rounded $US22,000 per quality-adjusted life year (QALY) gained (adjusted to $US, year 2008 values), which is equal to the rounded median cost-effectiveness in the peer-reviewed English-language literature according to a recent review. Many studies reported more than one strategy of IM with highly varying cost-effectiveness ratios. Generally, results differed according to test type, and tests for disease prognosis or screening appeared to be more favorable than tests to stratify patients by response or by risk of adverse effects. However, these results were not significant. Limitations: Different definitions of IM could have been used. Quality assessment of the studies was restricted to analyzing transparency. Conclusions: IM neither seems to display superior cost-effectiveness than other types of medical interventions nor to be economically inferior. Instead, rather than 'whether' healthcare was individualized, the question of 'how' it was individualized was of economic relevance.
PharmacoEconomics

Maier, W.; Scheidt-Nave, C.; Holle, R.; Kroll, L.E.; Lampert, T.; Du, Y.; Heidemann, C.; Mielck, A.
Area level deprivation is an independent determinant of prevalent type 2 diabetes and obesity at the national level in Germany. Results from the national telephone health interview surveys 'German Health Update' GEDA 2009 and 2010.
PLoS ONE 9:e89661 (2014)
OBJECTIVE: There is increasing evidence that prevention programmes for type 2 diabetes mellitus (T2DM) and obesity need to consider individual and regional risk factors. Our objective is to assess the independent association of area level deprivation with T2DM and obesity controlling for individual risk factors in a large study covering the whole of Germany. METHODS: We combined data from two consecutive waves of the national health interview survey 'GEDA' conducted by the Robert Koch Institute in 2009 and 2010. Data collection was based on computer-assisted telephone interviews. After exclusion of participants <30 years of age and those with missing responses, we included n=33,690 participants in our analyses. The outcome variables were the 12-month prevalence of known T2DM and the prevalence of obesity (BMI ≥30 kg/m(2)). We also controlled for age, sex, BMI, smoking, sport, living with a partner and education. Area level deprivation of the districts was defined by the German Index of Multiple Deprivation. Logistic multilevel regression models were performed using the software SAS 9.2. RESULTS: Of all men and women living in the most deprived areas, 8.6% had T2DM and 16.9% were obese (least deprived areas: 5.8% for T2DM and 13.7% for obesity). For women, higher area level deprivation and lower educational level were both independently associated with higher T2DM and obesity prevalence [highest area level deprivation: OR 1.28 (95% CI: 1.05-1.55) for T2DM and OR 1.28 (95% CI: 1.10-1.49) for obesity]. For men, a similar association was only found for obesity [OR 1.20 (95% CI: 1.02-1.41)], but not for T2DM. CONCLUSION: Area level deprivation is an independent, important determinant of T2DM and obesity prevalence in Germany. Identifying and targeting specific area-based risk factors should be considered an essential public health issue relevant to increasing the effectiveness of diabetes and obesity prevention.
PLoS ONE

Schmiedl, S.; Rottenkolber, M.; Hasford, J.; Rottenkolber, D.; Farker, K.; Drewelow, B.; Hippius, M.; Saljé, K.; Thürmann, P.
Self-medication with over-the-counter and prescribed drugs causing adverse-drug-reaction-related hospital admissions: Results of a prospective, long-term multi-centre study.
Drug Saf. 37, 225-235 (2014)
Background: Self-medication, including both the use of over-the-counter (OTC) drugs and the use of formerly prescribed drugs taken without a current physician's recommendation, is a public health concern; however, little data exist regarding the actual risk. Objective: We aimed to analyse self-medication-related adverse drug reactions (ADRs) leading to hospitalisation. Methods: In a multi-centre, observational study covering a hospital catchment area of approximately 500,000 inhabitants, we analysed self-medication-related ADRs leading to hospital admissions in internal medicine departments. Data of patients with ADRs were comprehensively documented, and ADR causality was assessed using Bégaud's algorithm. The included ADRs occurred between January 2000 and December 2008 and were assessed to be at least 'possibly' drug related. Results: Of 6,887 patients with ADRs, self-medication was involved in 266 (3.9 %) patients. In 143 (53.8 %) of these patients, ADRs were due to OTC drugs. Formerly prescribed drugs and potential OTC drugs accounted for the remaining ADRs. Most self-medication-related ADRs occurred in women aged 70-79 years and in men aged 60-69 years. Self-medication-related ADRs were predominantly gastrointestinal complaints caused by non-steroidal anti-inflammatory drugs (most frequently OTC acetylsalicylic acid [ASA, aspirin]). In 102 (38.3 %) of the patients with self-medication-related ADRs, a relevant drug-drug interaction (DDI), occurring between a self-medication and a prescribed medication, was present (most frequently ASA taken as an OTC drug and prescribed diclofenac). Conclusion: In the general population, self-medication plays a limited role in ADRs leading to hospitalisation. However, prevention strategies focused on elderly patients and patients receiving interacting prescribed drugs would improve patient safety.

Drug Safety

Fischer, K.E.; Leidl, R.
Analysing coverage decision-making: Opening Pandora's box?
Eur. J. Health Econ. 15, 899-906 (2014)
The European journal of health economics
Editorial
Editorial
Vogl, M.
Hospital financing: Calculating inpatient capital costs in Germany with a comparative view on operating costs and the English costing scheme.
Health Policy 115, 141-151 (2014)
Objectives: The paper analyzes the German inpatient capital costing scheme by assessing its cost module calculation. The costing scheme represents the first separated national calculation of performance-oriented capital cost lump sums per DRG. Methods: The three steps in the costing scheme are reviewed and assessed: (1) accrual of capital costs; (2) cost-center and cost category accounting; (3) data processing for capital cost modules. The assessment of each step is based on its level of transparency and efficiency. A comparative view on operating costing and the English costing scheme is given. Results: Advantages of the scheme are low participation hurdles, low calculation effort for G-DRG calculation participants, highly differentiated cost-center/cost category separation, and advanced patient-based resource allocation. The exclusion of relevant capital costs, nontransparent resource allocation, and unclear capital cost modules, limit the managerial relevance and transparency of the capital costing scheme. Conclusions: The scheme generates the technical premises for a change from dual financing by insurances (operating costs) and state (capital costs) to a single financing source. The new capital costing scheme will intensify the discussion on how to solve the current investment backlog in Germany and can assist regulators in other countries with the introduction of accurate capital costing.
Health Policy

Hatz, M.H.M.; Leidl, R.; Yates, N.A.; Stollenwerk, B.
A systematic review of the quality of economic models comparing thrombosis inhibitors in patients with acute coronary syndrome undergoing percutaneous coronary intervention.
Pharmacoeconomics 32, 377-393 (2014)
Background: Thrombosis inhibitors can be used to treat acute coronary syndromes (ACS). However, there are various alternative treatment strategies, of which some have been compared using health economic decision models. Objective: To assess the quality of health economic decision models comparing thrombosis inhibitors in patients with ACS undergoing percutaneous coronary intervention, and to identify areas for quality improvement. Data Sources: The literature databases MEDLINE, EMBASE, EconLit, National Health Service Economic Evaluation Database (NHS EED), Database of Abstracts of Reviews of Effects (DARE) and Health Technology Assessment (HTA). Study Appraisal and Synthesis Methods: A review of the quality of health economic decision models was conducted by two independent reviewers, using the Philips checklist. Results: Twenty-one relevant studies were identified. Differences were apparent regarding the model type (six decision trees, four Markov models, eight combinations, three undefined models), the model structure (types of events, Markov states) and the incorporation of data (efficacy, cost and utility data). Critical issues were the absence of particular events (e.g. thrombocytopenia, stroke) and questionable usage of utility values within some studies. Limitations: As we restricted our search to health economic decision models comparing thrombosis inhibitors, interesting aspects related to the quality of studies of adjacent medical areas that compared stents or procedures could have been missed. Conclusions: This review identified areas where recommendations are indicated regarding the quality of future ACS decision models. For example, all critical events and relevant treatment options should be included. Models also need to allow for changing event probabilities to correctly reflect ACS and to incorporate appropriate, age-specific utility values and decrements when conducting cost-utility analyses.
PharmacoEconomics

Wu, L.; Piotrowski, K.; Rau, T.T.; Waldmann, E.; Broedl, U.C.; Demmelmair, H.; Koletzko, B.; Stark, R.G.; Nagel, J.M.; Mantzoros, C.S.; Parhofer, K.G.
Walnut-enriched diet reduces fasting non-HDL-cholesterol and apolipoprotein B in healthy Caucasian subjects: A randomized controlled cross-over clinical trial.
Metabolism 63, 382-391 (2014)
BACKGROUND: Walnut consumption is associated with reduced risk of coronary heart disease (CHD). OBJECTIVE: We assessed the effect of walnuts on lipid and glucose metabolism, adipokines, inflammation and endothelial function in healthy Caucasian men and postmenopausal women ≥50years old. DESIGN: Forty subjects (mean±SEM: age 60±1years, BMI 24.9±0.6kg/m2; 30 females) were included in a controlled, cross-over study and randomized to receive first a walnut-enriched (43g/d) and then a Western-type (control) diet or vice-versa, with each lasting 8weeks and separated by a 2-week wash-out. At the beginning and end of each diet phase, measurements of fasting values, a mixed meal test and an assessment of postprandial endothelial function (determination of microcirculation by peripheral artery tonometry) were conducted. Area under the curve (AUC), incremental AUC (iAUC) and treatment×time interaction (shape of the curve) were evaluated for postprandial triglycerides, VLDL-triglycerides, chylomicron-triglycerides, glucose and insulin. RESULTS: Compared with the control diet, the walnut diet significantly reduced non-HDL-cholesterol (walnut vs. control: -10±3 vs. -3±2mg/dL; p=0.025) and apolipoprotein-B (-5.0±1.3 vs. -0.2±1.1mg/dL; p=0.009) after adjusting for age, gender, BMI and diet sequence. Total cholesterol showed a trend toward reduction (p=0.073). Fasting VLDL-cholesterol, LDL-cholesterol, HDL-cholesterol, triglycerides and glucose, insulin, HOMA-IR, and HbA1c did not change significantly. Similarly, fasting adipokines, C-reactive protein, biomarkers of endothelial dysfunction, postprandial lipid and glucose metabolism and endothelial function were unaffected. CONCLUSION: Daily consumption of 43g of walnuts for 8weeks significantly reduced non-HDL-cholesterol and apolipoprotein-B, which may explain in part the epidemiological observation that regular walnut consumption decreases CHD risk.
Metabolism: clinical and experimental

Rogowski, W.H.; Grosse, S.D.; Schmidtke, J.; Marckmann, G.
Criteria for fairly allocating scarce health-care resources to genetic tests: Which matter most?
Eur. J. Hum. Genet. 22, 25-31 (2014)

The use of genetic tests is expanding rapidly. Given limited health-care budgets throughout Europe and few national coverage decisions specifically for genetic tests, decisions about allocating scarce resources to genetic tests are frequently ad hoc and left to lower-level decision makers. This study assesses substantive ethical and economic criteria to prioritize genetic services in a reasonable and fair manner. Principles for allocating health-care resources can be classified into four categories: need-based allocation; maximizing total benefits; treating people equally; and promoting and rewarding social usefulness. In the face of scarcity, the degree of an individual's need for medical intervention is an important criterion. Also, different economic concepts of efficiency are of relevance in the theory and practice of prioritizing genetic tests. Equity concerns are most likely to be relevant in terms of avoiding undesirable inequities, which may also set boundaries to the use of efficiency as a prioritization criterion. The aim of promoting and rewarding social usefulness is unlikely to be relevant to the question of what priority a genetic test should have in clinical practice. Further work is needed to select an appropriate set of criteria; operationalize them; and assign weights before some kind of standardized priority information can be added to information sources for genetic services. Besides the substantive criteria, formal considerations like those pointed out in the framework of accountability for reasonableness need to be considered in decision making.
European Journal of Human Genetics

Kohlboeck, G.; Romanos, M.; Teuner, C.M.; Holle, R.; Tiesler, C.M.; Hoffmann, B.; Schaaf, B.; Lehmann, I.; Herbarth, O.; Koletzko, S.; Bauer, C.P.; von Berg, A.; Berdel, D.; Heinrich, J.
Healthcare use and costs associated with children's behavior problems.
Eur. Child Adolesc. Psych. 23, 701-714 (2014)
The objective of the study was to investigate associations between severity of behavior problems, specific symptom domains with healthcare use and costs in school-aged children. A cross-sectional study using data from the 10-year follow-up of two population-based birth cohorts was conducted on four rural and urban communities in Germany. There were 3,579 participants [1,834 boys (51%), 1,745 girls (49%)] on average aged 10.4 years. The severity levels (normal, at risk, abnormal) and symptom domains of behavioral problems were assessed by parent-reported strengths and difficulties questionnaire (SDQ).The outcomes were medical use categories (physicians, therapists, hospital, and rehabilitation), medical costs categories and total direct medical use and costs (calculated from parent-reported utilization of healthcare services during the last 12 months). Total direct medical costs showed a graded relationship with severity level (adjusted $p < 0.0001$). Average annual cost difference in total direct medical costs between at risk and normal total difficulties was Euro () 271 (SD 858), and 1,237 (SD 2,528) between abnormal and normal total difficulties. A significant increase in physician costs showed between children with normal and at risk total difficulties (1.30), and between normal and abnormal total difficulties (1.29; $p < 0.0001$). Between specific symptom domains, children with emotional symptoms showed highest costs for physicians, psychotherapist, and hospitalization as well as total direct medical costs. Children with hyperactivity/inattention showed highest costs for therapists and emergency room costs. Healthcare use and costs are related to the severity of child behavior problems. In general, children's costs for psychotherapy treatments have been low relative to general medical treatments which may indicate that some children with behavioral problems did not get appropriate care. To some degree, medical conditions may be attributable to some of the high hospitalization costs found in children with emotional symptom.
European Child and Adolescent Psychiatry

Jansen, L.; Eberle, A.; Emrich, K.; Gondos, A.; Holleczek, B.; Kajüter, H.; Maier, W.; Nennecke, A.; Pritzkuleit, R.; Brenner, H.
Socioeconomic deprivation and cancer survival in Germany: An ecological analysis in 200 districts in Germany.
Int. J. Cancer 134, 2951-2960 (2014)
Although socioeconomic inequalities in cancer survival have been demonstrated both within and between countries, evidence on the variation of the inequalities over time past diagnosis is sparse. Furthermore, no comprehensive analysis of socioeconomic differences in cancer survival in Germany has been conducted. Therefore, we analyzed variations in cancer survival for patients diagnosed with one of the 25 most common cancer sites in 1997-2006 in ten population-based cancer registries in Germany (covering 32 million inhabitants). Patients were assigned a socioeconomic status according to the district of residence at diagnosis. Period analysis was used to derive 3-month, 5-year and conditional 1-year and 5-year age-standardized relative survival for 2002-2006 for each deprivation quintile in Germany. Relative survival of patients living in the most deprived district was compared to survival of patients living in all other districts by model-based period analysis. For 21 of 25 cancer sites, 5-year relative survival was lower in the most deprived districts than in all other districts combined. The median relative excess risk of death over the 25 cancer sites decreased from 1.24 in the first 3 months to 1.16 in the following 9 months to 1.08 in the following 4 years. Inequalities persisted after adjustment for stage. These major regional socioeconomic inequalities indicate a potential for improving cancer care and survival in Germany. Studies on individual-level patient data with access to treatment information should be conducted to examine the reasons for these socioeconomic inequalities in cancer survival in more detail.
International Journal of Cancer

Rieger, A.; Mansmann, U.; Maier, W.; Seitz, L.; Brandt, T.; Strupp, M.; Bayer, O.
Versorgungssituation von Patienten mit dem Leitsymptom Schwindel.
Gesundheitswesen 76, e32-e38 (2014)
Vertigo and dizziness are common symptoms leading patients to consult a physician. The nationally representative "2003 Health Survey" depicts the epidemiology of the symptoms vertigo and dizziness across all of Germany. A breakdown of the data by region is not available.Routine data of the Bavarian Association of Statutory Health Insurance Physicians accounting centre ("Kassenärztliche Vereinigung Bayerns", KVB) from 2008 were analysed using multilevel models to investigate individual and regional factors and the relevance of nonspecific regional heterogeneity.Altogether, 866 086 of 9 269 729 (9.34%) inhabitants received an ambulatory diagnosis of vertigo or dizziness, including 1.77 times as many women as men. Visits to the doctor because of vertigo or dizziness increased with age. After adjustments for age and sex, a North-South divide and a higher prevalence in the urban centres were apparent within

Bavaria. The majority of patients were seen by their GP and nearby doctors. This held especially true for women. Also older patients were less likely to go to specialists further afield.This analysis of the KVB data of patients with vertigo or dizziness underlines the central role that is played by GPs in diagnosis and treatment. In order to correctly diagnose the underlying causes, treat patients or send them to specialists effectively, all doctors need to be trained about this relevant clinical symptom. The insufficient representation of clinically established vertigo disorders by the ICD-10 was problematic. The most frequently coded diagnosis was N95.1 "postmenopausal dizziness".
Gesundheitswesen, Das

Stark, R.G.; Kirchberger, I.; Hunger, M.; Heier, M.; Leidl, R.; von Scheidt, W.; Meisinger, C.; Holle, R.
Improving care of post-infarct patients: Effects of disease management programmes and care according to international guidelines.
Clin. Res. Cardiol. 103, 237-245 (2014)
BACKGROUND: Cardiac disease management programmes (CHD-DMPs) and secondary cardiovascular prevention guidelines aim to improve complex care of post-myocardial infarction (MI) patients. In Germany, CHD-DMPs, in addition to incorporating medical care according to guidelines (guideline-care), also ensure regular quarterly follow-up. Thus, our aim was to examine whether CHD-DMPs increase the frequency of guideline-care and whether CHD-DMPs and guideline-care improve survival over 4 years. METHODS: The study included 975 post-MI patients, registered by the KORA-MI Registry (Augsburg, Germany), who completed a questionnaire in 2006. CHD-DMP enrolment was reported by physicians. Guideline-care was based on patient reports regarding medical advice (smoking, diet, or exercise) and prescribed medications (statins and platelet aggregation inhibitors plus beta-blockers or renin-angiotensin inhibitors). All-cause mortality until December 31, 2010 was based on municipal registration data. Cox regression analyses were adjusted for age, sex, education, years since last MI, and smoking and diabetes. RESULTS: Physicians reported that 495 patients were CHD-DMP participants. CHD-DMP participation increased the likelihood of receiving guideline-care (odds ratio 1.55, 95 % CI 1.20; 2.02) but did not significantly improve survival (hazard rate 0.90, 95 % CI 0.64-1.27). Guideline-care significantly improved survival (HR 0.41, 95 % CI 0.28; 0.59). Individual guideline-care components, which significantly improved survival, were beta-blockers, statins and platelet aggregation inhibitors. However, these improved survival less than guideline-care. CONCLUSIONS: This study shows that CHD-DMPs increase the likelihood of guideline care and that guideline care is the important component of CHD-DMPs for increasing survival. A relatively high percentage of usual care patients receiving guideline-care indicate high quality of care of post-MI patients. Reasons for not implementing guideline-care should be investigated.
Clinical Research in Cardiology

Batscheider, A.; Rzehak, P.; Teuner, C.M.; Wolfenstetter, S.B.; Leidl, R.; von Berg, A.; Berdel, D.; Hoffmann, B.; Heinrich, J.; GINIplus Study Group (Wichmann, H.-E.; Heinrich, J.); LISAplus Study Group (Wichmann, H.-E.; Heinrich, J.)
Development of BMI values of German children and their healthcare costs.
Econ. Hum. Biol. 12, 56-66 (2014)
The aim of this study is to assess the association between different patterns of Body Mass Index (BMI) development from birth on and later healthcare utilisation and costs in children aged about 10 years based on two birth cohort studies: the GINIplus study (3287 respondents) and the LISAplus study (1762 respondents). Direct costs were estimated using information on healthcare utilisation given by parents in the 10-year follow-up. To meet this aim, we (i) estimate BMI-standard deviation score (BMIZ) trajectories using latent growth mixture models and (ii) examine the correlation between these trajectories and utilisation of healthcare services and resulting costs at the 10-year follow-up. We identified three BMI-trajectories: a normative BMIZ growth class (BMI development almost as in the WHO growth standards), a rapid BMIZ growth up to age 2 years class (with a higher BMI in the first two years of life as proposed by the WHO growth standards) and a persistent rapid BMIZ growth up to age 5 years class (with a higher BMI in the first five years of life as proposed by the WHO growth standards). Annual total direct medical costs of healthcare use are estimated to be on average €368 per child. These costs are doubled, i.e. on average €722 per child, in the group with the most pronounced growth (persistent rapid BMIZ growth up to age 5 years class).
Economics and Human Biology

Laxy, M.; Holle, R.; Döring, A.; Petter, A.; Hunger, M.
The longitudinal association between weight change and health-related quality of life: The KORA S4/F4 cohort study.
Int. J. Public Health 59, 279-288 (2014)
OBJECTIVES: Despite the increasing importance of patient-centered perspectives, the impact of weight change on the health-related quality of life (HRQL) has remained unclear. This work aims to investigate this longitudinal relationship. METHODS: Data was collected from a population-based cohort study of 3,080 Germans. Anthropometrics and HRQL were assessed at baseline and after a 7-year follow-up period. Using linear regression the average change in HRQL scores was calculated among 5 mutually exclusive weight change groups. Multilevel growth modeling was conducted to differentiate between interpersonal (cross-sectional) and intrapersonal (longitudinal) associations between body mass index (BMI)/BMI change and HRQL. RESULTS: Heavy weight gain (≥10 % body weight) was associated with impairments in physical health among women (-2.82 points, CI: -4.29, -1.34) and obese men (-4.33 points, CI: -7.62, -1.04) and with improvements in mental health among women (+3.20 points, CI: +1.37, +5.02). Results from the multilevel models were consistent, showing negative associations between BMI change and physical health, positive associations between BMI change and mental health and a high degree of similarity between interpersonal and intrapersonal associations. CONCLUSIONS: Weight gain leads to clinically relevant impairments in physical health. More research is needed to clarify the antipodal effects of weight change on physical and mental health components.
International Journal of Public Health

Stargardt, T.; Schreyögg, J.; Kondofersky, I.
Measuring the relationship between costs and outcomes: The example of acute myocardial infarction in German hospitals.
Health Econ. 23, 653-669 (2014)
In this paper, we propose a methodological approach to measure the relationship between hospital costs and health outcomes. We propose to investigate the relationship for each condition or

disease area by using patient-level data. We examine health outcomes as a function of costs and other patient-level variables by using the following: (1) two-stage residual inclusion with Murphy-Topel adjustment to address costs being endogenous to health outcomes, (2) random-effects models in both stages to correct for correlation between observation, and (3) Cox proportional hazard models in the second stage to ensure that the available information is exploited. To demonstrate its application, data on mortality following hospital treatment for acute myocardial infarction (AMI) from a large German sickness fund were used. Provider reimbursement was used as a proxy for treatment costs. We relied on the Ontario Acute Myocardial Infarction Mortality Prediction Rules as a disease-specific risk-adjustment instrument. A total of 12,284 patients with treatment for AMI in 2004-2006 were included. The results showed a reduction in hospital costs by €100 to increase the hazard of dying, that is, mortality, by 0.43%. The negative association between costs and mortality confirms that decreased resource input leads to worse outcomes for treatment after AMI.
Health Economics

Rottmann, M.; Mielck, A.
‚Walkability' und körperliche Aktivität - Stand der empirischen Forschung auf Basis der ‚Neighbourhood Environment Walkability Scale (NEWS)'.
Gesundheitswesen 76, 108-115 (2014)
Studienziel: ‚Walkability' (d. h. die ‚Bewegungsfreundlichkeit' des näheren Wohnumfeldes) wird zumeist über den NEWS-Fragebogen erfasst (Neighbourhood Environment Walkability Scale); in Deutschland ist er noch weitgehend unbekannt. Die hier vorgelegte Arbeit will dazu beitragen, diese Lücke zu schließen, durch die Bereitstellung eines systematischen Überblicks über die empirischen Arbeiten zum NEWS. Methodik: Gesucht wurde nach Originalarbeiten mit empirischen Analysen zum NEWS. Inhalt und Ergebnisse dieser Publikationen werden in Form von Tabellen kurz und zusammenfassend vorgestellt. Ergebnisse: Insgesamt konnten n=31 Publikationen gefunden werden. Die meisten untersuchen die Zusammenhänge mit der Variablen ‚körperliche Aktivität', oft werden dabei signifikante Zusammenhänge mit zumindest einigen Skalen des NEWS-Fragebogens berichtet. Aus methodischer Sicht lassen sich die Studien oft nur schwer miteinander vergleichen. Schlussfolgerung: Das ‚Walkability'-Konzept sollte auch in der deutschsprachigen Public Health Diskussion etabliert werden. Es sind aber noch einige methodische Herausforderungen zu bewältigen, z. B. die Identifizierung der Skalen und Items im NEWS, bei denen der Zusammenhang mit dem individuellen Gesundheitsverhalten besonders deutlich ist.
Gesundheitswesen, Das

2013
Graw, J.; Strobl, R.; Heier, M.; Linkohr, B.; Peters, A.; Holle, R.; Grill, E.
The KORA-AGE eye study: Eye diseases in the elderly.
Acta Ophthalmol. 91, DOI: 10.1111/j.1755-3768.2013.46 (2013)
Purpose To estimate the prevalence of major age-related eye diseases in a population-based regional study in Southern Germany. Methods 822 randomly selected persons (age 68-96 years) from the KORA AGE study were asked in 2012 in a standardized interview for the presence of major eye disorders like cataracts, glaucoma and age-related macula degeneration (AMD). In case of any positive reply, the ophthalmologist in charge was asked for validation and specification of any eye disease. Results 465 persons reported any eye disorder (57%); 71% of them could be validated and specified. There were 182 confirmed cases of cataracts, 7 of glaucoma and 5 of AMD. Additionally, there were 52 cases of cataracts and AMD, also 54 cases of cataract and glaucoma and 11 cases of cataract, glaucoma and AMD. In 62% cases cataracts developed prior to any of the other eye diseases. Adjusted for age, women had a significantly higher risk for cataracts (OR = 1.72) and for AMD (OR = 1.94) than men; no gender-specific difference was observed for glaucoma. Among patients with cataracts, 69% had lens surgery. Conclusion We confirmed cataracts as the major age-related eye diseases; however, the number of glaucoma and AMD were surprisingly low. Further analyses are planned to identify risk factors and to show how eye diseases are independent risk factors for increased frailty and disability in the aged. This study was supported by the German Federal Ministry of Education and Research (BMBF) within the programme "Healthy Ageing" (FKZ 01ET1003).
Acta Ophthalmologica
Meeting abstract

Kowall, B.; Rathmann, W.; Bongaerts, B.; Meisinger, C.; Peters, A.; Huth, C.; Zierer, A.; Ladwig, K.-H.; Holle, R.
In the grey zone of type 2 diabetes prediction: Can we separate poorly discriminated incident cases and non-cases?
Diabetologia 56, S171 (2013)
Diabetologia
Meeting abstract

Schipf, S.; Ittermann, T.; Tamayo, T.; Maier, W.; Meisinger, C.; Greiser, K.H.; Mueller, G.; Moebus, S.; Voelzke, H.
Regional differences in the incidence of known type 2 diabetes mellitus in 45-74 years old individuals: Results from five population-based studies in Germany.
Diabetologia 56, S126-S127 (2013)
Diabetologia
Meeting abstract

Schunk, M.; Reitmeir, P.; Meisinger, C.; Kluttig, A.; Hartwig, S.; Schipf, S.; Voelzke, H.; Peters, A.; Holle, R.
Health-related quality of life in adults with and without type 2 diabetes: Results of a pooled analysis of German population-based cohort studies.
Diabetologia 56, S57 (2013)
Diabetologia
Meeting abstract

Becklas, E.°; Mielck, A.; Böcken, J.°
Unterschiede zwischen gesetzlich und privat Versicherten.
Impulse 79, 6-7 (2013)
Impulse

Schleidgen, S.; Klingler, C.; Bertram, T.; Rogowski, W.H.; Marckmann, G.
What is personalized medicine: Sharpening a vague term based on a systematic literature review.
BMC Med. Ethics 14:55 (2013)
ACKGROUND: Recently, individualized or personalized medicine (PM) has become a buzz word in the academic as well as public debate surrounding health care. However, PM lacks a clear definition and is open to interpretation. This conceptual

vagueness complicates public discourse on chances, risks and limits of PM. Furthermore, stakeholders might use it to further their respective interests and preferences. For these reasons it is important to have a shared understanding of PM. In this paper, we present a sufficiently precise as well as adequate definition of PM with the potential of wide acceptance. METHODS: For this purpose, in a first step a systematic literature review was conducted to understand how PM is actually used in scientific practice. PubMed was searched using the keywords "individualized medicine", "individualised medicine", "personalized medicine" and "personalised medicine" connected by the Boolean operator OR. A data extraction tabloid was developed putting forward a means/ends-division. Full-texts of articles containing the search terms in title or abstract were screened for definitions. Definitions were extracted; according to the means/ends distinction their elements were assigned to the corresponding category. To reduce complexity of the resulting list, summary categories were developed inductively from the data using thematic analysis. In a second step, six well-known criteria for adequate definitions were applied to these categories to derive a so-called precising definition. RESULTS: We identified 2457 articles containing the terms PM in title or abstract. Of those 683 contained a definition of PM and were thus included in our review. 1459 ends and 1025 means were found in the definitions. From these we derived the precising definition: PM seeks to improve stratification and timing of health care by utilizing biological information and biomarkers on the level of molecular disease pathways, genetics, proteomics as well as metabolomics. CONCLUSIONS: Our definition includes the aspects that are specific for developments labeled as PM while, on the other hand, recognizing the limits of these developments. Furthermore, it is supported by the quantitative analysis of PM definitions in the literature, which suggests that it it is widely acceptable and thus has the potential to avoid the above mentioned issues.
BMC Medical Ethics

Grill, E.; Döring, A.; Heier, M.; Holle, R.; Ladwig, K.-H.; Linkohr, B.; Meisinger, C.; Mielck, A.; Schulz, H.; Thorand, B.; Peters, A.
Multi-morbidity and disability, findings from the KORA-Age study.
Vortrag: European Workshop on Health and Disability Surveilla, 22-23 November 2012, Berlin, Germany. (2013)
BMC Proceedings
Doiron, D.; Burton, P.R; Marcon, Y.; Gaye, A.; Wolffenbuttel, B.H.; Perola, M.; Stolk, R.P.; Foco, L.; Minelli, C.; Waldenberger, M.; Holle, R.; Kvaløy, K.; Hillege, H.L.; Tassé, A.M.; Ferretti, V.; Fortier, I.
Data harmonization and federated analysis of population-based studies: The BioSHaRE project.
Emerg. Themes Epidemiol. 10:12 (2013)
BACKGROUND: Individual-level data pooling of large population-based studies across research centres in international research projects faces many hurdles. The BioSHaRE (Biobank Standardisation and Harmonisation for Research Excellence in the European Union) project aims to address these issues by building a collaborative group of investigators and developing tools for data harmonization, database integration and federated data analyses. METHODS: Eight population-based studies in six European countries were recruited to participate in the BioSHaRE project. Through workshops, teleconferences and electronic communications, participating investigators identified a set of 96 variables targeted for harmonization to answer research questions of interest. Using each study's questionnaires, standard operating procedures, and data dictionaries, harmonization potential was assessed. Whenever harmonization was deemed possible, processing algorithms were developed and implemented in an open-source software infrastructure to transform study-specific data into the target (i.e. harmonized) format. Harmonized datasets located on server in each research centres across Europe were interconnected through a federated database system to perform statistical analysis. RESULTS: Retrospective harmonization led to the generation of common format variables for 73% of matches considered (96 targeted variables across 8 studies). Authenticated investigators can now perform complex statistical analyses of harmonized datasets stored on distributed servers without actually sharing individual-level data using the DataSHIELD method. CONCLUSION: New Internet-based networking technologies and database management systems are providing the means to support collaborative, multi-center research in an efficient and secure manner. The results from this pilot project show that, given a strong collaborative relationship between participating studies, it is possible to seamlessly co-analyse internationally harmonized research databases while allowing each study to retain full control over individual-level data. We encourage additional collaborative research networks in epidemiology, public health, and the social sciences to make use of the open source tools presented herein.
Emerging Themes in Epidemiology

Holle, R.; Teuner, C.M.; Wirt, A.
Epidemiologie.
In: Wirth, A.*; Hauner, H.* [Eds.]: Adipositas - Ätiologie, Folgekrankheiten, Diagnostik, Therapie. Heidelberg [u.a]: Springer, 2013. 25-45
Die Adipositas lässt sich epidemiologisch gut erheben, da zur Erfassung nur einfache Methoden angewendet werden müssen. Verlässlich sind allerdings nur Untersuchungen, in denen die Probanden auch wirklich gemessen und gewogen wurden; Selbstangaben von Patienten aufgrund von Befragungen sind weniger verlässlich. In den letzten Jahrzehnten hat die Adipositas in Industrienationen zu einer pandemischen Verbreitung geführt. Aufgrund der assoziierten Morbidität und Einschränkung der Lebensqualität hat die Adipositas auch eine erhebliche ökonomische Bedeutung, was für die Gesundheitspolitik und Kostenträger von Sozialleistungen von Interesse ist. Epidemiologische Daten tragen auch zu ätiologischen Erkenntnissen der Adipositas bei.
Meisinger, C.; Stollenwerk, B.; Kirchberger, I.; Seidl, H.; Wende, R.; Kuch, B.; Holle, R.
Effects of a nurse-based case management compared to usual care among aged patients with myocardial infarction: Results from the randomized controlled KORINNA study.
BMC Geriatr. 13:115 (2013)
BACKGROUND: Transition from hospital to home is a critical period for older persons with acute myocardial infarction (AMI). Home-based secondary prevention programs led by nurses have been proposed to facilitate the patients' adjustment to AMI after discharge. The objective of this study was to evaluate the effects of a nurse-based case management for elderly patients discharged after an AMI from a tertiary care hospital. METHODS: In a single-centre randomized two-armed parallel group trial of patients aged 65 years and older hospitalized with an AMI between September 2008 and May 2010 in the Hospital

of Augsburg, Germany, patients were randomly assigned to a case management or a control group receiving usual care. The case-management intervention consisted of a nurse-based follow-up for one year including home visits and telephone calls. Key elements of the intervention were to detect problems or risks and to give advice regarding a wide range of aspects of disease management (e.g. nutrition, medication). Primary study endpoint was time to first unplanned readmission or death. Block randomization per telephone call to a biostatistical center, where the randomization list was kept, was performed. Persons who assessed one-year outcomes and validated readmission data were blinded. Statistical analysis was based on the intention-to-treat approach and included Cox Proportional Hazards models. RESULTS: Three hundred forty patients were allocated to receive case-management (n=168) or usual care (n=172). The analysis is based on 329 patients (intervention group: n=161; control group: n=168). Of these, 62% were men, mean age was 75.4 years, and 47.1% had at least either diabetes or chronic heart failure as a major comorbidity. The mean follow-up time for the intervention group was 273.6 days, and for the control group it was 320.6 days. During one year, in the intervention group there were 57 firs unplanned readmissions and 5 deaths, while the control group had 75 first unplanned readmissions and 3 deaths. With respect to the endpoint there was no significant effect of the case management program after one year (Hazard Ratio 1.01, 95% confidence interval 0.72-1.41). This was also the case among subgroups according to sex, diabetes, living alone, and comorbidities. CONCLUSIONS: A nurse-based management among elderly patients with AMI had no significant influence on the rate of first unplanned readmissions or death during a one-year follow-up. A possible long-term influence should be investigated by further studies.Clinical trial registration: ISRCTN02893746.
BMC Geriatrics

Eska, K.; Graessel, E.; Donath, C.; Schwarzkopf, L.; Lauterberg, J.; Holle, R.
Predictors of institutionalization of dementia patients in mild and moderate stages: A 4-year prospective analysis.
Dement. Geriatr. Cogn. Disord. 3, 426-445 (2013)
Background: Institutionalization is the most important milestone in the care of dementia patients. This study was aimed at identifying relevant predictors of institutionalization in a broad empirical context and interpreting them on the basis of the predictor model proposed by Luppa et al. [Dement Geriatr Cogn Disord 2008;26:65-78]. Methods: At the start of this study, 357 patients with mild to moderate dementia were examined by their general practitioners, and a telephone interview was conducted with their caregivers. Four years later, the outcomes 'institutionalization' and 'death' were determined from health insurance data. Forty-one variables were examined for their predictive influence by univariate and multivariate Cox regression. Results: The risk of institutionalization increased significantly ($p \leq 0.05$) with older ages of patients [hazard ratio (HR) = 1.05] and caregivers (HR = 1.03), a higher educational level of the caregiver (HR = 1.83), greater use of community health services (HR = 1.59), greater caregiver burden (HR = 1.02), and when the caregiver and patient lived apart (HR = 1.97). Conclusion: The results show that there is a multifactorial influence on institutionalization of dementia patients by sociodemographic, health-related, and psychological aspects as well as the care situation, thus validating the predictor model by Luppa et al. [Dement Geriatr Cogn Disord 2008;26:65-78]. Caregiver burden was found to be the strongest predictor accessible to interventions.
Dementia and Geriatric Cognitive Disorders

Teuner, C.M.; Menn, P.; Heier, M.; Holle, R.; John, J.; Wolfenstetter, S.B.
Impact of BMI and BMI change on future drug expenditures in adults: Results from the MONICA/KORA cohort study.
BMC Health Serv. Res. 13:424 (2013)
BACKGROUND: The evidence on the long-term economic effects of obesity is still scarce. This study aims to analyse the impact of body mass index (BMI) and BMI-change on future pharmaceutical utilisation and expenditures. METHODS: Based on data from 2,946 participants in a German population-based health survey (MONICA/KORA, 1994/95) and the follow-up study (2004/05), drug intake and expenditures were estimated using a bottom-up approach. Using univariate and multivariate methods, we analysed the impact of baseline BMI and BMI-change on drug utilisation and expenditures after 10 years. RESULTS: The use of pharmaceuticals was more likely in moderately and severely obese compared to the normal weight group (OR 1.8 and 4.0, respectively). In those who reported pharmaceutical intake, expenditures were about 40% higher for the obese groups. A 1-point BMI-gain in 10 years was, on average, associated with almost 6% higher expenditures compared to a constant BMI. CONCLUSION: The results suggest that obesity as well as BMI-gain are strong predictors of future drug utilisation and associated expenditures in adults, and thus highlight the necessity of timely and effective intervention and prevention programmes. This study complements the existing literature and provides important information on the relevance of obesity as a health problem.
BMC Health Services Research

Holle, R.; Hunger, M.; Schunk, M.
Gesundheitsbezogene Lebensqualität bei Personen mit Typ-2-Diabetes: Ergebnisse aus bevölkerungsbasierten Studien in Deutschland.
Diabetes Stoffwechs. Herz 22, 313-315 (2013)
Diabetes, Stoffwechsel und Herz

Lüring, C.; Niethard, F.-U.; Günther, K.-P.; Schäfer, T.; Hannemann, F.; Pritzkuleit, R.; Maier, W.; Kirschner, S.
Faktencheck Gesundheit : Knieoperationen (Endoprothetik) - Regionale Unterschiede und ihre Einflussfaktoren.
Gütersloh: Bertelsmann Stiftung, 2013. 25 S.
Koerber, F.; Rolauffs, B.; Rogowski, W.H.
Early evaluation and value-based pricing of regenerative medicine technologies.
Regen. Med. 8, 747-758 (2013)
Since the first pioneering scientists explored the potential of using human cells for therapeutic purposes the branch of regenerative medicine has evolved to become a mature industry. The focus has switched from 'what can be done' to 'what can be commercialized'. Timely health economic evaluation supports successful marketing by establishing the value of a product from a healthcare system perspective. This article reports results from a research project on early health economic evaluation in collaboration with developers, clinicians and manufacturers. We present an approach to determine an early value-based price for a new treatment of cartilage defects of the knee from the area of

regenerative medicine. Examples of using evaluation results for the purpose of business planning, market entry, preparing the coverage decision and managed entry are discussed.
Regenerative Medicine

Korber, K.; Teuner, C.M.; Lampert, T.; Mielck, A.; Leidl, R.
Direkte Krankheitskosten von Diabetes mellitus in Deutschland: Erste Abschätzung der Unterschiede zwischen Bildungsgruppen.
Gesundheitswesen 75, 812-818 (2013)
There are many studies on health inequalities, but these are rarely combined with cost-of-illness analyses. If the cost-of-illness were to be calculated for the individual status groups, it would be possible to assess the economic potential of preventive measures aimed specifically at people from low status groups. The objective of this article is to demonstrate for the first time the preventive potential by taking the example of diabetes mellitus (DM) from an economic perspective.Based on a systematic literature review, the average direct costs per patient with DM were assessed. Then, the prevalence of DM among adults with different educational levels was estimated based on the nationwide survey 'German Health Update' (GEDA), conducted by the Robert Koch-Institute in Germany in 2009. Finally, the cost and prevalence data were used to calculate the direct costs for each educational level.The direct costs of DM amount to about 13.1 billion € per year; about 35% of these costs can be attributed to patients with a low educational level. Thus, their share of the total costs is about 67% higher than their share of the total population. If the prevalence in the group with 'low educational level' (14.8%) could be reduced to the prevalence in the group with 'middle educational level' (7.9%), this would save about 2.2 billion (about 16.5%) € of direct costs.The analysis provides a first estimate of the potential savings from an effective status specific prevention programme. However, the direct costs per patient used were only an average for all people with DM, as a breakdown by educational level was not available. Since education can also affect health behaviour and compliance, which are also determinants of cost, the analyses presented here are probably conservative.
Gesundheitswesen, Das

Claessen, H.; Strassburger, K.; Tepel, M.; Waldeyer, R.; Chernyak, N.; Jülich, F.; Albers, B.; Bächle, C.; Rathmann, W.; Meisinger, C.; Thorand, B.; Hunger, M.; Schunk, M.; Stark, R.; Rückert, I.-M.; Peters, A.; Huth, C.; Stöckl, D.; Giani, G.; Holle, R.; Icks, A.
Medication costs by glucose tolerance stage in younger and older women and men: Results from the population-based KORA survey in Germany.
Exp. Clin. Endocrinol. Diabet. 121, 614-623 (2013)
To estimate medication costs in individuals with diagnosed diabetes, undetected diabetes, impaired glucose regulation and normal blood glucose values in a population-based sample by age and sex.Using the KORA F4 follow-up survey, conducted in 2006-2008 (n=2611, age 40-82 years), we identified individuals' glucose tolerance status by means of an oral glucose tolerance test. We assessed all medications taken regularly, calculated age-sex specific medication costs and estimated cost ratios for total, total without antihyperglycemic drugs, and cardiovascular medication, using multiple 2-part regression models.Compared to individuals with normal glucose values, costs were increased in known diabetes, undetected diabetes and impaired glucose regulation, which was more pronounced in participants aged 40-59 years than in those aged 60-82 years (cost ratios for all medications: 40-59 years: 2.85; 95%-confidence interval: 1.78-4.54, 2.00; 1.22-3.29 and 1.53; 1.12-2.09; 60-82 years: 2.04; 1.71-2.43, 1.17; 0.90-1.51 and 1.09; 0.94-1.28). Compared to individuals with diagnosed diabetes, costs were significantly lower among individuals with impaired glucose regulation across all age and sex strata, also when antihyperglycemic medication was excluded (40-59 years: 0.60; 0.36-0.98, 60-82 years: 0.74; 0.60-0.90; men: 0.72; 0.56-0.93; women: 0.72; 0.54-0.96).We could quantify age- and sex-specific medication costs and cost ratios in individuals with diagnosed diabetes, undetected diabetes and impaired glucose regulation compared to those with normal glucose values, using data of a population-based sample, with oral glucose tolerance test-based identification of diabetes states. These results may help to validly estimate cost-effectiveness of screening and early treatment or prevention of diabetes.
Experimental and Clinical Endocrinology & Diabetes

Meyer-Bäumer, A.; Eickholz, P.; Reitmeir, P.; Staehle, H.J.; Frese, C.; Wohlrab, T.; Pretzl, B.
Caries experience after periodontal treatment in aggressive and chronic periodontitis: Results of a 10-year follow-up.
Acta Odontol. Scand. 71, 1129-1135 (2013)
Abstract Objective. To compare the increase of DMF-T and DMF-S in patients with aggressive periodontitis (AgP) and chronic periodontitis (ChP) after active periodontal therapy. Materials and methods. One hundred and thirty-six periodontally treated patients were re-examined after 10 years. Dental and periodontal status was assessed and patients' charts were screened for diagnosis, compliance to supportive periodontal treatment (SPT) and DMF-T/-S at baseline and re-examination. δDMF-T/-S was calculated and multi-level regression analyses were performed to identify factors contributing to increase of DMF-T/-S. Results. Thirty patients with AgP, 37 with moderate ChP and 69 with severe ChP could be included. δDMF-T between first visit and re-examination was 2.07 (SD = 2.51, range = 0-14 teeth), mean δDMF-S = 14.66 (SD = 14.54, range = 0-83 surfaces). Patients with AgP showed a similar increase in DMF-T/-S to those with ChP. Regression analysis identified compliance as the only factor significantly accounting for preventing an increase of DMF-S ($p = 0.017$). No factor had a significant impact on DMF-T. Conclusions. DMF-T and DMF-S developed similarly in periodontally-treated patients with AgP and ChP during a follow-up of 10 years. SPT showed a positive influence on avoiding decline in DMF-S in periodontally compromised patients. No significant impact was detected for all other studied factors.
Acta Odontologica Scandinavica

Wabitsch, M.; Moss, A.; Reinehr, T.; Wiegand, S.; Kiess, W.; Scherag, A.; Höll, R.; Holle, R.; Hebebrand, J.
Medical and psychosocial implications of adolescent extreme obesity - acceptance and effects of structured care short: Youth with Extreme Obesity Study (YES).
BMC Public Health 13:789 (2013)
BACKGROUND: Prevalence rates of overweight and obesity have increased in German children and adolescents in the last three decades. Adolescents with extreme obesity represent a distinct risk group. On the basis of data obtained by the German Child and Youth Survey (KiGGS) and the German district military offices we estimate that the group of extremely obese

adolescents (BMI >= 35 kg/m2) currently encompasses approximately 200.000 adolescents aged 14 to 21 yrs. Conventional approaches focusing on weight reduction have largely proven futile for them. In addition, only a small percentage of adolescents with extreme obesity seek actively treatment for obesity while contributing disproportionately strong to health care costs. Because of somatic and psychiatric co-morbidities and social problems adolescents with extreme obesity require special attention within the medical care system.We have initiated the project "Medical and psychosocial implications of adolescents with extreme obesity - acceptance and effects of structured care, short: 'Youths with Extreme Obesity Study (YES)'", which aims at improving the medical care and social support structures for youths with extreme obesity in Germany. METHODS: We focus on identification of these subjects (baseline examination) and their acceptance of diagnostic and subsequent treatment procedures. In a randomized controlled trial (RCT) we will investigate the effectiveness of a low key group intervention not focusing on weight loss but aimed at the provision of obesity related information, alleviation of social isolation, school and vocational integration and improvement of self-esteem in comparison to a control group treated in a conventional way with focus on weight loss. Interested individuals who fulfill current recommended criteria for weight loss surgery will be provided with a structured preparation and follow-up programs. All subjects will be monitored within a long-term observational study to elucidate medical and psychosocial outcomes. Our aim is to evaluate realistic treatment options. Therefore inclusion and exclusion criteria are minimized.We will recruit adolescents (age range 14--21 years) with extreme obesity (BMI >= 35 kg/m2) (extreme group) within 24 months (120 per centre, 5 centres) as well as obese adolescents being at risk for developing extreme obesity (BMI >= 30 -- 34.9 kg/m2) (at risk group). Follow-up evalutations will be performed biannually after inclusion and is planned to be extended in case of additional funding. In sum, we aim at establishing evaluated health care structures for extremely obese adolescents. DISCUSSION: The results of YES will be of importance for a frequently neglected group of individuals, for whom current medicine has little to offer in terms of structured access to empirically evaluated therapeutic programs. Thus, the results will be both a help for the adolescents within the study and for others in the future given that the trial will lead to a positive finding. Moreover, it will help practitioners and therapists to deal with this neglected group of individuals.Trial registrationProject registration numbers for each subproject: 1.) ClinicalTrials.gov: NCT01625325, NCT01703273, NCT01662271, NCT01632098; 2.) Germanctr.de: DRKS00004172, DRKS00004195, DRKS00004198, DRKS00004197.
BMC Public Health

Leidl, R.
Managing technologies or diseases? Two strategic approaches to health care for an ageing population.
In: Cheung, F.M.*; Woo, J.*; Law, C.* [Eds.]: Health Systems: Challenges, Visions, and Reforms from a Comparative Global Perspective. Hong Kong: Chinese Univ. Hong Kong, 2013. 83-107 (21st Century Book Series)

Müller, G.; Hartwig, S.; Greiser, K.H.; Moebus, S.; Pundt, N.; Schipf, S.; Völzke, H.; Maier, W.; Meisinger, C.; Tamayo, T.; Rathmann, W.; Berger, K.; DIAB-CORE Consortium ()
Gender differences in the association of individual social class and neighbourhood unemployment rate with prevalent type 2 diabetes mellitus: A cross-sectional study from the DIAB-CORE Consortium.
BMJ Open 3:e002601 (2013)
OBJECTIVE: To analyse gender differences in the relationship of individual social class, employment status and neighbourhood unemployment rate with present type 2 diabetes mellitus (T2DM). DESIGN: Five cross-sectional studies. SETTING: Studies were conducted in five regions of Germany from 1997 to 2006. PARTICIPANTS: The sample consisted of 8871 individuals residing in 226 neighbourhoods from five urban regions. PRIMARY AND SECONDARY OUTCOME MEASURES: Prevalent T2DM. RESULTS: We found significant multiplicative interactions between gender and the individual variables--social class and employment status. Social class was statistically significantly associated with T2DM in men and women, whereby this association was stronger in women (lower vs higher social class: OR 2.68 (95% CIs 1.66 to 4.34)) than men (lower vs higher social class: OR 1.78 (95% CI 1.22 to 2.58)). Significant associations of employment status and T2DM were only found in women (unemployed vs employed: OR 1.73 (95% CI 1.02 to 2.92); retired vs employed: OR 1.77 (95% CI 1.10 to 2.84); others vs employed: OR 1.64 (95% CI 1.01 to 2.67)). Neighbourhood unemployment rate was associated with T2DM in men (high vs low tertile: OR 1.52 (95% CI 1.18 to 1.96)). Between-study and between-neighbourhood variations in T2DM prevalence were more pronounced in women. The considered covariates helped to explain statistically the variation in T2DM prevalence among men, but not among women. CONCLUSIONS: Social class was inversely associated with T2DM in both men and women, whereby the association was more pronounced in women. Employment status only affected T2DM in women. Neighbourhood unemployment rate is an important predictor of T2DM in men, but not in women.
BMJ Open

Sickinger, S.; Payne, K.; Rogowski, W.H.
Probleme und Methoden der Gesundheitsökonomie: Personalisierte Medizin als Sonderfall?
Ethik Med. 25, 267-275 (2013)
Für ökonomische Evaluationen medizinischer Leistungen steht ein etabliertes Methodenspektrum zur Verfügung. Ziel der Arbeit ist, anhand ausgewählter Aspekte herauszuarbeiten, inwieweit diese Methoden für den derzeit viel diskutierten Bereich der Personalisierten Medizin anwendbar sind bzw. welche Besonderheiten dabei auftreten und wie diese adressiert werden können. Für die vorliegende Arbeit wurde eine explorative Literaturrecherche durchgeführt. In Abgrenzung zur herkömmlichen Medizin kann je nach Blickwinkel die Personalisierte Medizin entweder hinsichtlich der physiologischen Unterschiede oder hinsichtlich der individuellen Präferenzen der Beteiligten betrachtet werden. Je nach Betrachtungsweise ergeben sich unterschiedliche methodische Herausforderungen an gesundheitsökonomische Evaluationen. Verbesserte Ausrichtung der Versorgung an physiologischen Unterschieden stellt die Evaluation beispielsweise vor das Problem, dass aufgrund des oftmals kleinen Stichprobenumfangs häufig Evidenz zur Parametrisierung von Entscheidungsmodellen fehlt. Informationswertanalysen können Hinweise über den potenziellen Nutzen weiterer Forschung geben. Das Konzept des „Expected Value of Individualized Care“

bietet einen den Informationswertanalysen sehr ähnlichen Ansatz, um den potenziellen Wert eines Einbezugs individueller Präferenzen in die Versorgung zu quantifizieren. Welfarismus und Extra-Welfarismus bieten unterschiedliche Lösungsansätze, wie Nutzen Biomarker-basierter Information im Sinne von „Empowerment" in Evaluationen einbezogen werden können. Generell sind die Methoden der gesundheitsökonomischen Evaluation auch auf den Bereich der Personalisierten Medizin anwendbar. Es stellen sich jedoch eine Reihe spezifischer Herausforderungen, zu deren Lösung weiterer Forschungsbedarf besteht.
Ethik in der Medizin

Wacker, M.; Holle, R.; Heinrich, J.; Ladwig, K.-H.; Peters, A.; Leidl, R.; Menn, P.
The association of smoking status with healthcare utilisation, productivity loss and resulting costs: Results from the population-based KORA F4 study.
BMC Health Serv. Res. 13:278 (2013)
BACKGROUND: Smoking is seen as the most important single risk to health today, and is responsible for a high financial burden on healthcare systems and society. This population-based cross-sectional study compares healthcare utilisation, direct medical costs, and costs of productivity losses for different smoking groups: current smokers, former smokers, and never smokers. METHODS: Using a bottom-up approach, data were taken from the German KORA F4 study (2006/2008) on self-reported healthcare utilisation and work absence due to illness for 3,071 adults aged 32-81 years. Unit costs from a societal perspective were applied to utilisation. Utilisation and resulting costs were compared across different smoking groups using generalised linear models to adjust for age, sex, education, alcohol consumption and physical activity. RESULTS: Average annual total costs per survey participant were estimated as €3,844 [95% confidence interval: 3,447-4,233], and differed considerably between smoking groups with never smokers showing €3,237 [2,802-3,735] and former smokers causing €4,398 [3,796-5,058]. There was a positive effect of current and former smoking on the utilisation of healthcare services and on direct and indirect costs. Total annual costs were more than 20% higher ($p<0.05$) for current smokers and 35% higher ($p<0.01$) for former smokers compared with never smokers, which corresponds to annual excess costs of €743 and €1,108 per current and former smoker, respectively. CONCLUSIONS: Results indicate that excess costs for current and former smokers impose a large burden on society, and that previous top-down cost approaches produced lower estimates for the costs of care for smoking-related diseases. Efforts must be focused on prevention of smoking to achieve sustainable containment on behalf of the public interest.
BMC Health Services Research

Icks, A.; Claessen, H.; Strassburger, K.; Waldeyer, R.; Chernyak, N.; Jülich, F.; Rathmann, W.; Thorand, B.; Meisinger, C.; Huth, C.; Rückert, I.-M.; Schunk, M.; Giani, G.; Holle, R.
Patient time costs attributable to healthcare use in diabetes: Results from the population-based KORA survey in Germany.
Diabetic Med. 30, 1245-1249 (2013)
AIMS: Patient time costs have been described to be substantial; however, data are highly limited. We estimated patient time costs attributable to outpatient and inpatient care in study participants with diagnosed diabetes, previously undetected diabetes, impaired glucose regulation and normal glucose tolerance. METHODS: Using data of the population-based KORA S4 study (55-74 years, random sample of n = 350), we identified participants' stage of glucose tolerance by oral glucose tolerance test. To estimate mean patient time costs per year (crude and standardized with respect to age and sex), we used data regarding time spent with ambulatory visits including travel and waiting time and with hospital stays (time valued at a 2011 net wage rate of €20.63/h). The observation period was 24 weeks and data were extrapolated to 1 year. RESULTS: Eighty-nine to 97% of participants in the four groups (diagnosed diabetes, undetected diabetes, impaired glucose regulation and normal glucose tolerance.) had at least one physician contact and 4-14% at least one hospital admission during the observation period. Patient time [h/year (95% CI)] was 102.0 (33.7-254.8), 53.8 (15.0-236.7), 59.3 (25.1-146.8) and 28.6 (21.1-43.7), respectively. Age-sex standardized patient time costs per year (95% CI) were €2447.1 (804.5-6143.6), €880.4 (259.1-3606.7), €1151.6 (454.6-2957.6) and €589.2 (435.8-904.8). CONCLUSIONS: Patient time costs were substantial-even higher than medication costs in the same study population. They are higher in participants with diagnosed diabetes, but also in those with undetected diabetes and impaired glucose regulation compared with those with normal glucose tolerance. Research is needed in larger populations to receive more precise and certain estimates that can be used in health economic evaluation.
Diabetic Medicine

Rietveld, C.A.; Medland, S.E.; Derringer, J.; Yang, J.; Esko, T.; Martin, N.W.; Westra, H.J.; Shakhbazov, K.; Abdellaoui, A.; Agrawal, A.; Albrecht, E.; Alizadeh, B.Z.; Amin, N.; Barnard, J.; Baumeister, S.E.; Benke, K.S.; Bielak, L.F.; Boatman, J.A.; Boyle, P.A.; Davies, G.; de Leeuw, C.; Eklund, N.; Evans, D.S.; Ferhmann, R.; Fischer, K.; Gieger, C.; Gjessing, H.K.; Hägg, S.; Harris, J.R.; Hayward, C.; Holzapfel, C.; Ibrahim-Verbaas, C.A.; Ingelsson, E.; Jacobsson, B.; Joshi, P.K.; Jugessur, A.; Kaakinen, M.; Kanoni, S.; Karjalainen, J.; Kolcic, I.; Kristiansson, K.; Kutalik, Z.; Lahti, J.; Lee, S.H.; Lin, P.; Lind, P.A.; Liu, Y.; Lohman, K.; Loitfelder, M.; McMahon, G.; Vidal, P.M.; Meirelles, O.; Milani, L.; Myhre, R.; Nuotio, M.L.; Oldmeadow, C.J.; Petrovic, K.E.; Peyrot, W.J.; Polasek, O.; Quaye, L.; Reinmaa, E.; Rice, J.P.; Rizzi, T.S.; Schmidt, H.; Schmidt, R.; Smith, A.V.; Smith, J.A.; Tanaka, T.; Terracciano, A.; van der Loos, M.J.; Vitart, V.; Völzke, H.; Wellmann, J.; Yu, L.; Zhao, W.; Allik, J.; Attia, J.R.; Bandinelli, S.; Bastardot, F.; Beauchamp, J.; Bennett, D.A.; Berger, K.; Bierut, L.J.; Boomsma, D.I.; Bültmann, U.; Campbell, H.; Chabris, C.F.; Cherkas, L.; Chung, M.K.; Cucca, F.; de Andrade, M.; de Jager, P.L.; de Neve, J.E.; Deary, I.J.; Dedoussis, G.V.; Deloukas, P.; Dimitriou, M.; Eiriksdottir, G.; Elderson, M.F.; Eriksson, J.G.; Evans, D.M.; Faul, J.D.; Ferrucci, L.; Garcia, M.E.; Grönberg, H.; Guðnason, V.; Hall, P.; Harris, J.M.; Harris, T.B.; Hastie, N.D.; Heath, A.C.; Hernandez, D.G.; Hoffmann, W.; Hofman, A.; Holle, R.; Holliday, E.G.; Hottenga, J.J.; Iacono, W.G.; Illig, T.; Jarvelin, M.R.; Kähönen, M.; Kaprio, J.; Kirkpatrick, R.M.; Kowgier, M.; Latvala, A.; Launer, L.J.; Lawlor, D.A.; Lehtimäki, T.; Li, J.; Lichtenstein, P.; Lichtner, P.; Liewald, D.C.; Madden, P.A.; Magnusson, P.K.; Mäkinen, T.E.; Masala, M.; McGue, M.; Metspalu, A.; Mielck, A.; Miller, M.B.; Montgomery, G.W.; Mukherjee, S.; Nyholt, D.R.; Oostra, B.A.; Palmer, L.J.; Palotie, A.; Penninx, B.W.; Perola, M.; Peyser, P.A.; Preisig, M.; Räikkönen, K.; Raitakari, O.T.; Realo, A.; Ring, S.M.; Ripatti, S.; Rivadeneira, F.; Rudan, I.; Rustichini, A.; Salomaa, V.; Sarin, A.P.; Schlessinger, D.; Scott, R.J.; Snieder,

H.; St Pourcain, B.; Starr, J.M.; Sul, J.H.; Surakka, I.; Svento, R.; Teumer, A.; The LifeLines Cohort Study; Tiemeier, H.; van Rooij, F.J.; van Wagoner, D.R.; Vartiainen, E.; Viikari, J.; Vollenweider, P.; Vonk, J.M.; Waeber, G.; Weir, D.R.; Wichmann, H.-E.; Widen, E.; Willemsen, G.; Wilson, J.F.; Wright, A.F.; Conley, D.; Davey Smith, G.; Franke, L.; Groenen, P.J.; Johannesson, M.; Kardia, S.L.; Krueger, R.F.; Laibson, D.; Martin, N.G.; Meyer, M.N.; Posthuma, D.; Thurik, A.R.; Timpson, N.J.; Uitterlinden, A.G.; van Duijn, C.M.; Visscher, P.M.°; Benjamin, D.J.°; Cesarini, D.°; Koellinger, P.D.°
GWAS of 126,559 individuals identifies genetic variants associated with educational attainment.
Science 340, 1467-1471 (2013)
A genome-wide association study (GWAS) of educational attainment was conducted in a discovery sample of 101,069 individuals and a replication sample of 25,490. Three independent single-nucleotide polymorphisms (SNPs) are genome-wide significant (rs9320913, rs11584700, rs4851266), and all three replicate. Estimated effects sizes are small (coefficient of determination R(2) ≈ 0.02%), approximately 1 month of schooling per allele. A linear polygenic score from all measured SNPs accounts for ≈2% of the variance in both educational attainment and cognitive function. Genes in the region of the loci have previously been associated with health, cognitive, and central nervous system phenotypes, and bioinformatics analyses suggest the involvement of the anterior caudate nucleus. These findings provide promising candidate SNPs for follow-up work, and our effect size estimates can anchor power analyses in social-science genetics.
Science

Fischer, K.E.; Stollenwerk, B.; Rogowski, W.H.
Link between process and appraisal in coverage decisions: An analysis with structural equation modeling.
Med. Decis. Making 33, 1009-1025 (2013)
Background. To achieve fair-coverage decision making, both material criteria and criteria of procedural justice have been proposed. The relationship between these is still unclear. Objective. To analyze hypotheses underlying the assumption that more assessment, transparency, and participation have a positive impact on the reasonableness of coverage decisions. Methods. We developed a structural equation model in which the process components were considered latent constructs and operationalized by a set of observable indicators. The dependent variable “reasonableness” was defined by the relevance of clinical, economic, and other ethical criteria in technology appraisal (as opposed to appraisal based on stakeholder lobbying). We conducted an Internet survey among conference participants familiar with coverage decisions of third-party payers in industrialized countries between 2006 and 2011. Partial least squares path modeling (PLS-PM) was used, which allows analyzing small sample sizes without distributional assumptions. Data on 97 coverage decisions from 15 countries and 40 experts were used for model estimation. Results. Stakeholder participation (regression coefficient [RC] =0.289; P = 0.005) and scientific rigor of assessment (RC = 0.485; P < 0.001) had a significant influence on the construct of reasonableness. The path from transparency to reasonableness was not significant (RC = 0.289; P = 0.358). For the reasonableness construct, a considerable share of the variance was explained (R2 = 0.44). Biases from missing data and nesting effects were assessed through sensitivity analyses. Limitations. The results are limited by a small sample size and the overrepresentation of some decision makers. Conclusions. Rigorous assessment and intense stakeholder participation appeared effective in promoting reasonable decision making, whereas the influence of transparency was not significant. A sound evidence base seems most important as the degree of scientific rigor of assessment had the strongest effect.
Medical Decision Making

Schulz, H.; Flexeder, C.; Behr, J.; Heier, M.; Holle, R.; Huber, R.M.; Jörres, R.A.; Nowak, D.; Peters, A.; Wichmann, H.-E.; Heinrich, J.; Karrasch, S.
Reference values of impulse oscillometric lung function indices in adults of advanced age.
PLoS ONE 8:e63366 (2013)
BACKGROUND: Impulse oscillometry (IOS) is a non-demanding lung function test. Its diagnostic use may be particularly useful in patients of advanced age with physical or mental limitations unable to perform spirometry. Only few reference equations are available for Caucasians, none of them covering the old age. Here, we provide reference equations up to advanced age and compare them with currently available equations. METHODS: IOS was performed in a population-based sample of 1990 subjects, aged 45-91 years, from KORA cohorts (Augsburg, Germany). From those, 397 never-smoking, lung healthy subjects with normal spirometry were identified and sex-specific quantile regression models with age, height and body weight as predictors for respiratory system impedance, resistance, reactance, and other parameters of IOS applied. RESULTS: Women (n=243) showed higher resistance values than men (n=154), while reactance at low frequencies (up to 20 Hz) was lower (p<0.05). A significant age dependency was observed for the difference between resistance values at 5 Hz and 20 Hz (R5-R20), the integrated area of low-frequency reactance (AX), and resonant frequency (Fres) in both sexes whereas reactance at 5 Hz (X5) was age dependent only in females. In the healthy subjects (n=397), mean differences between observed values and predictions for resistance (5 Hz and 20 Hz) and reactance (5 Hz) ranged between -1% and 5% when using the present model. In contrast, differences based on the currently applied equations (Vogel & Smidt 1994) ranged between -34% and 76%. Regarding our equations the indices were beyond the limits of normal in 8.1% to 18.6% of the entire KORA cohort (n=1990), and in 0.7% to 9.4% with the currently applied equations. CONCLUSIONS: Our study provides up-to-date reference equations for IOS in Caucasians aged 45 to 85 years. We suggest the use of the present equations particularly in advanced age in order to detect airway dysfunction.
PLoS ONE

Müller, S.; Eickholz, P.; Reitmeir, P.; Eger, T.
Long-term tooth loss in periodontally compromised but treated patients according to the type of prosthodontic treatment. A retrospective study.
J. Oral Rehabil. 40, 358-367 (2013)
If prosthodontic treatment is considered after periodontal therapy, the questions arise i) does prosthodontic treatment affect the treatment outcome of the dentition in general and ii) which type of prosthesis is related to best treatment outcome of abutment teeth? Our goal was to compare long-term tooth loss after comprehensive periodontal therapy in patients with or without prosthodontic treatment. Ninety patients' charts with a

total of 1937 teeth who had received comprehensive periodontal treatment 517years ago by the same periodontist were retrospectively evaluated. Sixty-five patients received fixed dental prostheses (FDP; n=29) and/or removable partial dentures anchored with clips (RPDC; n=25) or double crowns (RPDD; n=25). Twenty-five patients were also periodontally compromised but treated without prosthodontic treatment and served as a control group. A total of 317 teeth and 70 abutment teeth were lost during 9 center dot 7 +/- 4 center dot 1years of observation. Thereof, 273 teeth and 48 abutment teeth were lost due to periodontal reasons. Mean tooth loss amounted to 1 center dot 2 +/- 1 center dot 5 (controls) and 4 center dot 4 +/- 3 center dot 4 (partial dentures). Abutment tooth loss was 0 center dot 4 +/- 1 center dot 1 (FDP), 1 center dot 0 +/- 1 center dot 2 (RPDC) and 1 center dot 3 +/- 1 center dot 0 (RPDD). Poisson regressions identified prosthodontic treatment, age, socio-economic status, diabetes mellitus, mean initial bone loss and aggressive periodontitis as factors significantly contributing to tooth loss. Age, diabetes and non-compliance contributed to abutment tooth loss. Not considering biomechanical factors, patients with prosthodontic reconstructions under long-term supportive periodontal therapy were at higher risk for further tooth loss than patients without prostheses. Not only the type of partial denture but also the patient-related risk factors were associated with abutment tooth loss.
Journal of Oral Rehabilitation

Fischer, K.E.; Rogowski, W.H.; Leidl, R.; Stollenwerk, B.
Transparency vs. closed-door policy: Do process characteristics have an impact on the outcomes of coverage decisions? A statistical analysis.
Health Policy 112, 187-196 (2013)
The aim of this study was to analyze influences of process- and technology-related characteristics on the outcomes of coverage decisions. Using survey data on 77 decisions from 13 countries, we examined whether outcomes differ by 14 variables that describe components of decision-making processes and the technology. We analyzed the likelihood of committees covering a technology, i.e. positive (including partial coverage) vs. negative coverage decisions. We performed non-parametric univariate tests and binomial logistic regression with a stepwise variable selection procedure. We identified a negative association between a positive decision and whether the technology is a prescribed medicine (p=0.0097). Other significant influences on a positive decision outcome included one disease area (p=0.0311) and whether a technology was judged to be (cost-)effective (p<0.0001). The first estimation of the logistic regression yielded a quasi-complete separation for technologies that were clearly judged (cost-)effective. In uncertain decisions, a higher number of stakeholders involved in voting (odds ratio=2.52; p=0.03) increased the likelihood of a positive outcome. The results suggest that decisions followed the lines of evidence-based decision-making. Despite claims for transparent and participative decision-making, the phase of evidence generation seemed most critical as decision-makers usually adopted the assessment recommendations. We identified little impact of process configurations.
Health Policy

Müller, G.; Kluttig, A.; Greiser, K.H.; Moebus, S.; Slomiany, U.; Schipf, S.; Völzke, H.; Maier, W.; Meisinger, C.; Tamayo, T.; Rathmann, W.; Berger, K.
Regional and neighborhood disparities in the odds of type 2 diabetes: Results from 5 population-based studies in Germany (DIAB-CORE Consortium).
Am. J. Epidemiol. 178, 221-230 (2013)
The objective of this study was to investigate the association between residential environment and type 2 diabetes. We pooled cross-sectional data from 5 population-based German studies (1997-2006): the Cardiovascular Disease, Living and Ageing in Halle Study, the Dortmund Health Study, the Heinz Nixdorf Recall Study, the Cooperative Health Research in the Region of Augsburg Study, and the Study of Health in Pomerania. The outcome of interest was the presence of self-reported type 2 diabetes. We conducted mixed logistic regression models in a hierarchical data set with 8,879 individuals aged 45-74 years on level 1; 226 neighborhoods on level 2; and 5 study regions on level 3. The analyses were adjusted for age, sex, social class, and employment status. The odds ratio for type 2 diabetes was highest in eastern Germany (odds ratio = 1.98, 95% confidence interval: 1.81, 2.14) and northeastern Germany (odds ratio = 1.58, 95% confidence interval: 1.40, 1.77) and lowest in southern Germany (reference) after adjustment for individual variables. Neighborhood unemployment rates explained a large proportion of regional differences. Individuals residing in neighborhoods with high unemployment rates had elevated odds of type 2 diabetes (odds ratio = 1.62, 95% confidence interval: 1.25, 2.09). The diverging levels of unemployment in neighborhoods and regions are an independent source of disparities in type 2 diabetes.
American Journal of Epidemiology

Genz, J.; Haastert, B.; Müller, H.; Verheyen, F.; Cole, D.; Rathmann, W.; Nowotny, B.; Roden, M.; Giani, G.; Mielck, A.; Ohmann, C.; Icks, A.
Effekt einer evidenzbasierten Patienteninformation zur Prävention von Typ 2-Diabetes.
Gesundheitswesen 77, S91-S92 (2013)
Verglichen wurde der Effekt einer eigens entwickelten web-basierten evidenzbasierten Patienteninformation (EBPI) über grenzwertig erhöhten Blutzucker mit den Standardinformationen zu Primärprävention des Diabetes auf die ‚informierte Entscheidung'. Die EBPI verbesserte signifikant das Wissen zum Thema erhöhte Blutzuckerwerte, steigerte allerdings auch den Entscheidungskonflikt und eine kritische Einstellung gegenüber Primärprävention. Die Absicht an einem Stoffwechseltest teilzunehmen, nahm ab.
Gesundheitswesen, Das

Kirsch, F.; Teuner, C.M.; Menn, P.; Leidl, R.
Krankheitskosten für Asthma und COPD bei Erwachsenen in der Bundesrepublik Deutschland.
Gesundheitswesen 75, 413-423 (2013)
Hintergrund: Asthma und COPD haben weltweit eine hohe und wachsende epidemiologische Bedeutung, und es gibt zahlreiche Hinweise auf hohe damit verbundene volkswirtschaftliche Kosten. Das Ziel dieses Review ist es, die Kosten beider Erkrankungen, bei Erwachsenen in der Bundesrepublik Deutschland abzuschätzen. Methode: Eine systematische Recherche wurde in den Datenbanken Pubmed, Embase, EconLit und Business Source Complete für die Jahre von 1995 bis 2012 durchgeführt, um deutsche Krankheitskostenstudien für Asthma und COPD in deutscher oder englischer Sprache zu finden. 6 Studien für Asthma, 7 Studien für COPD und 1 Studie

für beide Erkrankungen erfüllten die Aufnahmekriterien. Die Ergebnisse der identifizierten Studien wurden auf das Preisjahr 2010 inflationiert und innerhalb der einzelnen Krankheiten verglichen. Ergebnisse: Trotz der Heterogenität der Studien in Methodik und Ergebnissen wird deutlich, dass Arzneimittel für Asthma und COPD die größten Kostenverursacher im Bereich der direkten Kosten sind. Arbeitsunfähigkeit verursacht den größten Anteil an indirekten Kosten für Asthma und COPD. Insgesamt liegen die geschätzten Kosten pro Krankheitsfall und Jahr für Asthma zwischen 445 € und 2 543 €, für COPD zwischen 1 212 € und 3 492 €. Schlussfolgerung: Die analysierten Krankheitskostenstudien bestätigten, dass Asthma und COPD kostspielig sind, weisen aber eine deutliche Streuung der Ergebnisse auf. COPD verursacht aufgrund der höheren Kosten pro Erkranktem und einer ähnlichen Prävalenz die höheren volkswirtschaftlichen Gesamtkosten. Die Ergebnisse zeigen die hohe ökonomische Relevanz von Prävention und Krankheitsmanagement für diese Lungenerkrankungen auf.
Gesundheitswesen, Das

Liu, Y.; Dalal, K.; Stollenwerk, B.
The association between health system development and the burden of cardiovascular disease: An analysis of WHO country profiles.
PLoS ONE 8:e61718 (2013)
Background Several risk factors for cardiovascular disease (CVD) have been identified in recent decades. However, the association between the health system and the burden of CVD has not yet been sufficiently researched. The objective of this study was to analyse the association between health system development and the burden of CVD, in particular CVD-related disability-adjusted life–years (DALYs). Methods Univariate and multivariate generalized linear mixed models were applied to country-level data collected by the World Bank and World Health Organization. Response variables were the age-standardized CVD mortality and age-standardized CVD DALY rates. Results The amount of available health system resources, indicated by total health expenditures per capita, physician density, nurse density, dentistry density, pharmaceutical density and the density of hospital beds, was associated with reduced CVD DALY rates and CVD mortality. However, in the multivariate models, the density of nurses and midwives was positively associated with CVD. High out-of-pocket costs were associated with increased CVD mortality in both univariate and multivariate analyses. Conclusion A highly developed health system with a low level of out-of-pocket costs seems to be the most appropriate to reduce the burden of CVD. Furthermore, an efficient balance between human health resources and health technologies is essential.
PLoS ONE

van der Loos, M.J.; Rietveld, C.A.; Eklund, N.; Koellinger, P.D.; Rivadeneira, F.; Abecasis, G.R.; Ankra-Badu, G.A.; Baumeister, S.E.; Benjamin, D.J.; Biffar, R.; Blankenberg, S.; Boomsma, D.I.; Cesarini, D.; Cucca, F.; de Geus, E.J.; Dedoussis, G.; Deloukas, P.; Dimitriou, M.; Eiriksdottir, G.; Eriksson, J.; Gieger, C.; Gudnason, V.; Höhne, B.; Holle, R.; Hottenga, J.J.; Isaacs, A.; Jarvelin, M.R.; Johannesson, M.; Kaakinen, M.; Kähönen, M.; Kanoni, S.; Laaksonen, M.A.; Lahti, J.; Launer, L.J.; Lehtimäki, T.; Loitfelder, M.; Magnusson, P.K.; Naitza, S.; Oostra, B.A.; Perola, M.; Petrovic, K.; Quaye, L.; Raitakari, O.; Ripatti, S.; Scheet, P.; Schlessinger, D.; Schmidt, C.O.; Schmidt, H.; Schmidt, R.; Senft, A.; Smith, A.V.; Spector, T.D.; Surakka, I.; Svento, R.; Terracciano, A.; Tikkanen, E.; van Duijn, C.M.; Viikari, J.; Völzke, H.; Wichmann, H.-E.; Wild, P.S.; Willems, S.M.; Willemsen, G.; van Rooij, F.J.; Groenen, P.J.; Uitterlinden, A.G.; Hofman, A.; Thurik, A.R.
The molecular genetic architecture of self-employment.
PLoS ONE 8:e60542 (2013)
Economic variables such as income, education, and occupation are known to affect mortality and morbidity, such as cardiovascular disease, and have also been shown to be partly heritable. However, very little is known about which genes influence economic variables, although these genes may have both a direct and an indirect effect on health. We report results from the first large-scale collaboration that studies the molecular genetic architecture of an economic variable-entrepreneurship-that was operationalized using self-employment, a widely-available proxy. Our results suggest that common SNPs when considered jointly explain about half of the narrow-sense heritability of self-employment estimated in twin data (σg (2)/σP (2)=25%, h (2)=55%). However, a meta-analysis of genome-wide association studies across sixteen studies comprising 50,627 participants did not identify genome-wide significant SNPs. 58 SNPs with p<10(-5) were tested in a replication sample (n=3,271), but none replicated. Furthermore, a gene-based test shows that none of the genes that were previously suggested in the literature to influence entrepreneurship reveal significant associations. Finally, SNP-based genetic scores that use results from the meta-analysis capture less than 0.2% of the variance in self-employment in an independent sample (p≥0.039). Our results are consistent with a highly polygenic molecular genetic architecture of self-employment, with many genetic variants of small effect. Although self-employment is a multi-faceted, heavily environmentally influenced, and biologically distal trait, our results are similar to those for other genetically complex and biologically more proximate outcomes, such as height, intelligence, personality, and several diseases.
PLoS ONE

Lukaschek, K.; Baumert, J.J.; Kruse, J.; Emeny, R.T.; Lacruz, M.E.; Huth, C.; Thorand, B.; Holle, R.; Rathmann, W.; Meisinger, C.; Ladwig, K.-H.
Relationship between posttraumatic stress disorder and type 2 diabetes in a population-based cross-sectional study with 2970 participants.
J. Psychosomat. Res. 74, 340-345 (2013)
Objectives: To evaluate the association of posttraumatic stress disorder (PTSD) with type 2 diabetes (T2D) or prediabetes in a large population-based sample. Methods: In 2970 subjects (aged 32-81 years) drawn from the population-based cross-sectional study KORA F4 from the Augsburg region (Southern Germany) a PTSD screening was performed employing the. Posttraumatic Diagnostic Scale, the Impact of Event Scale, and interview data. The exposure variable PTSD was sub-classified into partial and full PTSD and additionally in subjects with traumatic event but no PTSD" to "The exposure variable PTSD was classified into (1) no traumatic event (2) traumatic event, but no PTSD, (3) partial PTSD, (4) full PTSD. A total of 50 (1.7%) subjects qualified for full PTSD, whereas 261 (8.8%) qualified for partial PTSD. A total of 333 subjects (11.2%) suffered from T2D and 498 (16.8%) from prediabetes as assessed by an oral glucose tolerance test and physicians' validation. The associations of PTSD with T2D and prediabetes were estimated by multinomial logistic regression analyses with adjustments for sociodemographic characteristics,

metabolic risk factors or psychopathological conditions. Results: In the model adjusted for sociodemographic characteristics and metabolic risk factors, full PTSD was significantly associated with T2D (OR: 3.90,95% CI: 1.61-9.45,p=0.003) compared to subjects with no traumatic event. Significance remained after additional adjustment for other psychopathological conditions (OR: 3.56, 95% CI: 1.43-8.85, p=0.006). Regarding prediabetes, no significant associations were observed. Conclusions: Suffering from PTSD might activate chronic stress symptoms and trigger physiological mechanisms leading to T2D. Prospective studies are needed to investigate temporal and causal relationships between PTSD and T2D.
Journal of Psychosomatic Research

Icks, A.; Claessen, H.; Strassburger, K.; Tepel, M.; Waldeyer, R.; Chernyak, N.; Albers, B.; Baechle, C.; Rathmann, W.; Meisinger, C.; Thorand, B.; Hunger, M.; Schunk, M.; Stark, R.G.; Rückert, I.-M.; Peters, A.; Huth, C.; Stöckl, D.; Giani, G.; Holle, R.
Drug costs in prediabetes and undetected diabetes compared with diagnosed diabetes and normal glucose tolerance: Results from the population-based KORA survey in Germany.
Diabetes Care 36, 53-54 (2013)
Diabetes Care

Severin, F.; Schmidtke, J.; Mühlbacher, A.; Rogowski, W.H.
Eliciting preferences for priority setting in genetic testing: A pilot study comparing best-worst scaling and discrete-choice experiments.
Eur. J. Hum. Genet. 21, 1202-1208 (2013)
Given the increasing number of genetic tests available, decisions have to be made on how to allocate limited health-care resources to them. Different criteria have been proposed to guide priority setting. However, their relative importance is unclear. Discrete-choice experiments (DCEs) and best-worst scaling experiments (BWSs) are methods used to identify and weight various criteria that influence orders of priority. This study tests whether these preference eliciting techniques can be used for prioritising genetic tests and compares the empirical findings resulting from these two approaches. Pilot DCE and BWS questionnaires were developed for the same criteria: prevalence, severity, clinical utility, alternatives to genetic testing available, infrastructure for testing and care established, and urgency of care. Interview-style experiments were carried out among different genetics professionals (mainly clinical geneticists, researchers and biologists). A total of 31 respondents completed the DCE and 26 completed the BWS experiment. Weights for the levels of the six attributes were estimated by conditional logit models. Although the results derived from the DCE and BWS experiments differed in detail, we found similar valuation patterns in the DCE and BWS experiments. The respondents attached greatest value to tests with high clinical utility (defined by the availability of treatments that reduce mortality and morbidity) and to testing for highly prevalent conditions. The findings from this study exemplify how decision makers can use quantitative preference eliciting methods to measure aggregated preferences in order to prioritise alternative clinical interventions. Further research is necessary to confirm the survey results.
European Journal of Human Genetics

Vogl, M.
Improving patient-level costing in the English and the German 'DRG' system.
Health Policy 109, 290-300 (2013)
Objectives: The purpose of this paper is to develop ways to improve patient-level cost apportioning (PLCA) in the English and German inpatient 'DRG' cost accounting systems, to support regulators in improving costing schemes, and to give clinicians and hospital management sophisticated tools to measure and link their management. Methods: The paper analyzes and evaluates the PLCA step in the cost accounting schemes of both countries according to the impact on the key aspects of DRG introduction: transparency and efficiency. The goal is to generate a best available PLCA standard with enhanced accuracy and managerial relevance, the main requirements of cost accounting. Results: A best available PLCA standard in 'DRG' cost accounting uses: (1) the cost-matrix from the German system; (2) a third axis in this matrix, representing service-lines or clinical pathways; (3) a scoring system for key cost drivers with the long-term objective of time-driven activity-based costing and (4) a point of delivery separation. Conclusion: Both systems have elements that the other system can learn from. By combining their strengths, regulators are supported in enhancing PLCA systems, improving the accuracy of national reimbursement and the managerial relevance of inpatient cost accounting systems, in order to reduce costs in health care.
Health Policy

Maier, W.; Holle, R.; Hunger, M.; Peters, A.; Meisinger, C.; Greiser, K.H.; Kluttig, A.; Völzke, H.; Schipf, S.; Moebus, S.; Bokhof, B.; Berger, K.; Mueller, G.; Rathmann, W.; Tamayo, T.; Mielck, A.
The impact of regional deprivation and individual socio-economic status on the prevalence of type 2 diabetes in Germany. A pooled analysis of five population-based studies.
Diabetic Med. 30, 78-86 (2013)
Aim Our objective was to test the hypothesis that the prevalence of Type2 diabetes increases with increasing regional deprivation even after controlling for individual socio-economic status. Methods We pooled cross-sectional data from five German population-based studies. The data set contained information on n=11688 study participants (men 50.1%) aged 4574years, of whom 1008 people had prevalent Type2 diabetes (men 56.2%). Logistic multilevel regression was performed to estimate odds ratios (OR) and 95% confidence intervals (CI) for diabetes prevalence. We controlled for sex, age and lifestyle risk factors, individual socio-economic status and regional deprivation, based on a new small-area deprivation measure, the German Index of Multiple Deprivation. Results Adjusted for sex, age, body mass index (BMI), physical activity, smoking status and alcohol consumption, the prevalence of Type2 diabetes showed a stepwise increase in risk with increasing area deprivation [OR1.88 (95%CI 1.163.04) in quintile4 and OR2.14 (95%CI 1.293.55) in quintile5 compared with the least deprived quintile1], even after controlling for individual socio-economic status. Focusing on individual socio-economic status alone, the risk of having diabetes was significantly higher for low compared with medium or high educational level [OR1.46 (95%CI 1.241.71)] and for the lowest compared with the highest income group [OR1.53 (95%CI 1.181.99)]. Conclusion Regional deprivation plays a significant part in the explanation of diabetes prevalence in Germany independently of individual socio-economic status. The results of the present study could help to target public health measures in deprived regions.
Diabetic Medicine

Becklas, E.; Mielck, A.; Böcken, J.
Das Arzt-Patienten-Verhältnis in der ambulanten Versorgung - Unterschiede zwischen GKV- und PKV-Versicherten.
In: Böcken, J.*; Braun, B.*; Repschläger, U.* [Eds.]: Gesundheitsmonitor 2012: Bürgerorientierung im Gesundheitswesen. Gütersloh: Verl. Bertelsmann Stiftung, 2013. 24-53

Künster, A.K.; Hägele, M.; Schunk, M.; Mielck, A.; Mosandl, A.; Kopecky-Wenzel, M.; Kurz-Adam, M.; Eder-Debye, R.; Fegert, J.; Ziegenhain, U.
Münchner Modell der Früherkennung und Frühen Hilfen für psychosozial hoch belastete Familien.
Psychol. Erz. Unterr. 60, 59-74 (2013)
Das „Münchner Modell der Früherkennung und Frühen Hilfen für ¬psychosozial hoch belastete Familien“ ist ein Präventionsprogramm zur rechtzeitigen und unbürokratischen Unterstützung von jungen Familien mithilfe interdisziplinär eingebundener Früher Hilfen. Es wurde vom Stadtjugendamt und dem Referat für Gesundheit und Umwelt initiiert und wird von diesen gesteuert. Berichtet wird die Fallbearbeitung durch die Fachkräfte für Frühe Hilfen anhand einer fortlaufenden Basisdokumentation von 524 Familien. Aus dieser Dokumentation der Fallbearbeitung lässt sich eine individuelle Anpassung des Beratungsprozesses an die jeweiligen Bedürfnisse der Familie ableiten. Ein breites Repertoire von Hilfemöglichkeiten im Rahmen der bestehenden Regelstrukturen wurde zur Unterstützung der Familien genutzt. Die Evaluation der Ergebnisqualität der Frühen Hilfen konnte mithilfe eines quasi-experimentellen Designs mit Prä-Post-Messungen u. a. eine Steigerung der elterlichen Feinfühligkeit sowie eine Verbesserung des psychosozialen Funktionsniveaus der Hauptbezugsperson zeigen. Einschränkend muss genannt werden, dass die Evaluation der Frühen Hilfen ausschließlich auf den Angaben der Fachkräfte für Frühe Hilfen beruht, die die Familien betreuen. Das Münchner Modell ist eines der wenigen Frühe-Hilfen-Projekte in Deutschland, in denen Frühe Hilfen tatsächlich im Sinne früher Beziehungsförderung konzipiert und umgesetzt werden.
Psychologie in Erziehung und Unterricht

Vogel, B.; Schunk, M.; Lack, N.; Mielck, A.
Ermittlung von Stadtgebieten mit hohem Bedarf an Frühen Hilfen in München: Vorstellung eines neuen Verfahrens auf Basis von Daten zur regionalen Sozialstruktur und zum gesundheitlichen Risiko von Neugeborenen.
Gesundheitswesen 75, 131-138 (2013)
Hintergrund: In Deutschland sind körperliche Bestrafungen und seelische Verletzungen zur Maßregelung von Kindern rechtlich verboten. Bei Verstößen gegen diese Verbote kommt es bei den Kindern häufig zu großen gesundheitlichen Beeinträchtigungen. Frühe Hilfen sind präventiv ausgerichtete Unterstützungs- und Hilfsmaßnahmen für Familien in belasteten Lebenslagen; sie sollen vor allem die Chancen für ein gesundes Aufwachsen der Kinder verbessern. Mithilfe regionaler Bedarfs-Karten lässt sich aufzeigen, in welchen (Stadt-)gebieten der Bedarf an Frühen Hilfen besonders groß ist. Sie können daher einen wichtigen Beitrag leisten zur Fokussierung der Frühe Hilfe - Angebote auf die Familien mit besonders großem Bedarf. Methode: Die hier vorgestellte Methode zur Analyse des regionalspezifischen Bedarfs für Frühe Hilfen basiert auf dem folgenden Verfahren: (a) Suche nach Daten zur Erfassung der Prädiktoren für kindliche Vernachlässigung, Misshandlung und Missbrauch und Abbildung dieser Daten auf die Postleitzahlgebiete in München; (b) Bildung des Summenscores ‚Anzahl der Prädiktoren, die auf erhöhten Bedarf an Frühen Hilfen schließen lassen‘; (c) Einteilung der Postleitzahlgebiete auf Basis dieses Summenscores; (d) kartografische Darstellung der regionalen Verteilung. Ergebnisse: Nach Prüfung der für München verfügbaren Daten konnten auf Ebene der Postleitzahlgebiete 5 Variablen zur Erfassung des regional-spezifischen Bedarfs an Frühen Hilfen definiert werden: Kaufkraftindex, Anteil der Personen mit Hauptschulabschluss, Anteil der Personen mit Migrationshintergrund, Anteil alleinstehender Mütter, Anteil der Neugeborenen mit einem Geburtsgewicht unter 2 500 g. Wird ‚besonders hoher Bedarf an Frühen Hilfen‘ definiert als ‚oberes Quintil der Verteilung bei 3, 4 oder 5 Variablen‘, dann wäre pro Jahr ein Versorgungsbedarf bei insgesamt 1 087 Neugeborenen vorhanden (d. h. bei ca. 10% aller Neugeborenen in München). Schlussfolgerung: Die Angebote der Frühen Hilfen sollten so wenig stigmatisierend sein wie möglich und vor allem die Personen erreichen, bei denen der Bedarf besonders groß ist. Wenn nicht alle Familien in der gesamten Kommune erreicht werden können, dann ist eine Fokussierung auf die Stadtgebiete sinnvoll, in denen besonders viele Familien mit Hilfebedarf wohnen. Eine wissenschaftlich begründete Methode zur Erstellung derartiger Bedarfs-Karten war u. E. jedoch bislang noch nicht vorhanden. Das hier vorgeschlagene Verfahren sollte methodisch weiterentwickelt werden. Es ist flexibel zu handhaben und leicht auf andere Kommunen zu übertragen.
Gesundheitswesen, Das

Schäfer, T.; Pritzkuleit, R.; Jeszenszky, C.; Malzahn, J.; Maier, W.; Günther, K.P.; Niethard, F.
Trends and geographical variation of primary hip and knee joint replacement in Germany.
Osteoarthr. Cartil. 21, 279-288 (2013)
OBJECTIVE: Considerable variation in total hip replacement and total knee replacement (THR/TKR) between regions has been described. The aim of this study was to explore geographical variation in THR and TKR in Germany and to analyse potentially explanatory variables. METHOD: We used data of Germany's largest statutory health insurer. Between 2005 and 2009 451,108 THR and 335,022 TKR were performed. Age-standardised joint replacement rates were calculated for 16 federal states and 407 counties. We performed cluster (Moran's I) and spatial error regression analyses including regional deprivation, osteoarthritis rate, urbanity and number of orthopaedic specialists as dependent variables on county level. RESULTS: In 2009 the overall age-standardised and crude rates were 148.9 (95% CI (confidence interval) 147.6-151.1) and 290.2 for THR, and 132.5 (95% CI 131.3-133.6) and 232.7 for TKR. Between counties THR rates differed by factor 2 (106.1-215.8) and showed significant clusters with high utilisation in South and Northwest Germany. TKR rates differed by factor 3.2 (69.1-219.5) and were also high in South Germany whereas almost all areas in East Germany showed low replacement rates. Differences were pronounced when restricting the analysis to cases with an indication of osteoarthritis. All tested predictors could be identified as significant explanatory variables (each $P < 0.001$). CONCLUSION: This study proofed considerable and consistent geographic variation of THR and TKR in Germany. Thereby relevant explanatory factors were identified. These results may foster the discussion and future research in health services

which should include areas of patients' and doctors' expectation, financial aspects and an outcome-based definition of appropriate supply.
Osteoarthritis and Cartilage

Stollenwerk, B.; Gandjour, A.; Lüngen, M.; Siebert, U.
Accounting for increased non-target-disease-specific mortality in decision-analytic screening models for economic evaluation.
Eur. J. Health Econ. 14, 1035-1048 (2013)
BACKGROUND: Positive screening results are often associated not only with target-disease-specific but also with non-target-disease-specific mortality. In general, this association is due to joint risk factors. Cost-effectiveness estimates based on decision-analytic models may be biased if this association is not reflected appropriately. OBJECTIVE: To develop a procedure for quantifying the degree of bias when an increase in non-target-disease-specific mortality is not considered. METHODS: We developed a family of parametric functions that generate hazard ratios (HRs) of non-target-disease-specific mortality between subjects screened positive and negative, with the HR of target-disease-specific mortality serving as the input variable. To demonstrate the efficacy of this procedure, we fitted a function within the context of coronary artery disease (CAD) risk screening, based on HRs related to different risk factors extracted from published studies. Estimates were embedded into a decision-analytic model, and the impact of 'modelling increased non-target-disease-specific mortality' was assessed. RESULTS: In 55-year-old German men, based on a risk screening with 5 % positively screened subjects, and a CAD risk ratio of 6 within the first year after screening, incremental quality-adjusted life-years were 19 % higher and incremental costs were 8 % lower if no adjustment was made. The effect varied depending on age, gender, the explanatory power of the screening test and other factors. CONCLUSION: Some bias can occur when an increase in non-target-disease-specific mortality is not considered when modelling the outcomes of screening tests.
The European journal of health economics

Schwarzkopf, L.; Menn, P.; Leidl, R.; Graessel, E.; Holle, R.
Are community-living and institutionalized dementia patients cared for differently? Evidence on service utilization and costs of care from German insurance claims data.
BMC Health Serv. Res. 13:2 (2013)
Background: Dementia patients are often cared for in institutional arrangements, which are associated with substantial spending on professional long-term care services. Nevertheless, there is little evidence on the exact cost differences between community-based and institutional dementia care, especially when it comes to the distinct health care services. Adopting the perspective of the German social security system, which combines Statutory Health Insurance and Compulsory Long-Term Care Insurance (payer perspective), our study aimed to compare community-living and institutionalized dementia patients regarding their health care service utilization profiles and to contrast the respective expenditures. Methods: We analysed 2006 claims data for 2,934 institutionalized and 5,484 community-living individuals stratified by so-called care levels, which reflect different needs for support in activities of daily living. Concordant general linear models adjusting for clinical and demographic differences were run for each stratum separately to estimate mean per capita utilization and expenditures in both settings. Subsequently, spending for the community-living and the institutionalized population as a whole was compared within an extended overall model. Results: Regarding both settings, health and long-term care expenditures rose the higher the care level. Thus, long-term care spending was always increased in nursing homes, but health care spending was comparable. However, the underlying service utilization profiles differed, with nursing home residents receiving more frequent visits from medical specialists but fewer in-hospital services and anti-dementia drug prescriptions. Altogether, institutional care required additional yearly per capita expenses of ca. (sic)200 on health and ca. (sic)11,200 on long-term care. Conclusion: Community-based dementia care is cost saving from the payer perspective due to substantially lower long-term care expenditures. Health care spending is comparable but community-living and institutionalized individuals present characteristic service utilization patterns. This apparently reflects the existence of setting-specific care strategies. However, the bare economic figures do not indicate whether these different concepts affect the quality of care provision and disregard patient preferences and caregiver-related aspects. Hence, additional research combining primary and secondary data seems to be required to foster both, sound allocation of scarce resources and the development of patient-centred dementia care in each setting.
BMC Health Services Research

Hunger, M.; Schwarzkopf, L.; Heier, M.; Peters, A.; Holle, R.; KORA Study Group (Holle, R.; Wichmann, H.-E.; John, J.; Illig, T.; Meisinger, C.; Peters, A.)
Official statistics and claims data records indicate non-response and recall bias within survey-based estimates of health care utilization in the older population.
BMC Health Serv. Res. 13:1 (2013)
UNLABELLED: ABSTRACT: BACKGROUND: The validity of survey-based health care utilization estimates in the older population has been poorly researched. Owing to data protection legislation and a great number of different health care insurance providers, the assessment of recall and non-response bias is challenging to impossible in many countries. The objective of our study was to compare estimates from a population-based study in older German adults with external secondary data. METHODS: We used data from the German KORA-Age study, which included 4,127 people aged 65-94 years. Self-report questions covered the utilization of long-term care services, inpatient services, outpatient services, and pharmaceuticals. We calculated age- and sex-standardized mean utilization rates in each domain and compared them with the corresponding estimates derived from official statistics and independent statutory health insurance data. RESULTS: The KORA-Age study underestimated the use of long-term care services (-52%), in-hospital days (-21%) and physician visits (-70%). In contrast, the assessment of drug consumption by postal self-report questionnaires yielded similar estimates to the analysis of insurance claims data (-9%). CONCLUSION: Survey estimates based on self-report tend to underestimate true health care utilization in the older population. Direct validation studies are needed to disentangle the impact of recall and non-response bias.
BMC Health Services Research

Rottmann, M.; Maier, W.; von Klot, S.; Döring, A.; Mielck, A.

Zusammenhang zwischen dem sozialen Status eines Stadtgebietes und den gesundheitlichen Risiken seiner Bewohner: Ergebnisse einer Mehrebenenanalyse zu Übergewicht, Hypertonie und Gesundheitszustand am Beispiel Augsburg.
Gesundheitswesen 75, 134-139 (2013)
Einleitung: In empirischen Studien wurde wiederholt gezeigt, dass der sozioökonomische Status (SES) einer Region den Gesundheitszustand der Bewohner beeinflussen kann, auch nach statistischer Kontrolle individueller Faktoren des SES. In Deutschland sind dazu erst wenige Arbeiten erschienen, zumeist beziehen sie sich auf relativ große Raumeinheiten wie Landkreise. Am Beispiel eines Vergleichs zwischen Stadtgebieten in Augsburg soll in der vorliegenden Arbeit untersucht werden, ob diese regionalen Effekte auch auf innerstädtischer Ebene vorhanden sind. Material und Methoden: In die Analyse eingeschlossen wurden 1 888 Probanden des KORA S4 Surveys im Alter von 25 bis 74 Jahren. Die Stadtgebiete wurden entsprechend der Arbeitslosenquote eingeteilt (niedrig, mittel, hoch). Als abhängige Variablen dienten Angaben zum selbst-eingeschätzten Gesundheitszustand sowie zu 3 Risikofaktoren (Adipositas, hohe Waist-Hip-Ratio und Hypertonie). Als unabhängige Variablen wurden auf individueller Ebene Alter, Geschlecht, Bildung und Arbeitslosigkeit eingeschlossen. Die Auswertung erfolgte mit logistischen Multilevel-Analysen. Ergebnisse: Nach statistischer Kontrolle der individuellen Variablen (Alter, Geschlecht, Bildung, Arbeitslosigkeit) zeigte sich ein signifikanter Zusammenhang zwischen hoher regionaler Arbeitslosenquote und ‚hoher Waist-Hip-Ratio' (OR 1,53; 95% Konf. Intervall 1,03-2,26). Für Adipositas ergab sich ein ähnliches Bild. Für Hypertonie und den selbst-eingeschätzten Gesundheitszustand konnten dagegen keine signifikanten Zusammenhänge mit der regionalen Arbeitslosenquote gefunden werden. Schlussfolgerung: Offenbar gibt es gesundheitliche Risiken, die in Stadtgebieten mit hoher Arbeitslosigkeit besonders groß sind. Eine praktische Folgerung wäre, dass sich die Maßnahmen zur Verringerung dieser Risiken auch und vor allem auf die Stadtgebiete konzentrieren sollten, in denen die Arbeitslosenquote besonders hoch ist. Weitere Untersuchungen sollten sich den Ursachen der hier gezeigten sozialen und räumlichen Ungleichheit widmen.
Gesundheitswesen, Das

Peters, A.; von Klot, S.; Mittleman, M.A.; Meisinger, C.; Hörmann, A.; Kuch, B.; Wichmann, H.-E.
Triggering of acute myocardial infarction by different means of transportation.
Eur. J. Prev. Cardiol. 20, 750-758 (2013)
Background: Prior studies have reported an association between traffic-related air pollution in urban areas and exacerbation of cardiovascular disease. We assess here whether time spent in different modes of transportation can trigger the onset of acute myocardial infarction (AMI).Design: We performed a case-crossover study. We interviewed consecutive cases of AMI in the KORA Myocardial Infarction Registry in Augsburg, Southern Germany between February 1999 and December 2003 eliciting data on potential triggers in the four days preceding myocardial infarction onset.Results: A total of 1459 cases with known date and time of AMI symptom onset, who had survived 24 hours after the onset, completed the registry's standard interview on potential triggers of AMI. An association between exposure to traffic and AMI onset 1 hour later was observed (odds ratio: 3.2; 95% confidence interval [CI]: 2.7-3.9, $p < 0.001$). Using a car was the most common source of traffic exposure; nevertheless, times spent in public transport or on a bicycle were similarly associated with AMI onset 1 hour later. While the highest risk for AMI onset was within 1 hour of exposure to traffic, the elevated risk persisted for up to 6 hours. Women, patients aged 65 years or older, patients not part of the workforce, and those with a history of angina or diabetes exhibited the largest associations between times spent in traffic and AMI onset 1 hour later.Conclusion: The data suggest that transient exposure to traffic regardless of the means of transportation may increase the risk of AMI transiently.
European Journal of Preventive Cardiology

Rogowski, W.H.
An economic theory of the fourth hurdle.
Health Econ. 22, 600-610 (2013)
Third party payers' decision processes for financing health technologies ('fourth hurdle' processes) are subject to intensive descriptive empirical investigation. This paper addresses the need for a theoretical foundation of this research and develops a theoretical framework for analysing fourth hurdle processes from an economics perspective. On the basis of a decision-analytic framework and the theory of agents, fourth hurdle processes are described as sets of institutions to maximize the value derived from finite healthcare resources. Benefits are assumed to arise from the value of better information about and better implementation of the most cost-effective choice. Implementation is improved by decreased information asymmetries and better alignment of incentives. This decreases the effects of ex ante and ex post moral hazard on service provision. Potential indicators of high benefit include high costs associated with wrong decisions and large population sizes affected by the decision. The framework may serve as a basis both for further theoretical work, for example, on the appropriate degree of participation as well as further empirical work, for example, on comparative assessments of fourth hurdle processes. It needs to be complemented by frameworks for analysing fourth hurdle institutions developed by other disciplines such as bioethics or law.
Health Economics

Mielck, A.
Social epidemiology and health economics: The need to find common grounds.
Eur. J. Public Health 23:2 (2013)
There is an ever increasing number of studies focusing on health inequalities, expanding also into areas such as life course analyses and regional inequalities. By describing these inequalities in much detail, they continuously add to our understanding of the underlying causes, such as exposures during childhood and obesogenic environment. Today, it is widely acknowledged that more research is needed with a focus on interventions that could help to reduce health inequalities, and that a closer cooperation is needed between public health researchers and policy makers. It is less often pointed out that closer cooperation also is needed between social epidemiologists and health economists. Policy makers need to answer tough questions: How effective are interventions aimed at reducing health inequalities, and how much do they cost? What are the most cost-effective strategies, and how do they compare with the cost-effectiveness of other public health

programs? How could we compare the 'benefit' between interventions that target health inequalities and other interventions that are directed towards improving health in the total population? These questions are rarely addressed in public health research.
European Journal of Public Health
Editorial
Editorial

Schenkel, J.; Reitmeir, P.; von Reden, S.; Holle, R.; Boy, S.; Haberl, R.; Audebert, H.
Kostenanalyse telemedizinischer Schlaganfallbehandlung. Veränderung der stationären Behandlungskosten und Pflegekosten am Beispiel des Telemedizinischen Projekts zur integrierten Schlaganfallversorgung in Bayern (TEMPiS).
Gesundheitswesen 75, 405-412 (2013)
Hintergrund: Die Behandlung auf TeleStroke-Units führt im Vergleich zur unspezialisierten Schlaganfalltherapie zu einem verbesserten Patienten-Outcome. Diese Arbeit untersucht, wie sich dieses neue Behandlungskonzept auf die Kosten der stationären und der nachstationären Versorgung auswirkt. Methoden: Analysiert wurden die stationären Behandlungskosten und die Pflegeversicherungs-Leistungen von Schlaganfallpatienten (versichert bei der AOK Bayern), die im telemedizinisch unterstützten Schlaganfall-Netzwerk TEMPiS (Telemedizinisches Projekt zur integrierten Schlaganfallversorgung) behandelt wurden, im Vergleich zu Schlaganfallpatienten aus gematchten Kliniken ohne spezialisiertes Therapieangebot und ohne Telemedizinanbindung. Die Kosten der Kranken- und Pflegeversicherung wurden über 30 Monate nachbeobachtet. Zum Ausschluss von vorbestehenden Unterschieden zwischen den Kliniken wurde zusätzlich ein Zeitraum vor der Netzwerk-Einführung untersucht. Ergebnisse: Im Zeitraum nach der Netzwerkeinführung wurden 1 277 Schlaganfallpatienten (767 TEMPiS-Kliniken; 510 Vergleichskliniken) untersucht. Die Patienten der Interventions-Kliniken hatten über 30 Monate einen signifikant günstigeren Verlauf hinsichtlich der Pflegestufen-Einteilung. Diese Behandlung war zwar mit höheren akutstationären Kosten (5 309 € vs. 4 901 €, p=0,04), jedoch mit geringeren Pflegeversicherungs-Leistungen (3 946 € vs. 5 132 €; p=0,04) verbunden. Die erfassten absoluten Gesamtkosten im Beobachtungszeitraum waren in beiden Gruppen gleich - die Pflegeversicherungs-Leistungen pro überlebtem Patientenjahr in der Interventionsgruppe niedriger (1 953 € vs. 2 635 €; p=0,005). Im Zeitraum vor TEMPiS-Einführung ergaben sich keine signifikanten Outcome- und Kostendifferenzen zwischen den Klinikgruppen. Schlussfolgerungen: Die erhöhten Kosten für die akute telemedizinische Schlaganfall-Behandlung im Netzwerk wurden durch niedrigere Folgekosten kompensiert.
Gesundheitswesen, Das

Fuller, N.R.; Colagiuri, S.; Schofield, D.; Olson, A.D.; Shrestha, R.; Holzapfel, C.; Wolfenstetter, S.B.; Holle, R.; Ahern, A.L.; Hauner, H.; Jebb, S.A.; Caterson, I.D.
A within-trial cost-effectiveness analysis of primary care referral to a commercial provider for weight loss treatment, relative to standard care - an international randomised controlled trial.
Int. J. Obes. 37, 828-834 (2013)
Background:Due to the high prevalence of overweight and obesity there is a need to identify cost-effective approaches for weight loss in primary care and community settings.Objective:We evaluated the cost effectiveness of two weight loss programmes of 1-year duration, either standard care (SC) as defined by national guidelines, or a commercial provider (Weight Watchers) (CP).Design:This analysis was based on a randomised controlled trial of 772 adults (87% female; age 47.4±12.9 years; body mass index 31.4±2.6 kg m(-2)) recruited by health professionals in primary care in Australia, United Kingdom and Germany. Both a health sector and societal perspective were adopted to calculate the cost per kilogram of weight loss and the ICER, expressed as the cost per quality adjusted life year (QALY).Results:The cost per kilogram of weight loss was USD122, 90 and 180 for the CP in Australia, the United Kingdom and Germany, respectively. For SC the cost was USD138, 151 and 133, respectively. From a health-sector perspective, the ICER for the CP relative to SC was USD18 266, 12 100 and 40 933 for Australia, the United Kingdom and Germany, respectively. Corresponding societal ICER figures were USD31 663, 24 996 and 51 571.Conclusion:The CP was a cost-effective approach from a health funder and societal perspective. Despite participants in the CP group attending two to three times more meetings than the SC group, the CP was still cost effective even including these added patient travel costs. This study indicates that it is cost effective for general practitioners (GPs) to refer overweight and obese patients to a CP, which may be better value than expending public funds on GP visits to manage this problem.
International Journal of Obesity

Koller, D.; Hoffmann, F.; Maier, W.; Tholen, K.; Windt, R.; Glaeske, G.
Variation in antibiotic prescriptions: Is area deprivation an explanation? Analysis of 1.2 million children in Germany.
Infection 41, 121-127 (2013)
PURPOSE: Inadequate use of antibiotics can lead to problems such as resistance. Overuse is especially a problem for children, since they are more affected by acute (often virus-caused) infections. While the problem has been addressed internationally over the past several years, regional variations in prescriptions are striking. Therefore, the present study aims to analyze regional variations in antibiotic prescription on a district level in Germany and tries to identify reasons for those variations through adding possible influencing factors to the analysis on individual and district levels. METHODS: We analyzed 1.2 million children insured in a German health insurance fund. Antibiotic prescriptions were quantified in 2010 and reasons for prescriptions were analyzed in multilevel regressions based on the district of residence, regional deprivation, and age and sex of the child. RESULTS: Thirty-six percent of all children aged 0-17 years received an antibiotic prescription in 2010. In the south, prevalences are generally lower, and also to the very north. The highest prevalences are found in the close-to-border districts in the west, as well as in a band throughout the middle of Germany, in rather low population density areas. Regional variation in the prevalence range from 19 to 53 % between districts. Regional deprivation can explain part of this variation. CONCLUSIONS: Including area deprivation measures helped identify an influence of especially regional income and occupational deprivation on antibiotic prescriptions for children. Regional analysis such as this can help identify specific regions and groups of persons to address information programs on the risks of preventable antibiotic consumption and alternative treatment methods.
Infection - A Journal of Infectious Disease

Karrasch, S.; Flexeder, C.; Behr, J.; Holle, R.; Huber, R.M.; Jörres, R.A.; Nowak, D.; Peters, A.; Wichmann, H.-E.; Heinrich, J.; Schulz, H.
Spirometric reference values for advanced age from a South German population.
Respiration 85, 210-219 (2013)
Background: The diagnostic use of lung function using spirometry depends on the validity of reference equations. A multitude of spirometric prediction values have been published, but in most of these studies older age groups are underrepresented. Objectives: The aim of the present study was to establish new spirometric reference values for advanced age and to compare these to recent prediction equations from population-based studies. Methods: In the present study spirometry was performed in a population-based sample from the KORA-F4 and KORA-Age cohorts (2006-2009, Augsburg, Germany) comprising 592 never-smoking subjects aged 42-89 years and with no history of respiratory disease. Using quantile regression analysis, equations for the median and lower limit of normal were derived for indices characterizing the expiratory flow-volume curve: forced expiratory volume in 1 s (FEV(1)), forced vital capacity (FVC), FEV(1)/FVC, peak expiratory flow (PEF), and forced expiratory flow rates at 25, 50 and 75% of exhaled FVC (FEF(25), FEF(50) and FEF(75)). Results: FEV(1) and FVC were slightly higher, and PEF was lower compared to recently published equations. Importantly, forced expiratory flow rates at middle and low lung volume, as putative indicators of small airway disease, were in good agreement with recent data, especially for older age. Conclusion: Our study provides up-to-date reference equations for all major indices of flow-volume curves in middle and advanced age in a South German population. The small deviations from published equations indicate that there might be some regional differences of lung function within the Caucasian population of advanced age in Europe.
Respiration

Mielck, A.; Reitmeir, P.; Vogelmann, M.; Leidl, R.
Impact of educational level on health-related quality of life (HRQL): Results from Germany based on the EuroQol 5D (EQ-5D).
Eur. J. Public Health 23, 45-49 (2013)
BACKGROUND: To date, there is hardly any study focussing on the question how the concept of HRQL could deepen our understanding of health inequalities. The study aims at describing this potential by analysing data for adults from Germany. METHODS: The analyses are based on three national, representative surveys conducted from 2006 to 2008. HRQL was assessed by the EuroQol-5D (EQ-5D), the descriptive part (problems in five dimensions) and the valuation of health by visual analogue scale (VAS) rendering a value between '0' (worst) and '100' (best imaginable). The major independent variable is educational level (high vs. low). Four other variables were included (i.e. age, sex, per capita income and chronic disease). Multivariate analyses were performed by logistic and linear regression. RESULTS: Data were available for 5676 persons aged ≥20 years (response rate 73%). The prevalence of 'moderate or severe problems' is especially high in the dimension 'pain/discomfort' (low resp. high educational level: 46.3% resp. 25.0%). The mean VAS-value is 79.8 (low resp. high educational level: 75.3 resp. 83.6). Bivariate and multivariate analyses show that similar differences in VAS-values can be seen even after restricting the analyses to participants with a chronic disease. CONCLUSION: Empirical analyses concerning HRQL could further our understanding of health inequalities. They indicate that low status groups are faced with a double burden, first by increased levels of health impairments, and second by lower levels of HRQL once health is impaired. Thus, the extent of health inequalities could be underestimated if measures of HRQL are not taken into account.
European Journal of Public Health

2012
Blankart, C.R.B.
The organization on healthcare and its impact on outcomes, availability, and access to care.
, Diss., 2012, 1183 S.
Leidl, R.; Reitmeir, P.
Measuring health or choosing which health to buy? A comparison of two types of value sets for the EQ-5D in a German population of chronically ill persons.
Poster: 29th Scientific Plenary Meeting of the EuroQol Group, 13 - 15 September 2012, Rotterdam (2012)
Langer, A.E.
Economic evaluation of disease detection and management: Examples from medical imaging and newborn screening.
München, Ludwig-Maximilians-Universität, Fakultät für Betriebswirtschaft, Diss., 2012, 134 S.
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München, Ludwig-Maximilians-Universität, Diss., 2012, 193 S.
Roll, K.; Stargardt, T.; Schreyögg, J.
Effect of type of insurance and income on waiting time for outpatient care.
Geneva Pap. Risk Insurance: Iss. Pract. 37, 609-632 (2012)
This paper analyses the impact of type of insurance, income and reason for appointment on waiting time for an appointment and waiting time in the physician's practice in the outpatient sector. Data was obtained from a German patient survey conducted between 2007 and 2009. We differentiated between general practitioner (GP) and specialist and controlled for socioeconomic, structural and institutional characteristics as well as interactions between type of insurance and control variables. Our results reveal that private health insurance plays a significant role in faster access to care at GP and specialist practices. Access to care is also highly influenced by the reason for an appointment. We also found that increased income had a negative effect on waiting time in practices and on waiting time for an appointment in GP practices. Whether inequalities in access to health care also impact overall quality of treatment needs to be investigated in future research.
Geneva Papers on Risk and Insurance, The : Issues and Practice

Walter, U.; Gold, C.; Hoffmann, W.; Jahn, I.; Töppich, J.; Wildner, M.; Dubben, S.; Franze, M.; John, J.; Kliche, T.; Lehmann, H.; Naegele, G.; Nöcker, G.; Plaumann, M.; Pott, E.; Robra, B.P.
Memorandum - Forschungsförderung Prävention.
Gesundheitswesen 74, 526-532 (2012)
The memorandum of the research funding of prevention has been devised within the framework of the Prevention Research

Funding Programme of the Federal Ministry of Education and Research. It consists not only of the obtained findings of the research-practice co-operation but also of recommendations for the implementation of prospective, innovational, effective, practice-oriented and sustainable research. The respective knowledge has been acquired from quantitative surveys on the experiences of scientists and practice partners within the prevention research funding project as well as from extensive qualitative methods of structured group evaluation. A participatory co-operation between research and practice based on mutual respect, trust and recognition is seen as mandatory for the further development of both prevention and health promotion research. Research and practice partners are required to engage in an ab initio collaboration starting from the conception phase, whereby it is advisable to encourage and fortify the communication between research, practice and funding partners by systematic surveillance in form of a meta-project. In addition, the inclusion of the target population from the outset and on a collaborative basis is considered as beneficial in order to ensure the practical application of the research findings. Furthermore, innovatory research designs which are able to provide a framework for internal flexibility, continuous re-assessment and adjustment are fundamental for the implementation of practice-oriented research. Moreover, a dynamic co-operation between different groups of interest not only depends on sharing responsibility but also on sufficient funding for both research and practice, which is particularly important for the transfer and communication of the attained findings. With regard to the evaluation of both effectiveness and sustainability of interventions, a research funding project is required which makes long-term results possible through the utilization of regulated monitoring and guarantees quality and continuous effectiveness. Furthermore, in order to stimulate progress within the basic theories of prevention and health promotion, it is also essential for a funding project to focus on elementary concepts. Additionally, for the efficient and sustainable development of health within a population it is advisable to apply both self-contained research and the involvement of primary prevention and health promotion to research projects concerning health, social affairs, education, work and environment.
Gesundheitswesen, Das

Tiemann, O.; Schreyögg, J.
Changes in hospital efficiency after privatization.
Health Care Manag. Sci. 15, 310-326 (2012)
We investigated the effects of privatization on hospital efficiency in Germany. To do so, we obtained boot-strapped data envelopment analysis (DEA) efficiency scores in the first stage of our analysis and subsequently employed a difference-in-difference matching approach within a panel regression framework. Our findings show that conversions from public to private for-profit status were associated with an increase in efficiency of between 2.9 and 4.9%. We defined four alternative post-privatization periods and found that the increase in efficiency after a conversion to private for-profit status appeared to be permanent. We also observed an increase in efficiency for the first three years after hospitals were converted to private non-profit status, but our estimations suggest that this effect was rather transitory. Our findings also show that the efficiency gains after a conversion to private for-profit status were achieved through substantial decreases in staffing ratios in all analyzed staff categories with the exception of physicians and administrative staff. It was also striking that the efficiency gains of hospitals converted to for-profit status were significantly lower in the diagnosis-related groups (DRG) era than in the pre-DRG era. Altogether, our results suggest that converting hospitals to private for-profit status may be an effective way to ensure the scarce resources in the hospital sector are used more efficiently.
Health Care Management Science

Mielck, A.
Armut und Gesundheit in München.
In: Enke, M.* [Eds.]: Proceedings (Armut macht krank - Krankheit macht arm?!. Dokumentation einer gemeinsamen Fachtagung des Regionalen Knotens Bayern, München, 3.12.2012). München: LZG, Regionaler Knoten Bayern, 2012. 16-21
John, J.; Teuner, C.M.
Combating pediatric obesity in Germany: The role of economic findings in informing policy.
Expert Rev. Pharmacoecon. Outcomes Res. 12, 733-743 (2012)
As in most countries, overweight and obesity among children and adolescents have dramatically increased in Germany over the last two decades. This serious public-health challenge has stimulated many efforts to curb the pediatric obesity epidemic. In this article, the authors briefly describe these efforts and examine the role of health economics in informing German health policies and evaluating the outcomes of interventions aimed at reducing pediatric obesity. The findings indicate that the tools of health-economic analysis have rarely been used to guide the development of strategies to prevent pediatric obesity and to support decision-making on the use of the scarce resources available for preventive actions. The authors give some reasons why health economics has not been an important policy tool so far and make some recommendations for how this could be changed. Reasons impeding health economics playing a more important role in this area are the existence of many unsolved issues in the methods of health economic evaluation and large gaps in the knowledge base on the effectiveness of interventions. Nevertheless, these methods should be considered to be indispensible tools of health policy development. However, taking into account the broad range of political and societal concerns related to pediatric obesity, decision-making in this area will ultimately rest on a process of deliberate thinking integrating different perspectives among, which health economics will be one.
Expert Review of Pharmacoeconomics and Outcomes Research

Mielck, A.
Inklusion und Exklusion - die Folgen für den Gesundheitszustand.
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Bolte, G.; Bunge, C.; Hornberg, C.; Köckler, H.; Mielck, A.
Umweltgerechtigkeit. Chancengleichheit bei Umwelt und Gesundheit. Eine Einführung in die Thematik und Zielsetzung dieses Buches.
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Bolte, G.; Voigtländer, S.; Razum, O.; Mielck, A.
Modelle zur Erklärung des Zusammenhangs zwischen sozialer Lage, Umwelt und Gesundheit.

In: Bolte, G.*; Bunge, C.*; Hornberg, C.*; Köckler, H.*; Mielck, A.* [Eds.]: Umweltgerechtigkeit. Chancengleichheit bei Umwelt und Gesundheit: Konzepte, Datenlage und Handlungsperspektiven. Bern: Huber, 2012. 39-50

Bolte, G.; Bunge, C.; Hornberg, C.; Köckler, H.; Mielck, A.
Akteure vor Ort: Einleitung.
In: Bolte, G.*; Bunge, C.*; Hornberg, C.*; Köckler, H.*; Mielck, A.* [Eds.]: Umweltgerechtigkeit. Chancengleichheit bei Umwelt und Gesundheit: Konzepte, Datenlage und Handlungsperspektiven. Bern: Huber, 2012. 329

Bolte, G.; Bunge, C.; Hornberg, C.; Köckler, H.; Mielck, A.
Mehr Umweltgerechtigkeit erreichen.
In: Bolte, G.*; Bunge, C.*; Hornberg, C.*; Köckler, H.*; Mielck, A.* [Eds.]: Umweltgerechtigkeit. Chancengleichheit bei Umwelt und Gesundheit: Konzepte, Datenlage und Handlungsperspektiven. Bern: Huber, 2012. 421-426

Bäumler, M.; Stargardt, T.; Schreyögg, J.; Busse, R.
Cost effectiveness of drug-eluting stents in acute myocardial infarction patients in Germany: Results from administrative data using a propensity score-matching approach.
Appl. Health Econ. Health Policy 10, 235-248 (2012)
BACKGROUND: The high number of patients with acute myocardial infarction (AMI) has facilitated greater research, resulting in the development of innovative medical devices. So far, results from economic evaluations that compared drug-eluting stents (DES) and bare-metal stents (BMS) have not shown clear evidence that one intervention is more cost effective than the other. OBJECTIVE: The aim of this study was to measure the cost effectiveness of DES compared with BMS in routine care. METHODS: We used administrative data from a large German sickness fund to compare the costs and effectiveness of DES and BMS in patients with AMI. Patients with hospital admission after AMI in 2004 and 2005 were followed up for 1 year after hospital discharge. The cost of treatment and survival after 365 days were compared for patients treated with DES and BMS. We adjusted for covariates defined according to the Ontario Acute Myocardial Infarction Mortality Prediction Rules using propensity score matching. After matching, we calculated incremental cost-effectiveness ratios (ICERs) by (i) using sample means based on bootstrapping procedures and (ii) estimating generalized linear mixed models for costs and survival. RESULTS: After propensity score matching, the sample included 719 patients treated with DES and 719 patients treated with BMS. A comparison of sample means resulted in average costs of € 12 714 and € 11 714 for DES and BMS, respectively, in 2005 German euros. Difference in 365-day survival was not statistically significant (700 patients with DES and 701 with BMS). The ICER of DES versus BMS was -€ 718 709 per life saved. Bootstrapping resulted in DES being dominated by BMS in 54.5% of replications and DES being a dominant strategy in 2.7% of replications. Results from regression models and sensitivity analyses confirm these results. CONCLUSION: Treatment with DES after admission with AMI is less cost effective than treatment with BMS. Our results are in line with other cost-effectiveness analyses that used administrative data, i.e. under routine care conditions. However, our results do not preclude that DES may be cost effective in specific patient subgroups.
Applied Health Economics and Health Policy

Tamayo, T.; Schipf, S.; Maier, W.
Regional differences in the abundance of type 2 diabetes in Germany. What influence does the structural disadvantage of a region have?
Diabetes Stoffwechs. Herz 21, 326-329 (2012)
Diabetes, Stoffwechsel und Herz

Langer, A.; Brockow, I.; Nennstiel-Ratzel, U.; Menn, P.
The cost-effectiveness of tracking newborns with bilateral hearing impairment in Bavaria: A decision-analytic model.
BMC Health Serv. Res. 12:418 (2012)
Background: Although several countries, including Germany, have established newborn hearing screening programmes for early detection and treatment of newborns with hearing impairments, nationwide tracking systems for follow-up of newborns with positive test results until diagnosis of hearing impairment have often not been implemented. However, a recent study on universal newborn hearing screening in Bavaria showed that, in a high proportion of newborns, early diagnosis was only possible with the use of a tracking system. The aim of this study was, therefore, to assess the cost-effectiveness of tracking newborns with bilateral hearing impairment in Bavaria. Methods: Data from a Bavarian pilot project on newborn hearing screening and Bavarian newborn hearing screening facilities were used to assess the cost-effectiveness of the inclusion of a tracking system within a newborn hearing screening programme. A model-based cost-effectiveness analysis was conducted. The time horizon of the model was limited to the newborn hearing screening programme. Costs of the initial hearing screening test and subsequent tests were included, as well as costs of diagnosis and costs of tracking. The outcome measure of the economic analysis was the cost per case of bilateral hearing impairment detected. In order to reflect uncertainty, deterministic and probabilistic sensitivity analyses were performed. Results: The incremental cost-effectiveness ratio of tracking vs. no tracking was (sic)1,697 per additional case of bilateral hearing impairment detected. Conclusions: Compared with no tracking, tracking resulted in more cases of bilateral hearing impairment detected as well as higher costs. If society is willing to pay at least (sic)1,697 per additional case of bilateral hearing impairment detected, tracking can be recommended.
BMC Health Services Research

Rückert, I.-M.; Maier, W.; Mielck, A.; Schipf, S.; Völzke, H.; Kluttig, A.; Greiser, K.-H.; Berger, K.; Müller, G.; Ellert, U.; Neuhauser, H.; Rathmann, W.; Tamayo, T.; Moebus, S.; Andrich, S.; Meisinger, C.
Personal attributes that influence the adequate management of hypertension and dyslipidemia in patients with type 2 diabetes. Results from the DIAB-CORE cooperation.
Cardiovasc. Diabetol. 11:120 (2012)
Background: Hypertension and dyslipidemia are often insufficiently controlled in persons with type 2 diabetes (T2D) in Germany. In the current study we evaluated individual characteristics that are assumed to influence the adequate treatment and control of hypertension and dyslipidemia and aimed to identify the patient group with the most urgent need for improved health care. Methods: The analysis was based on the DIAB-CORE project in which cross-sectional data from five regional population-based studies and one nationwide German study, conducted between 1997 and 2006, were pooled. We compared the frequencies of socio-economic and lifestyle factors along with comorbidities in hypertensive participants with or

without the blood pressure target of < 140/90 mmHg. Similar studies were also performed in participants with dyslipidemia with and without the target of total cholesterol/HDL cholesterol ratio < 5. Furthermore, we compared participants who received antihypertensive/lipid lowering treatment with those who were untreated. Univariable and multivariable logistic regression models were used to assess the odds of potentially influential factors. Results: We included 1287 participants with T2D of whom n = 1048 had hypertension and n = 636 had dyslipidemia. Uncontrolled blood pressure was associated with male sex, low body mass index (BMI), no history of myocardial infarction (MI) and study site. Uncontrolled blood lipid levels were associated with male sex, no history of MI and study site. The odds of receiving no pharmacotherapy for hypertension were significantly greater in men, younger participants, those with BMI < 30 kg/m2 and those without previous MI or stroke. Participants with dyslipidemia received lipid lowering medication less frequently if they were male and had not previously had an MI. The more recent studies HNR and CARLA had the greatest numbers of well controlled and treated participants. Conclusion: In the DIAB-CORE study, the patient group with the greatest odds of uncontrolled co-morbidities and no pharmacotherapy was more likely comprised of younger men with low BMI and no history of cardiovascular disease.
Cardiovascular Diabetology

Gruber, E.V.; Stock, S.; Stollenwerk, B.
Breast cancer attributable costs in Germany: A top-down approach based on sickness funds data.
PLoS ONE 7:e51312 (2012)
Background Breast cancer is the leading cause of death from cancer among women in Germany. Despite its clinical and economic relevance, no attributable costs for breast cancer have been reported for Germany so far. The objective of this study is to estimate age-specific breast cancer attributable health expenditures for Germany. Methods Sickness fund data from 1999 representing about 26 million insured (i.e. 32% of the total German population) have been analysed using generalized additive models and the error propagation law. Costs have been inflated to 2010. Results Breast cancer attributable costs decreased with age. Among breast cancer patients aged 30–45 years, about 90% of all health expenditures were due to breast cancer, whereas in breast cancer patients aged 80–90 years, about 50% were due to breast cancer. Breast cancer attributable costs amounted to about €9,000 annually for patients below 55 years of age and declined to about €3,000 in 90-year-old breast cancer patients. Conclusion This analysis provides estimates of attributable breast cancer costs in Germany. Compared with the international literature, the estimates were plausible but had a tendency to underestimate breast cancer attributable costs.
PLoS ONE

Maier, W.; Koller, D.; Mielck, A.
Regionale Deprivation und gesundheitliche Risiken als Indikatoren für Umweltgerechtigkeit.
In: Bolte, G.*; Bunge, C.*; Hornberg, C.*; Köckler, H.*; Mielck, A.* [Eds.]: Umweltgerechtigkeit. Chancengleichheit bei Umwelt und Gesundheit: Konzepte, Datenlage und Handlungsperspektiven. Bern: Huber, 2012. 61-72
Hunger, M.; Döring, A.; Holle, R.
Longitudinal beta regression models for analyzing health-related quality of life scores over time.
BMC Med. Res. Methodol. 12:144 (2012)
ABSTRACT: BACKGROUND: Health-related quality of life (HRQL) has become an increasingly important outcome parameter in clinical trials and epidemiological research. HRQL scores are typically bounded at both ends of the scale and often highly skewed. Several regression techniques have been proposed to model such data in cross-sectional studies, however, methods applicable in longitudinal research are less well researched. This study examined the use of beta regression models for analyzing longitudinal HRQL data using two empirical examples with distributional features typically encountered in practice. METHODS: We used SF-6D utility data from a German older age cohort study and stroke-specific HRQL data from a randomized controlled trial. We described the conceptual differences between mixed and marginal beta regression models and compared both models to the commonly used linear mixed model in terms of overall fit and predictive accuracy. RESULTS: At any measurement time, the beta distribution fitted the SF-6D utility data and strokespecific HRQL data better than the normal distribution. The mixed beta model showed better likelihood-based fit statistics than the linear mixed model and respected the boundedness of the outcome variable. However, it tended to underestimate the true mean at the upper part of the distribution. Adjusted group means from marginal beta model and linear mixed model were nearly identical but differences could be observed with respect to standard errors. CONCLUSIONS: Understanding the conceptual differences between mixed and marginal beta regression models is important for their proper use in the analysis of longitudinal HRQL data. Beta regression fits the typical distribution of HRQL data better than linear mixed models, however, if focus is on estimating group mean scores rather than making individual predictions, the two methods might not differ substantially.
BMC Medical Research Methodology

Wolfenstetter, S.B.; Menn, P.; Holle, R.; Mielck, A.; Meisinger, C.; von Lengerke, T.
Body weight changes and outpatient medical care utilisation: Results of the MONICA/KORA cohorts S3/F3 and S4/F4.
GMS Psycho-Social-Medicine 9:Doc09 (2012)
Objectives: To test the effects of body weight maintenance, gain, and loss on health care utilisation in terms of outpatient visits to different kinds of physicians in the general adult population.Methods: Self-reported utilisation data were collected within two population-based cohorts (baseline surveys: MONICA-S3 1994/95 and KORA-S4 1999/2001; follow-ups: KORA-F3 2004/05 and KORA-F4 2006/08) in the region of Augsburg, Germany, and were pooled for present purposes. N=5,147 adults (complete cases) aged 25 to 64 years at baseline participated. Number of visits to general practitioners (GPs), internists, and other specialists as well as the total number of physician visits at follow-up were compared across 10 groups defined by body mass index (BMI) category maintenance or change. Body weight and height were measured anthropometrically. Hierarchical generalized linear regression analyses with negative binomial distribution adjusted for sex, age, socioeconomic status (SES), survey, and the need factors incident diabetes and first cancer between baseline and follow-up were conducted.Results: In fully adjusted models, compared to the group of participants that maintained normal weight from baseline to follow-up, the following groups had significantly higher GP utilisation rates: weight gain from normal weight

(+36%), weight loss from preobesity (+39%), maintained preobesity (+34%), weight gain after preobesity (+43%), maintained moderate obesity (+48%), weight gain from moderate obesity (+107%), weight loss from severe obesity (+114%), and maintained severe obesity (+83%). Regarding internists, those maintaining moderate obesity reported +107% more visits; those with weight gain from moderate obesity reported +91%. The latter group also had +41% more consultations with other physicians. Across all physicians, mean number of visits were estimated at 7.8 per year for maintained normal weight, 9 for maintained preobesity, 11 for maintained moderate obesity, and 12 for maintained severe obesity. Among those with weight loss, the mean number of visits were 8.7, 10.6 and 10.8 for baseline preobesity, moderate obesity, and severe obesity, respectively. Finally, those with weight gain from normal weight and preobesity reported 9.4 and 9.3 visits, respectively, and those with baseline moderate and follow-up severe obesity reported 13.1 visits (the most overall). Women reported higher GP and other physician utilisation. While all utilisation rates increased with age, GP utilisation was lower in middle to high SES groups.Conclusion: Compared to maintained normal weight over a 7- to 10-year period, maintained overweight, weight gain and weight loss are associated with higher outpatient physician utilisation in adults, especially after baseline obesity. These effects only partly became insignificant after inclusion of incident diabetes or first cancer into the model. Future research should further elucidate the associations between weight development and health care utilisation by BMI status and the mechanisms underlying these associations.
GMS Psycho-Social Medicine

Seidl, H.; Meisinger, C.; Wende, R.; Holle, R.
Empirical analysis shows reduced cost data collection may be an efficient method in economic clinical trials.
BMC Health Serv. Res. 12:318 (2012)
BACKGROUND: Data collection for economic evaluation alongside clinical trials is burdensome and cost-intensive. Limiting both the frequency of data collection and recall periods can solve the problem. As a consequence, gaps in survey periods arise and must be filled appropriately. The aims of our study are to assess the validity of incomplete cost data collection and define suitable resource categories. METHODS: In the randomised KORINNA study, cost data from 234 elderly patients were collected quarterly over a 1-year period. Different strategies for incomplete data collection were compared with complete data collection. The sample size calculation was modified in response to elasticity of variance. RESULTS: Resource categories suitable for incomplete data collection were physiotherapy, ambulatory clinic in hospital, medication, consultations, outpatient nursing service and paid household help.Cost estimation from complete and incomplete data collection showed no difference when omitting information from one quarter. When omitting information from two quarters, costs were underestimated by 3.9% to 4.6%.With respect to the observed increased standard deviation, a larger sample size would be required, increased by 3%. Nevertheless, more time was saved than extra time would be required for additional patients. CONCLUSION: Cost data can be collected efficiently by reducing the frequency of data collection. This can be achieved by incomplete data collection for shortened periods or complete data collection by extending recall windows. In our analysis, cost estimates per year for ambulatory healthcare and non-healthcare services in terms of three data collections was as valid and accurate as a four complete data collections. In contrast, data on hospitalisation, rehabilitation stays and care insurance benefits should be collected for the entire target period, using extended recall windows. When applying the method of incomplete data collection, sample size calculation has to be modified because of the increased standard deviation. This approach is suitable to enable economic evaluation with lower costs to both study participants and investigators.Trial registrationThe trial registration number is ISRCTN02893746.
BMC Health Services Research

Mielck, A.
Armut und Gesundheit in München. Expertise für den Münchner Armutsbericht 2011/2012
Armutsbericht 2011, 1-38 (2012)
Der 'Münchner Armutsbericht 2000' (Sozialreferat 2002a) enthält ein längeres Kapitel über 'Kinderarmut und Gesundheit'. Bezogen auf München wurden hier vor allem Ergebnisse aus den folgenden Datenquellen vorgestellt: Schuleingangsuntersuchung, schulärztliche Unter-suchung der 10-12jährigen Kinder, Befragung von Berufsschülern/innen aus dem Jahr 1999, Befragung bei Personen aus der Altersgruppe 13-25 aus dem Jahr 1995. Die Auswertungen bestätigen, dass die in anderen Studien immer wieder gefundenen Zusammenhänge zwischen Armut und Gesundheit auch in München vorhanden sind. In den nächsten beiden Armuts-berichten 'Fortschreibung 2002' (Sozialreferat 2002b) und 'Fortschreibung 2004' (Sozialreferat 2006) taucht das Thema 'Gesundheit' kaum auf. Im letzten Münchner Armutsbericht (Sozialreferat 2008) werden in einem kurzen Abschnitt zum Thema 'Gesundheit' einige Ergebnisse aus der Münchner Gesundheitsberichterstattung (siehe unten) vorgestellt. Weiter-gehende Analysen sind nicht enthalten. Es ist daher sehr zu begrüßen, dass dem Thema 'Armut und Gesundheit' im neuen Münchner Armutsbericht jetzt wieder mehr Aufmerksamkeit gewidmet wird. In letzter Zeit häufen sich in Deutschland nicht nur die Armutsberichte, sondern auch die Berichte über den Zusammenhang zwischen der sozialen Ungleichheit einerseits und dem Gesundheitszustand andererseits. In einer kaum mehr überschaubaren Vielzahl von Arbeiten ist immer wieder gezeigt worden, dass Personen mit niedrigem sozialen Status zumeist einen besonders schlechten Gesundheitszustand aufweisen, dass sie kränker sind und früher sterben als Personen mit höherem sozialen Status (Mielck 2005; Richter/Hurrelmann 2009). Es ist daher bestimmt sinnvoll, auch in den Armutsberichten auf diese Problematik hinzuweisen. Im Folgenden werden zunächst einige empirische Analysen aus München vorgestellt. Sie sollen verdeutlichen, dass Armut und Gesundheit auch in einer so vergleichsweise wohlhabenden Stadt wie München miteinander zusammenhängen. Das anschließende Kapitel ist überschrieben mit: Weitere Stellungnahmen in München zum Thema 'Armut und Gesundheit'. Hier wird darauf hingewiesen, dass (gesundheits-)politische Stellungnahmen zum Thema 'Armut und Gesundheit' in München schon seit vielen Jahren vorhanden sind, dass dieses Thema also schon lange im 'politischen Bewusstsein' angekommen ist. Im nächsten Kapitel werden Ergebnisse aus der 'Münchner Bürgerinnen- und Bürgerbefragung 2010' vorgestellt. Die Befragung enthält zwar keine Fragen zum Gesundheitszustand und zum Gesundheitsverhalten, wohl aber Fragen zu einigen gesundheitlichen Belastungen und

Ressourcen (z.B. Lärm und Luftverschmutzung, Erreichbarkeit und Attraktivität von Grünflächen und Sportanlagen, Zufriedenheit mit der gesundheitlichen Versorgung). Die Analyse dieser Daten kann somit aktuelle Informationen bereitstellen auch über die sozialen Unterschiede bei diesen gesundheitlichen Belastungen und Ressourcen. Im fünften Kapitel wird dann der Blick auf die allgemeine wissenschaftliche Diskussion zum Thema 'Armut und Gesundheit' erweitert, um so die Ergebnisse aus München einordnen und die künftigen Herausforderungen besser ableiten zu können. Der Abschluss wird durch ein kurzes Kapitel zu 'Zusammenfassung und Ausblick' gebildet.
Rezension
Recension

Batscheider, A.; Zakrzewska, S.; Heinrich, J.; Teuner, C.M.; Menn, P.; Bauer, C.P.; Hoffmann, U.; Koletzko, S.; Lehmann, I.; Herbarth, O.; von Berg, A.; Berdel, D.; Krämer, U.; Schaaf, B.; Wichmann, H.-E.; Leidl, R.
Exposure to second-hand smoke and direct healthcare costs in children - results from two German birth cohorts, GINIplus and LISAplus.
BMC Health Serv. Res. 12:344 (2012)
ABSTRACT: BACKGROUND: Although the negative health consequences of the exposure to second hand tobacco smoke during childhood are already known, evidence on the economic consequences is still rare. The aim of this study was to estimate excess healthcare costs of exposure to tobacco smoke in German children. METHODS: The study is based on data from two birth cohort studies of 3,518 children aged 9-11 years with information on healthcare utilisation and tobacco smoke exposure: the GINIplus study (German Infant Study On The Influence Of Nutrition Intervention Plus Environmental And Genetic Influences On Allergy Development) and the LISAplus study (Influence of Life-Style Factors On The Development Of The Immune System And Allergies In East And West Germany Plus The Influence Of Traffic Emissions And Genetics). Direct medical costs were estimated using a bottom-up approach (base year 2007). We investigated the impact of tobacco smoke exposure in different environments on the main components of direct healthcare costs using descriptive analysis and a multivariate two-step regression analysis. RESULTS: Descriptive analysis showed that average annual medical costs (physician visits, physical therapy and hospital treatment) were considerably higher for children exposed to second-hand tobacco smoke at home (indoors or on patio/balcony) compared with those who were not exposed. Regression analysis confirmed these descriptive trends: the odds of positive costs and the amount of total costs are significantly elevated for children exposed to tobacco smoke at home after adjusting for confounding variables. Combining the two steps of the regression model shows smoking attributable total costs per child exposed at home of [euro sign]87 [10--165] (patio/balcony) and [euro sign]144 [6--305] (indoors) compared to those with no exposure. Children not exposed at home but in other places showed only a small, but not significant, difference in total costs compared to those with no exposure. CONCLUSIONS: This study shows adverse economic consequences of second-hand smoke in children depending on proximity of exposure. Tobacco smoke exposure seems to affect healthcare utilisation in children who are not only exposed to smoke indoors but also if parents reported exclusively smoking on patio or balcony. Preventing children from exposure to second-hand tobacco smoke might thus be desirable not only from a health but also from an economic perspective.
BMC Health Services Research

Fischer, K.E.
Empirical analyses of coverage decision-making on health technologies.
München, Ludwig-Maximilians-Universität, Fakultät für Betriebswirtschaft, Diss., 2012, 171 S.

Langer, A.; Holle, R.; John, J.
Specific guidelines for assessing and improving the methodological quality of economic evaluations of newborn screening.
BMC Health Serv. Res. 12:300 (2012)
Background: Economic evaluation of newborn screening poses specific methodological challenges. Amongst others, these challenges refer to the use of quality adjusted life years (QALYs) in newborns, and which costs and outcomes need to be considered in a full evaluation of newborn screening programmes. Because of the increasing scale and scope of such programmes, a better understanding of the methods of high-quality economic evaluations may be crucial for both producers/authors and consumers/reviewers of newborn screening-related economic evaluations. The aim of this study was therefore to develop specific guidelines designed to assess and improve the methodological quality of economic evaluations in newborn screening. Methods: To develop the guidelines, existing guidelines for assessing the quality of economic evaluations were identified through a literature search, and were reviewed and consolidated using a deductive iterative approach. In a subsequent test phase, these guidelines were applied to various economic evaluations which acted as case studies. Results: The guidelines for assessing and improving the methodological quality of economic evaluations in newborn screening are organized into 11 categories: "bibliographic details", "study question and design", "modelling", "health outcomes", "costs", "discounting", "presentation of results", "sensitivity analyses", "discussion", "conclusions", and "commentary". Conclusions: The application of the guidelines highlights important issues regarding newborn screening-related economic evaluations, and underscores the need for such issues to be afforded greater consideration in future economic evaluations. The variety in methodological quality detected by this study reveals the need for specific guidelines on the appropriate methods for conducting sound economic evaluations in newborn screening.
BMC Health Services Research

Shenoy, A.U.; Aljutaili, M.; Stollenwerk, B.
Limited economic evidence of carotid artery stenosis diagnosis and treatment: A systematic review.
Eur. J. Vasc. Endovasc. Surg. 44, 505-513 (2012)
The objective of this article is to assess the availability and validity of economic evaluations of carotid artery stenosis (CS) diagnosis and treatment. DESIGN: Systematic review of economic evaluations of the diagnosis and treatment of CS. METHODS: Systematic review of full economic evaluations published in Medline and Google Scholar up until 28 February 2012. Based on economic checklists (Evers and Philips), the identified studies were classified as high, medium, or low quality. RESULTS: Twenty-three evaluations were identified. The study quality ranged from 26% to 84% of all achievable points (Evers).

Seven studies were of high, eight of medium and eight of low quality. No comparison was made between carotid angioplasty and stenting (CAS) and best medical treatment (BMT). For subjects with severe stenosis, comparisons of carotid endarterectomy (CEA) and BMT were also missing. Three of five studies dealing with pre-operative imaging found that duplex Doppler ultrasound (US) was cost-effective compared with carotid angiogram (AG). CONCLUSIONS: There is a huge lack of high-quality studies and of studies that confirm published results. Also, for a given study quality, the most cost-effective treatment strategy is still unknown in some cases ('CAS' vs. 'BMT', 'US combined with magnetic resonance angiography supplemented with AG' vs. 'US combined with computer tomography angiography').
European Journal of Vascular and Endovascular Surgery

Rottenkolber, D.; Schmiedl, S.; Rottenkolber, M.; Thuermann, P.A.; Hasford, J.
Drug-induced blood consumption: The impact of adverse drug reactions on demand for blood components in German departments of internal medicine.
Basic Clin. Pharmacol. Toxicol. 111, 240-247 (2012)
Therapy for adverse drug reactions (ADRs) often results in the application of blood components. This study aims to assess the demand for blood components and the resulting economic burden (hospital perspective) in German hospitals induced by ADRs leading to admissions to departments of internal medicine. In this prospective study, ADRs leading to hospitalization were surveyed in four regional pharmacovigilance centres in Germany during the years 20002007. ADRs assessed as possible, likely or very likely were included. Market prices for blood components and hospitalization data were determined by desktop research. A probabilistic sensitivity analysis was performed. A total of 6099 patients were admitted to internal medicine departments because of an outpatient ADR of whom 1165 patients (19.1%; mean age, 73.0 +/-13.0 years) required treatment with blood components owing to major bleeding events. Overall consumption was 4185 erythrocyte concentrates (EC), 426 fresh frozen plasma (FFP) and 48 thrombocyte (TC) units. On the basis of statistical hospital data, we estimated a nationwide demand of approximately 132,020 EC, 13,440 FFP and 1515 TC units, resulting in total costs of 12.66 pound million per year for all German hospitals. Some 19.2% of all ADR cases were assessed as preventable. Theoretically, a nationwide decreased demand for blood components and a savings potential of 2.43 pound million per year could be achieved by preventing ADRs in Germany. Blood components are used in one-fifth (mainly gastrointestinal bleeding) of all ADRs, leading to hospitalizations in internal medicine departments. Both blood demand and hospital procurement costs can be significantly lowered by preventing ADRs.
Basic and Clinical Pharmacology and Toxicology

Rottenkolber, D.; Hasford, J.; Stausberg, J.
Costs of adverse drug events in German hospitals - a microcosting study.
Value Health 15, 868-875 (2012)
Objective: In Germany, only limited data are available to quantify the attributable resource utilization associated with adverse drug events (ADEs). The aim of this study was twofold: first, to calculate the direct treatment costs associated with ADEs leading to hospitalization and, second, to derive the excess costs and extra hospital days attributable to ADEs of inpatient treatments in selected German hospitals. Methods: This was a retrospective and medical record-based study performed from the hospitals' perspective based on administrative accounting data from three hospitals (49,462 patients) in Germany. Total treatment costs ("analysis 1") and excess costs (i.e., incremental resource utilization) between patients suffering from an ADE and those without ADEs were calculated by means of a propensity score-based matching algorithm ("analysis 2"). Results: Mean treatment costs ("analysis 1") of ADEs leading to hospitalization (n = 564) were (sic)1,978 +/- 2,036 (range (sic)191-18,147; median (sic)1,446; (sic)843-2,480 [Q1-Q3]). In analysis 2, the mean costs of inpatients suffering from an ADE (n = 1,891) as a concomitant disease or complication ((sic)5,113 +/- 10,059; range (sic)179-246,288; median (sic)2,701; (sic)1,636-5,111 [Q1-Q3]) were significantly higher ((sic)970; P < 0.0001) than those of non-ADE inpatients ((sic)4,143 +/- 6,968; range (sic)154-148,479; median (sic)2,387; (sic)1,432-4,701 [Q1-Q3]). Mean inpatient length of stay of ADE patients (12.7 +/- 17.2 days) and non-ADE patients (9.8 +/- 11.6 days) differed by 2.9 days (P < 0.0001). A nationwide extrapolation resulted in annual total treatment costs of (sic)1.058 billion. Conclusions: This is one of the first administrative data-based analyses calculating the economic consequences of ADEs in Germany. Further efforts are necessary to improve pharmacotherapy and relieve health care payers of preventable treatment costs.
Value in Health

Rückert, I.-M.; Schunk, M.; Holle, R.; Schipf, S.; Völzke, H.; Kluttig, A.; Greiser, K.H.; Berger, K.; Müller, G.; Ellert, U.; Neuhauser, H.; Rathmann, W.; Tamayo, T.; Moebus, S.; Andrich, S.; Meisinger, C.
Blood pressure and lipid management fall far short in persons with type 2 diabetes: Results from the DIAB-CORE consortium including six German population-based studies.
Cardiovasc. Diabetol. 11:50 (2012)
Background: Although most deaths among patients with type 2 diabetes (T2D) are attributable to cardiovascular disease, modifiable cardiovascular risk factors appear to be inadequately treated in medical practice. The aim of this study was to describe hypertension, dyslipidemia and medical treatment of these conditions in a large population-based sample. Methods: The present analysis was based on the DIAB-CORE project, in which data from five regional population-based studies and one nationwide German study were pooled. All studies were conducted between 1997 and 2006. We assessed the frequencies of risk factors and co-morbidities, especially hypertension and dyslipidemia, in participants with and without T2D. The odds of no or insufficient treatment and the odds of pharmacotherapy were computed using multivariable logistic regression models. Types of medication regimens were described. Results: The pooled data set comprised individual data of 15, 071 participants aged 45-74 years, including 1287 (8.5%) participants with T2D. Subjects with T2D were significantly more likely to have untreated or insufficiently treated hypertension, i.e. blood pressure of > = 140/90 mmHg (OR = 1.43, 95% CI 1.26-1.61) and dyslipidemia i.e. a total cholesterol/HDL-cholesterol ratio > = 5 (OR = 1.80, 95% CI 1.59-2.04) than participants without T2D. Untreated or insufficiently treated blood pressure was observed in 48.9% of participants without T2D and in 63.6% of participants with T2D. In this latter group, 28.0% did not receive anti-hypertensive medication and

72.0% were insufficiently treated. In non-T2D participants, 28.8% had untreated or insufficiently treated dyslipidemia. Of all participants with T2D 42.5% had currently elevated lipids, 80.3% of these were untreated and 19.7% were insufficiently treated. Conclusions: Blood pressure and lipid management fall short especially in persons with T2D across Germany. The importance of sufficient risk factor control besides blood glucose monitoring in diabetes care needs to be emphasized in order to prevent cardiovascular sequelae and premature death.
Cardiovascular Diabetology

Menn, P.; Holle, R.; Kunz, S.; Donath, C.; Lauterberg, J.; Leidl, R.; Marx, P.; Mehlig, H.; Ruckdäschel, S.; Vollmar, H.C.; Wunder, S.; Gräßel, E.
Dementia care in the general practice setting: A cluster randomized trial on the effectiveness and cost impact of three management strategies.
Value Health 15, 851-859 (2012)
OBJECTIVE: To compare a complex nondrug intervention including actively approaching counseling and caregiver support groups with differing intensity against usual care with respect to time to institutionalization in patients with dementia. METHODS: Within this three-armed cluster-randomized controlled trial, 390 community-dwelling patients aged 65 years or older with physician-diagnosed mild to moderate dementia and their caregivers were enrolled via 129 general practitioners in Middle Franconia, Germany. The intervention included general practitioners' training in dementia care and their recommendation of support groups and actively approaching caregiver counseling. Primary study end point was time to institutionalization over 2 years. In addition, long-term intervention effects were assessed over a time horizon of 4 years. Secondary end points included cognitive functioning, (instrumental) activities of daily living, burden of caregiving, and health-related quality of life after 2 years. Frailty models with strict intention-to-treat approach and mixed linear models were applied to account for cluster randomization. Health care costs were assessed from the societal perspective. RESULTS: After 2 (4) years, 12% (24%) of the patients were institutionalized and another 21% (35%) died before institutionalization. No significant differences between study groups were observed with respect to time to institutionalization after 2 and 4 years (P 0.25 and 0.71, respectively). Secondary end points deteriorated, but differences were not significant between study groups. Almost 80% of the health care costs were due to informal care. Total annual costs amounted to more than €47,000 per patient and did not differ between study arms. CONCLUSION: The intervention showed no effects on time to institutionalization and secondary outcomes.
Value in Health

Schunk, M.; Reitmeir, P.; Schipf, S.; Völzke, H.; Meisinger, C.; Rückert, I.-M.; Kluttig, A.; Greiser, K.H.; Berger, K.; Müller, G.; Ellert, U.; Neuhauser, H.; Tamayo, T.; Rathmann, W.; Holle, R.
Die Bedeutung des Typ-2-Diabetes für die gesundheitsbezogene Lebensqualität. Ergebnisse aus bevölkerungsbasierten Studien in Deutschland (DIAB-CORE Verbund).
Med. Welt 63, 263-268 (2012)
Gesundheitsbezogene Lebensqualität (HRQL) ist ein wichtiger Ergebnisparameter in der Versorgungsforschung und Gesundheitsökonomie. Durch die gemeinsame Auswertung von fünf bevölkerungsbasierten epidemiologischen Studien sollen Referenzwerte für Personen mit und ohne Typ-2-Diabetes für Deutschland ermittelt und der Einfluss von Vor- und Begleiterkrankungen, Lebensstilfaktoren und sozioökonomischen Variablen untersucht werden. Die gesundheitsbezogene Lebensqualität wurde in allen Studien mit der deutschen Version des SF-36v1 bzw. des SF-12v1 erfasst. Die Ergebnisse zeigen bei Personen mit Typ-2-Diabetes (N = 846) eine deutlich schlechtere körperlichen Lebensqualität im Vergleich zu nicht an Diabetes erkrankten Personen (N = 8733). Auch unter Berücksichtigung von Begleiterkrankungen wie Herzinfarkt und Schlaganfall bleiben diese Unterschiede signifikant bestehen. Bei der psychischen Lebensqualität ist ein entsprechender signifikanter Unterschied nur bei mit Insulin behandelten Frauen zu beobachten. Unabhängig vom Diabetesstatus ist Lebensqualität positiv mit gesunder Lebensführung, Normalgewicht und höherem Einkommen assoziiert.
Medizinische Welt, Die

Langer, A.
A framework for assessing Health Economic Evaluation (HEE) quality appraisal instruments.
BMC Health Serv. Res. 12:253 (2012)
ABSTRACT: BACKGROUND: Health economic evaluations support the health care decision-making process by providing information on costs and consequences of health interventions. The quality of such studies is assessed by health economic evaluation (HEE) quality appraisal instruments. At present, there is no instrument for measuring and improving the quality of such HEE quality appraisal instruments. Therefore, the objectives of this study are to establish a framework for assessing the quality of HEE quality appraisal instruments to support and improve their quality, and to apply this framework to those HEE quality appraisal instruments which have been subject to more scrutiny than others, in order to test the framework and to demonstrate the shortcomings of existing HEE quality appraisal instruments. METHODS: To develop the quality assessment framework for HEE quality appraisal instruments, the experiences of using appraisal tools for clinical guidelines are used. Based on a deductive iterative process, clinical guideline appraisal instruments identified through literature search are reviewed, consolidated, and adapted to produce the final quality assessment framework for HEE quality appraisal instruments. RESULTS: The final quality assessment framework for HEE quality appraisal instruments consists of 36 items organized within 7 dimensions, each of which captures a specific domain of quality. Applying the quality assessment framework to four existing HEE quality appraisal instruments, it is found that these four quality appraisal instruments are of variable quality. CONCLUSIONS: The framework described in this study should be regarded as a starting point for appraising the quality of HEE quality appraisal instruments. This framework can be used by HEE quality appraisal instrument producers to support and improve the quality and acceptance of existing and future HEE quality appraisal instruments. By applying this framework, users of HEE quality appraisal instruments can become aware of methodological deficiencies inherent in existing HEE quality appraisal instruments. These shortcomings of existing HEE quality appraisal instruments are illustrated by the pilot test.
BMC Health Services Research

Mielck, A.; Lüngen, M.; Siegel, M.; Korber, K.

Folgen unzureichender Bildung im Bereich Gesundheit.
In: Warum Sparen in der Bildung teuer ist: Folgekosten unzureichender Bildung für die Gesellschaft. Gütersloh: Verl. Bertelsmann Stiftung, 2012. 133-170 (Wirksame Bildungsinvestitionen)

Mielck, A.
Mehr Gleichheit und mehr Gesundheit.
In: Buggler, R.* [Eds.]: Proceedings (5. Regional Salzburger Armutskonferenz. 20.10.2011, St. Virgil Salzburg). Salzburg: Salzburger Armutskonferenz - Förderverein, 2012. 27-31 (; Gleichheit ist Glück. Salzburg braucht Mut.)
In letzter Zeit häufen sich in Deutschland nicht nur die Armutsberichte, sondern auch die Berichte über den Zusammenhang zwischen der sozialen Ungleichheit einerseits und dem Gesundheitszustand andererseits. In einer kaum mehr überschaubaren Vielzahl von Arbeiten ist immer wieder gezeigt worden, dass Personen mit niedrigem sozialen Status zumeist einen besonders schlechten Gesundheitszustand aufweisen, dass sie kränker sind und früher sterben als Personen mit höherem sozialen Status [Mielck 2005, RichterIHurrelmann 20091. In derwissenschaftlichen Diskussion wird dieser Zusammenhang zwischen Sozialstatus und Morbidität bzw. Mortalität als ..gesundheitliche Ungleichheit" bezeichnet. Wichtig ist nicht nur die Existenz. sondern auch das Ausmaß dieser gesundheitlichen Ungleichheit. Im Folgenden werden dazu einige zentrale Ergebnisse vorgestellt

Mielck, A.
Risiken und Nebenwirkungen.
K3 15, 20-21 (2012)
Der „Münchner Armutsbericht“ enthält regelmäßig Aussagen zu „Kinderarmut und Gesundheit“. Erwiesen ist, dass Personen mit niedrigem sozialen Status oft einen schlechteren Gesundheitszustand aufweisen als Menschen mit höherem sozialen Status.
K3 : das Magazin

Heimeshoff, M.; Hollmeyer, H.; Schreyögg, J.; Tiemann, O.; Staab, D.
Cost of illness of cystic fibrosis in Germany: Results from a large cystic fibrosis centre.
Pharmacoeconomics 30, 763-777 (2012)
Background: Cystic fibrosis (CF) is the most common life-shortening genetic disorder among Whites worldwide. Because many of these patients experience chronic endobronchial colonization and have to take antibiotics and be treated as inpatients, societal costs of CF may be high. As the disease severity varies considerably among patients, costs may differ between patients. Objectives: Our objectives were to calculate the average total costs of CF per patient and per year from a societal perspective; to include all direct medical and non-medical costs as well as indirect costs; to identify the main cost drivers; to investigate whether patients with CF can be grouped into homogenous cost groups; and to determine the influence of specific factors on different cost categories. Methods: Resource utilization data were collected for 87 patients admitted to an inpatient unit at a CF treatment centre during the first 6 months of 2004 and 125 patients who visited the centre's CF outpatient unit during the entire year. Fifty-four patients were admitted to the hospital and also visited the outpatient unit. Since all patients were exclusively treated at the centre, data could be aggregated. Costs that varied greatly between patients were measured per patient. The remaining costs were summarized as overhead costs and allocated on the basis of days of treatment or contacts per patient. Costs of the outpatient and inpatient units and costs for drugs patients received at the outpatient pharmacy were summarized as direct medical costs. Direct non-medical costs (i.e. travel expenses), as well as indirect costs (i. e. absence from work, productivity losses), were also included in the analysis. Main cost drivers were detected by the analysis of different cost categories. Patients were classified according to a diagnosis-related severity model, and median comparison tests (Wilcoxon-Mann-Whitney tests) were performed to investigate differences between the severity groups. Generalized least squares (GLS) regressions were used to identify variables influencing different cost categories. A sensitivity analysis using Monte Carlo simulation was performed. Results: The mean total cost per patient per year was 41 468 (year 2004 values). Direct medical costs accounted for more than 90% of total costs and averaged (sic)38 869 ((sic)3876 to (sic)88 096), whereas direct non-medical costs were minimal. Indirect costs amounted to (sic)2491 (6% of total costs). Costs for drugs patients received at the outpatient pharmacy were the main cost driver. Costs rose with the degree of severity. Patients with moderate and severe disease had significantly hieher direct costs than the relatively milder group. Regression analysis revealed that direct costs were mainly affected by the diagnosis-related severity level and the expiratory volume; the coefficient indicating the relationship between costs for mild CF patients and other patients rose with the degree of severity. A similar result was obtained for drug costs per patient as the dependent variable. Monte Carlo simulation suggests that there is a 90% probability that annual costs will be lower than (sic)37 300. Conclusions: The share of indirect costs as a percentage of total costs for CF was rather low in this study. However, the relevance of indirect costs is likely to increase in the future as the life expectancy of CF patients increases, which is likely to lead to a rising work disability rate and thus increase indirect costs. Moreover we found that infection with Pseudomonas aeruginosa increases costs substantially. Thus, a decrease of the prevalence of P. aeruginosa would lead to substantial savings for society.
PharmacoEconomics

Tamayo, T.; Schipf, S.; Maier, W.
Regionale Unterschiede in der Häufigkeit des Typ-2-Diabetes in Deutschland. Welchen Einfluss hat die strukturelle Benachteiligung einer Region?
Diabetes Stoffwechs. Herz 21, 326-330 (2012)
Diabetes, Stoffwechsel und Herz

Schwarzkopf, L.; Menn, P.; Holle, R.
Methodische Ermessensspielräume bei der Sekundärdatenanalyse von GKV-Daten und ihre Auswirkungen - explorative Darstellung am Beispiel einer Kostenstudie zu Demenz.
Gesundheitswesen 74, e76-e83 (2012)
Kassendatenbasierte Studien liefern wichtige Einblicke in die Gesundheitsversorgung innerhalb des Systems der gesetzlichen Krankenversicherung. Bislang wird kaum thematisiert, dass dabei Ermessensspielräume bei der Aufbereitung der Leistungsdaten bestehen. Am Beispiel eines Samples mit 9 147 AOK-versicherten Demenzpatienten vergleicht dieser Artikel verschiedene Definitionsansätze für Leistungsinanspruchnahme und die damit verbundenen Versorgungskosten. Letztendlich führen die verschiedenen Ansätze nicht zwangsläufig zu

unterschiedlichen Nutzungsvolumina bzw. unterschiedlichen Kosten pro Kopf. Das Ausmaß der Varianz hängt vielmehr maßgeblich von der relativen Häufigkeit mehrfach interpretierbarer Leistungen in der Studienpopulation ab. Ausgehend von diesen Erkenntnissen lassen sich Empfehlungen für künftige Auswertungsstandards ableiten.
Gesundheitswesen, Das

Vogl, M.
Assessing DRG cost accounting with respect to resource allocation and tariff calculation: The case of Germany.
Health Econ. Rev. 2:15 (2012)
ABSTRACT: The purpose of this paper is to analyze the German diagnosis related groups (G-DRG) cost accounting scheme by assessing its resource allocation at hospital level and its tariff calculation at national level. First, the paper reviews and assesses the three steps in the G-DRG resource allocation scheme at hospital level: (1) the groundwork; (2) cost-center accounting; and (3) patient-level costing. Second, the paper reviews and assesses the three steps in G-DRG national tariff calculation: (1) plausibility checks; (2) inlier calculation; and (3) the "one hospital" approach. The assessment is based on the two main goals of G-DRG introduction: improving transparency and efficiency. A further empirical assessment attests high costing quality. The G-DRG cost accounting scheme shows high system quality in resource allocation at hospital level, with limitations concerning a managerially relevant full cost approach and limitations in terms of advanced activity-based costing at patient-level. However, the scheme has serious flaws in national tariff calculation: inlier calculation is normative, and the "one hospital" model causes cost bias, adjustment and representativeness issues. The G-DRG system was designed for reimbursement calculation, but developed to a standard with strategic management implications, generalized by the idea of adapting a hospital's cost structures to DRG revenues. This combination causes problems in actual hospital financing, although resource allocation is advanced at hospital level.
Health Economics Review

Reincke, M.; Fischer, E.; Gerum, S.; Merkle, K.; Schulz, S.; Pallauf, A.; Quinkler, M.; Hanslik, G.; Lang, K.; Hahner, S.; Allolio, B.; Meisinger, C.; Holle, R.; Beuschlein, F.; Bidlingmaier, M.; Endres, S.
Observational study mortality in treated primary aldosteronism: The German Conn's registry.
Hypertension 60, 618-624 (2012)
In comparison with essential hypertension, primary aldosteronism (PA) is associated with an increased risk of cardiovascular morbidity. To date, no data on mortality have been published. We assessed mortality of patients treated for PA within the German Conn's registry and identified risk factors for adverse outcome in a case-control study. Patients with confirmed PA treated in 3 university centers in Germany since 1994 were included in the analysis. All of the patients were contacted in 2009 and 2010 to verify life status. Subjects from the population-based F3 survey of the Cooperative Health Research in the Region of Augsburg served as controls. Final analyses were based on 600 normotensive controls, 600 hypertensive controls, and 300 patients with PA. Kaplan-Meyer survival curves were calculated for both cohorts. Ten-year overall survival was 95% in normotensive controls, 90% in hypertensive controls, and 90% in patients with PA (P value not significant). In multivariate analysis, age (hazard ratio, 1.09 per year [95% CI, 1.03-1.14]), angina pectoris (hazard ratio, 3.6 [95% CI, 1.04 -12.04]), and diabetes mellitus (hazard ratio, 2.55 [95% CI, 1.07-6.09]) were associated with an increase in all-cause mortality, whereas hypokalemia (hazard ratio, 0.41 per mmol/ L [95% CI, 0.17-0.99]) was associated with reduced mortality. Cardiovascular mortality was the main cause of death in PA (50% versus 34% in hypertensive controls; P < 0.05). These data indicate that cardiovascular mortality is increased in patients treated for PA, whereas all-cause mortality is not different from matched hypertensive controls. (Hypertension. 2012; 60: 618-624.). Online Data Supplement
Hypertension

Schwarzkopf, L.; Menn, P.; Leidl, R.; Wunder, S.; Mehlig, H.; Marx, P.; Graessel, E.; Holle, R.
Excess costs of dementia disorders and the role of age and gender - an analysis of German health and long-term care insurance claims data.
BMC Health Serv. Res. 12:165 (2012)
Background: Demographic ageing is associated with an increasing number of dementia patients, who reportedly incur higher costs of care than individuals without dementia. Regarding Germany, evidence on these excess costs is scarce. Adopting a payer perspective, our study aimed to quantify the additional yearly expenditures per dementia patient for various health and long-term care services. Additionally, we sought to identify gender-specific cost patterns and to describe age-dependent cost profiles. Methods: The analyses used 2006 claims data from the AOK Bavaria Statutory Health Insurance fund of 9,147 dementia patients and 29,741 age- and gender-matched control subjects. Cost predictions based on two-part regression models adjusted for age and gender and excess costs of dementia care refer to the difference in model-estimated means between both groups. Corresponding analyses were performed stratified for gender. Finally, a potentially non-linear association between age and costs was investigated within a generalized additive model. Results: Yearly spending within the social security system was circa (sic)12,300 per dementia patient and circa (sic)4,000 per non-demented control subject. About two-thirds of the additional expenditure for dementia patients occurred in the long-term care sector. Within our study sample, male and female dementia patients incurred comparable total costs. However, women accounted for significantly lower health and significantly higher long-term care expenditures. Long-term care spending increased in older age, whereupon health care spending decreased. Thus, at more advanced ages, women incurred greater costs than men of the same age. Conclusions: Dementia poses a substantial additional burden to the German social security system, with the long-term care sector being more seriously challenged than the health care sector. Our results suggest that female dementia patients need to be seen as a key target group for health services research in an ageing society. It seems clear that strategies enabling community-based care for this vulnerable population might contribute to lowering the financial burden caused by dementia. This would allow for the sustaining of comprehensive dementia care within the social security system.
BMC Health Services Research

Bolte, G.; Bunge, C.; Hornberg, C.; Köckler, H.; Mielck, A.

Umweltgerechtigkeit. Chancengleichheit bei Umwelt und Gesundheit: Konzepte, Datenlage und Handlungsperspektiven.
Bern: Verl. Hans Huber, 2012. 440 S.
Umweltgerechtigkeit ist ein Querschnittsthema, das zahlreiche Disziplinen anspricht, von Public Health über Stadt- und Raumplanung, Geographie, Umwelt- und Sozialwissenschaften bis hin zu Rechts- und Wirtschaftswissenschaften. Der Diskussion in Deutschland fehlt es bislang weitgehend am transdisziplinären Austausch mit dem notwendigen Praxisbezug. Dieses Grundlagenwerk schließt die Lücke und vermittelt erstmals einen integrierten, fach- und politikübergreifenden Einblick in die Probleme, aber auch Potenziale von Umweltgerechtigkeit. Orientiert am Politik-Zyklus werden dargestellt: - theoretische Konzepte, empirische Daten und Analysen - Entwicklung von Handlungsstrategien - konkrete Beispiele bereits implementierter Projekte und Programme - Evaluation von Maßnahmen zur Verbesserung der Chancengleichheit bei Umwelt und Gesundheit. Systematisch werden Forschungsansätze und Handlungsfelder verbunden, sodass das Handbuch sowohl für WissenschaftlerInnen und Studierende als auch für in der Praxis tätige AkteurInnen (z.B. in Umwelt-, Gesundheits- und Stadtentwicklungsämtern, Quartiersmanagementeinrichtungen, Verbänden und Bürgerinitiativen), für Politik und Verwaltung theoretisches Wissen für praktisches Handeln zugänglich macht.

Menn, P.; Leidl, R.; Holle, R.
A lifetime Markov model for the economic evaluation of chronic obstructive pulmonary disease.
Pharmacoeconomics 30, 825-840 (2012)
Background: Chronic obstructive pulmonary disease (COPD) is currently the fourth leading cause of death worldwide. It has serious health effects and causes substantial costs for society. Objectives: The aim of the present paper was to develop a state-of-the-art decision-analytic model of COPD whereby the cost effectiveness of interventions in Germany can be estimated. To demonstrate the applicability of the model, a smoking cessation programme was evaluated against usual care. Methods: A seven-stage Markov model (disease stages I to IV according to the GOLD [Global Initiative for Chronic Obstructive Lung Disease] classification, states after lung-volume reduction surgery and lung transplantation, death) was developed to conduct a cost-utility analysis from the societal perspective over a time horizon of 10, 40 and 60 years. Patients entered the cohort model at the age of 45 with mild COPD. Exacerbations were classified into three levels: mild, moderate and severe. Estimation of stage-specific probabilities (for smokers and quitters), utilities and costs was based on German data where possible. Data on effectiveness of the intervention was retrieved from the literature. A discount rate of 3% was applied to costs and effects. Probabilistic sensitivity analysis was used to assess the robustness of the results. Results: The smoking cessation programme was the dominant strategy compared with usual care, and the intervention resulted in an increase in health effects of 0.54 QALYs and a cost reduction of €1115 per patient (year 2007 prices) after 60 years. In the probabilistic analysis, the intervention dominated in about 95% of the simulations. Sensitivity analyses showed that uncertainty primarily originated from data on disease progression and treatment cost in the early stages of disease. Conclusions: The model developed allows the long-term cost effectiveness of interventions to be estimated, and has been adapted to Germany. The model suggests that the smoking cessation programme evaluated was more effective than usual care as well as being cost-saving. Most patients had mild or moderate COPD, stages for which parameter uncertainty was found to be high. This raises the need to improve data on the early stages of COPD.
PharmacoEconomics

Zindel, S.; Stock, S.; Müller, D.; Stollenwerk, B.
A multi-perspective cost-effectiveness analysis comparing rivaroxaban with enoxaparin sodium for thromboprophylaxis after total hip and knee replacement in the German healthcare setting.
BMC Health Serv. Res. 12:192 (2012)
BACKGROUND: Patients undergoing major orthopaedic surgery (MOS), such as total hip (THR) or total knee replacement (TKR), are at high risk of developing venous thromboembolism (VTE). For thromboembolism prophylaxis, the oral anticoagulant rivaroxaban has recently been included in the German diagnosis related group (DRG) system. However, the cost-effectiveness of rivaroxaban is still unclear from both the German statutory health insurance (SHI) and the German hospital perspective. Objectives To assess the cost-effectiveness of rivaroxaban from the German statutory health insurance (SHI) perspective and to analyse financial incentives from the German hospital perspective. METHODS: Based on data from the RECORD trials and German cost data, a decision tree was built. The model was run for two settings (THR and TKR) and two perspectives (SHI and hospital) per setting. RESULTS: Prophylaxis with rivaroxaban reduces VTE events (0.02 events per person treated after TKR; 0.007 after THR) compared with enoxaparin. From the SHI perspective, prophylaxis with rivaroxaban after TKR is cost saving (E27.3 saving per patient treated). However, the costeffectiveness after THR (E17.8 cost per person) remains unclear because of stochastic uncertainty. From the hospital perspective, for given DRGs, the hospital profit will decrease through the use of rivaroxaban by E20.6 (TKR) and E31.8 (THR) per case respectively. CONCLUSIONS: Based on our findings, including rivaroxaban for reimbursement in the German DRG system seems reasonable. Yet, adequate incentives for German hospitals to use rivaroxaban are still lacking.
BMC Health Services Research

Fischer, K.E.
Decision-making in healthcare: A practical application of partial least square path modelling to coverage of newborn screening programmes.
BMC Med. Inform. Decis. Mak. 12:83 (2012)
BACKGROUND: Decision-making in healthcare is complex. Research on coverage decision-making has focused on comparative studies for several countries, statistical analyses for single decision-makers, the decision outcome and appraisal criteria. Accounting for decision processes extends the complexity, as they are multidimensional and process elements need to be regarded as latent constructs that are not observed directly. The objective of this study was to present a practical application of partial least square path modelling (PLS-PM) to evaluate how it offers a method for empirical analysis of decision-making in healthcare. METHODS: Empirical approaches that applied PLS-PM to decision-making in healthcare were identified through a systematic literature search. PLS-PM was used as an estimation technique for a structural equation model that specified hypotheses between the components of decision processes and the reasonableness of decision-making in terms of medical, economic and other ethical

criteria. The model was estimated for a sample of 55 coverage decisions on the extension of newborn screening programmes in Europe. Results were evaluated by standard reliability and validity measures for PLS-PM. RESULTS: After modification by dropping two indicators that showed poor measures in the measurement models' quality assessment and were not meaningful for newborn screening, the structural equation model estimation produced plausible results. The presence of three influences was supported: the links between both stakeholder participation or transparency and the reasonableness of decision-making; and the effect of transparency on the degree of scientific rigour of assessment. Reliable and valid measurement models were obtained to describe the latent constructs of 'transparency', 'participation', 'scientific rigour' and 'reasonableness'. CONCLUSIONS: The structural equation model was among the first applications of PLS-PM to coverage decision-making. It allowed testing of hypotheses in situations where there are links between several non-observable constructs. PLS-PM was compatible in accounting for the complexity of coverage decisions to obtain a more realistic perspective for empirical analysis. The model specification can be used for hypothesis testing by using larger sample sizes and for data in the full domain of health technologies.
BMC Medical Informatics and Decision Making

Fischer, K.E.
A systematic review of coverage decision-making on health technologies - evidence from the real world.
Health Policy 107, 218-230 (2012)
OBJECTIVE: Quantitative analysis of real-world coverage decision-making offers insights into the revealed preferences of appraisal committees. Aim of this review was to structure empirical evidence of coverage decisions made in practice based on the components 'methods and evidence', 'criteria and standards', 'decision outcome' and 'processes'. METHODS: Several electronic databases, key journals and decision committees' websites were searched for publications between 1993 and June 2011. Inclusion criteria were the analysis of past decisions and application of quantitative methods. Each study was categorized by the scope of decision-making and the components covered by the variables used in quantitative analysis. RESULTS: Thirty-two studies were identified. Many focused on pharmaceuticals, the UK NICE or the Australian PBAC. The components were covered comprehensively, but heterogeneously. Seventy-two variables were identified of which the following were more prevalent: specifications of the decision outcome; the indications considered for appraisal, identification of incremental cost-effectiveness ratios, appropriateness of evaluation methods, type of economic or clinical evidence used for assessment, and the decision date. CONCLUSIONS: Research was dominated by analysis of decision outcomes and appraisal criteria. Although common approaches were identified, the complexity of coverage decision-making - reflected by the heterogeneity of identified variables - will continue to challenge empirical research.
Health Policy

Italia, S.; Batscheider, A.; Heinrich, J.; Wenig, C.M.; Bauer, C.P.; Koletzko, S.; Lehmann, I.; Herbarth, O.; von Berg, A.; Berdel, D.; Hoffmann, B.; Schaaf, B.; Wolfenstetter, S.B.
Utilization and costs of conventional and alternative pharmaceuticals in children: Results from the German GINIplus and LISAplus birth cohort studies.
Pharmacoepidemiol. Drug Saf. 21, 1102-1111 (2012)
PURPOSE: The socioeconomic determinants for drug utilization, especially in children, have not been investigated sufficiently so far. The study's aim was the estimation of prevalences and determinants of conventional, homeopathic and phytotherapeutic drugs and expenditures. METHODS: Population-based data on drug utilization of 3,642 children in two German birth cohorts (GINIplus and LISAplus, 10-year follow-up) were collected using a self-administered questionnaire. For analysis, the reported drugs (use within the last four weeks) were classified into the therapeutic categories of 'conventional medicine', 'homeopathy', 'phytotherapy' and 'others'. Drug costs were estimated using pharmaceutical identification numbers. RESULTS: In all, 42.3% of the children reported drug use; 24.1% of the drugs were homeopathic and 11.5% were phytotherapeutic. The proportion of children who took at least one homeopathic remedy was 14.3%. Drugs prescribed by physicians were dominated by conventional medicine (76.5%), whereas in non-prescribed drugs, both homeopathy and conventional medicine accounted for 37% each. Boys (OR = 0.78) used less homeopathy than girls. Income showed only a weak influence. Education had a strong effect on the use of phytotherapy such that children of mothers with higher school education (>10 years vs. <10 years) used more phytotherapy (OR = 2.01). If out-of-pocket payments arose (n = 613), the mean was €20. On average, total drug expenditures summed up to €39 in 4 weeks for drug users if only clearly identifiable prices for drugs were considered (58% of all data). CONCLUSIONS: Utilization of homeopathy is common in children from the analyzed cohort. User profiles of homeopathy and phytotherapy differ from each other and should be analyzed separately.
Pharmacoepidemiology and Drug Safety

Genz, J.; Haastert, B.; Müller, H.; Verheyen, F.; Cole, D.; Rathmann, W.; Nowotny, B.; Roden, M.; Giani, G.; Mielck, A.; Ohmann, C.; Icks, A.
Blood glucose testing and primary prevention of type 2 diabetes - evaluation of the effect of evidence-based patient information: A randomized controlled trial.
Diabetic Med. 29, 1011-1020 (2012)
Diabet. Med. 29, 10111020 (2012) Abstract Aims To compare the effect of our newly developed online evidence-based patient information vs. standard patient information about sub-threshold elevated blood glucose levels and primary prevention of diabetes on informed patient decision making. Methods We invited visitors to the cooperating health insurance company, Techniker Krankenkasse, and the German Diabetes Center websites to take part in a web-based randomized controlled trial. The population after randomization comprised 1120 individuals aged between 40 and 70 years without known diabetes, of whom 558 individuals were randomly assigned to the intervention group receiving evidence-based patient information, and 562 individuals were randomly assigned to the control group receiving standard information from the Internet. The primary endpoint was acquired knowledge of elevated blood glucose level issues and the secondary outcomes were attitude to metabolic testing, intention to undergo metabolic testing, decisional conflict and satisfaction with the information. Results Overall, knowledge of elevated glucose level issues and the

intention to undergo metabolic testing were high in both groups. Participants who had received evidence-based patient information, however, had significantly higher knowledge scores. The secondary outcomes in the evidence-based patient information subgroup that completed the 2-week follow-up period yielded significantly lower intention to undergo metabolic testing, significantly more critical attitude towards metabolic testing and significantly higher decisional conflict than the control subgroup (n = 466). Satisfaction with the information was not significantly different between both groups. Conclusions Evidence-based patient information significantly increased knowledge about elevated glucose levels, but also increased decisional conflict and critical attitude to screening and treatment options. The intention to undergo metabolic screening decreased. Future studies are warranted to assess uptake of metabolic testing and satisfaction with this decision in a broader population of patients with unknown diabetes.
Diabetic Medicine

Hunger, M.; Schunk, M.; Meisinger, C.; Peters, A.; Holle, R.
Estimation of the relationship between body mass index and EQ-5D health utilities in individuals with type 2 diabetes: Evidence from the population-based KORA studies.
J. Diab. Complic. 26, 413-418 (2012)
OBJECTIVES: Obesity is known to be an important risk factor for type 2 diabetes and its related comorbid conditions; however, its specific impact on generic health-related quality of life (HRQL) is less clear. The objective of this study was to estimate the association between body mass index (BMI) and HRQL in individuals with type 2 diabetes. METHODS: The EQ-5D quality of life questionnaire was administered in a follow-up of 10,385 participants aged 33-94 of the population-based German MONICA/KORA surveys. 1033 participants with type 2 diabetes were identified by self-report combined with validated physician diagnoses. Semiparametric additive regression models were used to estimate the effect of BMI on EQ-5D health utilities adjusted for age, sex, education and comorbidities. RESULTS: BMI was significantly associated with EQ-5D health utilities even after adjustment for macro- and microvascular complications. The functional relationship between BMI and utilities was nonlinear, reflecting optimal health around 26kg/m(2) and significantly decreasing health utilities with increasing levels of overweight and obesity (-0.09 points between BMI values 26 and 40). Among the diabetic complications, the history of a stroke (-0.13) and neuropathy (-0.10) were the strongest predictors of reduced health utility scores. CONCLUSIONS: BMI is strongly associated with health utilities in persons with type 2 diabetes. This suggests that lifestyle measures to reduce obesity can markedly improve patients' health-related quality of life and that the negative effect of potential weight gain should be taken into account when determining patient preferences for different type 2 diabetes treatment options.
Journal of Diabetes and its Complications

Huber, C.; Rüesch, P.; Mielck, A.; Böcken, J.; Rosemann, T.; Meyer, P.C.
Effects of cost sharing on seeking outpatient care: A propensity-matched study in Germany and Switzerland.
J. Eval. Clin. Pract. 18, 781-787 (2012)
Background Several studies have assessed the effect of cost sharing on health service utilization (HSU), mostly in the USA. Results are heterogeneous, showing different effects. Whereas previous studies compared insurants within one health care system but different modes of insurance, we aimed at comparing two different health care systems in Europe: Germany and Switzerland. Furthermore, we assessed the impact of cost sharing depending on socio-demographic factors as well as health status. Methods Two representative samples of 5197 Swiss insurants with and 5197 German insurants without cost sharing were used to assess the independent association between cost sharing and the use of outpatient care. To minimize confounding, we performed cross-sectional analyses between propensity score matched Swiss and German insurants. We investigated subgroups according to health and socio-economic status to assess a potential social gradient in HSU. Results We found a significant association between health insurance scheme and the use of outpatient services. German insurants without cost sharing (visit rate: 4.8 per year) consulted a general practitioner or specialist more frequently than Swiss insurants with cost sharing (visit rate: 3.0 per year; $P < 0.01$). Subgroup analyses showed that vulnerable populations were differently affected by cost sharing. In the group of respondents with poor health and low socio-economic status, the cost-sharing effect was strongest. Conclusion Cost-sharing models reduce HSU. The challenge is to create cost-sharing models which do not preclude vulnerable populations from seeking essential health care.
Journal of Evaluation in Clinical Practice

Schunk, M.; Reitmeir, P.; Schipf, S.; Völzke, H.; Meisinger, C.; Thorand, B.; Kluttig, A.; Greiser, K.H.; Berger, K.; Müller, G.; Ellert, U.; Neuhauser, H.; Tamayo, T.; Rathmann, W.; Holle, R.
Health-related quality of life in subjects with and without type 2 diabetes: Pooled analysis of five population-based surveys in Germany.
Diabetic Med. 29, 646-653 (2012)
Aims To estimate population values of health-related quality of life (HRQL) in subjects with and without Type 2 diabetes mellitus across several large population-based survey studies in Germany. Systematic differences in relation to age and sex were of particular interest. Methods Individual data from four population-based studies from different regions throughout Germany and the nationwide German National Health Interview and Examination Survey (GNHIES98) were included in a pooled analysis of primary data (N = 9579). HRQL was assessed using the generic index instrument SF-36 (36-item Short Form Health Survey) or its shorter version, the SF-12 (12 items). Regression analysis was carried out to examine the association between Type 2 diabetes and the two component scores derived from the SF-36/SF-12, the physical component summary score (PCS-12) and the mental component summary score (MCS-12), as well as interaction effects with age and sex. Results The PCS-12 differed significantly by -4.1 points in subjects with Type 2 diabetes in comparison with subjects without Type 2 diabetes. Type 2 diabetes was associated with significantly lower MCS-12 in women only. Higher age was associated with lower PCS-12, but with an increase in MCS-12, for subjects with and without Type 2 diabetes. Conclusions Pooled analysis of population-based primary data offers HRQL values for subjects with Type 2 diabetes in Germany, stratified by age and sex. Type 2 diabetes has negative consequences for HRQL, particularly for women. This underlines the burden of disease and the importance of diabetes prevention. Factors that disadvantage women with Type 2 diabetes need to be researched more thoroughly.

Diabetic Medicine

Rathmann, W.; Kowall, B.; Tamayo, T.; Giani, G.; Holle, R.; Thorand, B.; Heier, M.; Huth, C.; Meisinger, C.
Hemoglobin A1c and glucose criteria identify different subjects as having type 2 diabetes in middle-aged and older populations: The KORA S4/F4 study.
Ann. Med. 44, 170-177 (2012)
Objective. The American Diabetes Association (ADA) has recently recommended HbA1c for diagnosing diabetes as an alternative to glucose-based criteria. We compared the new HbA1c-based criteria for diagnosis of diabetes and prediabetes with the glucose-based criteria. Research design and methods. In the population-based German KORA surveys (S4/F4) 1,764 non-diabetic participants aged 31-60 years and 896 participants aged 61-75 years underwent measurements of HbA1c, fasting plasma glucose (FPG), and 2-h glucose. Results. Only 20% of all subjects diagnosed with diabetes by glucose or HbA1c criteria had diabetes by both criteria; for prediabetes, the corresponding figure was 23%. Using HbA1c >= 6.5%, the prevalence of diabetes was strongly reduced compared to the glucose criteria (0.7% instead of 2.3% in the middle-aged, 2.9% instead of 7.9% in the older subjects). Only 32.0% (middle-aged) and 43.2% (older group) of isolated impaired glucose tolerance (i-IGT) cases were detected by the HbA1c criterion (5.7% <= HbA1c < 6.5%). Conclusion. By glucose and the new HbA1c diabetes criteria, different subjects are diagnosed with type 2 diabetes in middle-aged as well as older subjects. The new HbA1c criterion lacks sensitivity for impaired glucose tolerance.
Annals of Medicine

Heinrich, J.; Brüske, I.; Schnappinger, M.; Standl, M.; Flexeder, C.; Thiering, E.; Tischer, C.G.; Tiesler, C.M.; Kohlböck, G.; Wenig, C.M.; Bauer, C.P.; Schaaf, B.; von Berg, A.; Berdel, D.; Krämer, U.; Cramer, C.; Lehmann, I.; Herbarth, O.; Behrendt, H.; Ring, J.; Kühnisch, J.; Koletzko, S.
Die zwei deutschen Geburtskohorten GINIplus and LISAplus.
Bundesgesundheitsbl.-Gesund. 55, 864-874 (2012)
Numerous chronic diseases in childhood and adulthood have their origins in perinatal life and are potentially influenced by trans-generational epigenetic processes. Therefore, prospective birth cohorts can substantially contribute to our knowledge about the etiology of diseases including modifiable risk factors. The two population-based German birth cohorts GINIplus and LISAplus aim to describe the natural course of chronic diseases and intermediate phenotypes in childhood and its determinants, and to identify potential genetic effect modifications. In the mid-1990s, 5,991 (GINIplus) and 3,097 (LISAplus) healthy, term newborns were recruited for long-term follow-up in four regions of Germany. The follow-up rate for the first 10 years was about 55%. We analyzed the growth and development of overweight, infections and allergic diseases, mental and oral health, metabolic and inflammatory parameters and the role of potential risk factors including genetics. The results of these two birth cohorts substantially contribute to the current knowledge about the natural course of these health parameters. These data were included in many international projects and consortia for purposes of international comparisons of prevalence and consistency of findings, and to increase the power of the analyses.
Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz

Röllke, L.; Schacher, B.; Wohlfeil, M.; Kim, T.-S.; Kaltschmitt, J.; Krieger, J.; Krigar, D.M.; Reitmeir, P.; Eickholz, P.
Regenerative therapy of infrabony defects with or without systemic doxycycline. A randomized placebo-controlled trial.
J. Clin. Periodontol. 39, 448-456 (2012)
AIM: Comparison of regenerative therapy of infrabony defects with and without administration of postsurgical systemic doxycycline (DOXY). METHODS: In each of 61 patients one infrabony defect was treated with enamel matrix derivative (EMD), EMD plus filler or membrane at two centres. By random assignment patients received either 200 mg DOXY per day or placebo (PLAC) for 7 days after surgery. Prior to and 6 months after surgery probing pocket depths (PPD) and vertical attachment level (PAL-V) were obtained. RESULTS: Fifty-four patients (DOXY: 27; PLAC: 27) were re-examined after 6 months and had been treated exclusively with EMD. Seven to 8 days after surgery 81% of defects in both groups showed complete flap closure. In both groups significant ($p < 0.001$) PPD reduction (DOXY: 3.87 ± 1.44 mm; PLAC: 3.67 ± 1.30 mm) and PAL-V gain (DOXY: 3.11 ± 1.50 mm; PLAC: 3.32 ± 1.83 mm) were observed. However, the differences failed to be statistically significant (PPD: 0.20; $p = 0.588$; PAL-V: 0.21; $p = 0.657$). CONCLUSIONS: Two hundred milligram systemic DOXY administered for 7 days after therapy of infrabony defects with EMD failed to result in better PPD reduction and PAL-V gain compared with PLAC which may be due to low power (50%) and, thus, random chance.
Journal of Clinical Periodontology

von Lengerke, T.; Mielck, A.
Body weight dissatisfaction by socioeconomic status among obese, preobese and normal weight women and men: Results of the cross-sectional KORA Augsburg S4 population survey.
BMC Public Health 12:342 (2012)
BACKGROUND: Body weight dissatisfaction is an important factor in preventing weight gain and promoting weight loss or maintenance. This study focuses on differences in the rates of body weight dissatisfaction among obese, preobese and normal weight women and men by socioeconomic status within a general adult population in Germany. METHODS: Data were analyzed from 4186 adults aged 25 to 74 who participated in a cross-sectional, representative population-based health survey (KORA S4, 1999-2001, Augsburg region/Germany). Body mass was measured anthropometrically and indexed following international standards. Among the 2123 women participating in the survey, 40.3% had a normal weight, 34.9% were preobese, and 24.8% were obese (compared to 25.9%, 51.4% and 22.6% among men, respectively). Body weight dissatisfaction, educational level, household income and occupational status were assessed by computer-aided personal interviewing. An index for socioeconomic status was calculated and categorized into quintiles. Multiple logistic regressions were performed to test for differences in the odds of body weight dissatisfaction across socioeconomic strata in normal weight, preobese and obese groups. Body mass index, age, family status, place of residence and health behaviors were adjusted for. RESULTS: Overall, being dissatisfied with one's body weight was more prevalent in women (48.3%) than in men (33.2%). In the normal weight group, no significant differences in the odds of being dissatisfied were found across socioeconomic groups among women or men. Among preobese men, compared to the lowest

socioeconomic stratum, increased odds of being dissatisfied with one's body weight were associated with the highest socioeconomic index group (OR=2.3, 95% CI: 1.4-3.8), middle and high educational level (OR=1.6, 95% CI: 1.1-2.3, and OR=1.9, 95% CI: 1.3-3.7), high income (OR=1.8, 95% CI: 1.2-2.7), and middle and high occupational status (both OR=1.8, 95% CI: 1.2-2.6). Among preobese women, the odds of being dissatisfied were only significantly elevated in those with a middle educational level (OR=1.6, 95% CI: 1.1-2.3). Among obese men, elevated odds were found in the highest socioeconomic index group (OR=3.7, 95% CI: 1.8-7.5) and in those with a high educational level (OR=2.3, 95% CI: 1.3-4.1), high income (OR=2.6, 95% CI: 1.4-4.7), and middle and high occupational status (both OR=2.2, 95% CI: 1.3-3.6). The odds of dissatisfaction among obese women were not associated with socioeconomic status as a whole, but were associated with a high educational level, albeit with a comparatively large confidence interval (OR=3.6, 95% CI: 1.0-12.8). CONCLUSIONS: In Germany, body weight dissatisfaction is more prevalent among obese and preobese men in high socioeconomic status groups, a pattern not found in women. The exception to this is a greater prevalence of dissatisfaction among obese and preobese women with a high educational level (albeit inconsistently). Moreover, there is a social gradient in body weight dissatisfaction, especially in obese men, which may partly explain why obesity is more prevalent in men with low socioeconomic status. It also suggests that they are a target group for obesity care in which body weight satisfaction is an important topic.
BMC Public Health

Rogowski, W.H.; Grosse, S.D.; Meyer, E.; John, J.; Palmer, S.
Die Nutzung von Informationswertanalysen in Entscheidungen über angewandte Forschung. Der Fall des genetischen Screenings auf Hämochromatose in Deutschland.
Bundesgesundheitsbl.-Gesund. 55, 700-709 (2012)
Angesichts der Vielzahl neuer genetischer Tests sehen sich öffentliche Geldgeber der Forderung gegenüber, in Forschung zu deren Wirksamkeit und Wirtschaftlichkeit zu investieren. Solche Untersuchungen rentieren sich aber nur, wenn die daraus gewonnenen Ergebnisse einen relevanten Einfluss auf die Versorgungspraxis haben. Eine Obergrenze für den Wert zusätzlicher Informationen, die die Entscheidungsgrundlage für die Erstattung einzelner Gentests verbessern würden, ist durch den Erwartungswert perfekter Information (Expected Value of Perfect Information, EVPI) gegeben. Die vorliegende Studie illustriert die Bedeutung des EVPI auf Grundlage einer probabilistischen Kosteneffektivitätsanalyse des Screenings auf hereditäre Hämochromatose bei Männern in Deutschland. Hier ist die Einführung eines Bevölkerungsscreenings bei Schwellenwerten von 50.000 oder 100.000 Euro pro gewonnenem Lebensjahr kaum zu empfehlen, und auch der maximal erreichbare Nutzen weiterer Forschung, die zur Revidierung dieser Entscheidung führen könnte, ist gering: Bei den genannten Schwellenwerten beträgt der EVPI 500.000 beziehungsweise 2,2 Mio. Euro. Eine Analyse des EVPI für einzelne Parameter (-gruppen) zeigt, dass Studien über die Adhärenz zur präventiven Phlebotomie den größten potenziellen Nutzen haben. Der Informationswert hängt auch von methodischen Annahmen zum Zeithorizont der Berechnung ab sowie von Szenarien zur Zahl der betroffenen Patienten und der Wirtschaftlichkeit des Screenings.
Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz

John, J.; Wolfenstetter, S.B.; Wenig, C.M.
An economic perspective on childhood obesity: Recent findings on cost of illness and cost effectiveness of interventions.
Nutrition 28, 829-839 (2012)
OBJECTIVE: This review aims to put an economic perspective on childhood and adolescent obesity by providing an overview on the latest literature on obesity-related costs and the cost effectiveness of interventions to prevent or manage the problem. METHODS: The review is based on a comprehensive PubMed/Medline search performed in October 2011. RESULTS: Findings on the economic burden of childhood obesity are inconclusive. Considering the different cost components and age groups, most but not all studies found excess health care costs for obese compared with normal-weight peers. The main limitations relate to short study periods and the strong focus on health care costs, neglecting other components of the economic burden of childhood obesity. The results of the economic evaluations of childhood and adolescent obesity programs support the expectation that preventive and management interventions with acceptable cost effectiveness do exist. Some interventions may even be cost saving. However, owing to the differences in various methodologic aspects, it is difficult to compare preventive and treatment approaches in their cost effectiveness or to determine the most cost-effective timing of preventive interventions during infancy and adolescence. CONCLUSION: To design effective public policies against the obesity epidemic, a better understanding and a more precise assessment of the health care costs and the broader economic burden are necessary but, critically, depend on the collection of additional longitudinal data. The economic evaluation of childhood obesity interventions poses various methodologic challenges, which should be addressed in future research to fully use the potential of economic evaluation as an aid to decision making.
Nutrition

Mielck, A.
Soziale Ungleichheit und Gesundheit: Empirische Belege für die zentrale Rolle der schulischen und beruflichen Bildung.
In: Brähler, E.*; Kiess, J.*; Schubert, C.*; Kiess, W.* [Eds.]: Gesund und gebildet: Voraussetzungen für eine moderne Gesellschaft. Göttingen: Vandenhoeck & Ruprecht, 2012. 129-145
In letzter Zeit häufen sich in Deutschland nicht nur die Armutsberichte, sondern auch die Berichte über den Zusammenhang zwischen der sozialen Ungleichheit einerseits und dem Gesundheitszustand andererseits. In einer kaum mehr überschaubaren Vielzahl von Arbeiten ist immer wieder gezeigt worden, dass Personen mit niedrigem sozialen Status zumeist einen besonders schlechten Gesundheitszustand aufweisen, dass sie kränker sind und früher sterben als Personen mit höherem sozialen Status (Mielck, 2005; Richter u. Hurrelmann, 2009). In der wissenschaftlichen Diskussion wird dieser Zusammenhang zwischen Sozialstatus und Morbidität bzw. Mortalität als >gesundheitliche Ungleichheit< bezeichnet. Wichtig ist nicht nur die Existenz, sondern auch das Ausmaß dieser gesundheitlichen Ungleichheit. Im Folgenden werden dazu einige zentrale Ergebnisse vorgestellt.
Meyer, E.; Rees, R.

Watchfully waiting: Medical intervention as an optimal investment decision.
J. Health Econ. 31, 349-358 (2012)
Watchfully waiting involves monitoring a patient's health state over time and deciding whether to undertake a medical intervention, or to postpone it and continue observing the patient. In this paper, we consider the timing of medical intervention as an optimal stopping problem. The development of the patient's health state in the absence of intervention follows a stochastic process (geometric Brownian motion). Spontaneous recovery occurs in case the absorbing state of "good health" is reached. We determine optimal threshold values for initiating the intervention, and derive comparative statics results with respect to the model parameters. In particular, an increase in the degree of uncertainty over the patient's development in most cases makes waiting more attractive. However, this may not hold if the patient's health state has a tendency to improve. The model can be extended to allow for risk aversion and for sudden, Poisson-type shocks to the patient's health state.
Journal of Health Economics

Wolfenstetter, S.B.; Schweikert, B.; John, J.
Programme costing of a physical activity programme in primary prevention: Should the costs of health asset assessment and participatory programme development count?
Adv. Prev. Med. 2012:601631 (2012)
This analysis aims to discuss the implications of the “health asset concept”, introduced by the WHO, and the “investment for health model” requiring a “participatory approach” of cooperative programme development applied on a physical activity programme for socially disadvantaged women and to demonstrate the related costing issues as well as the relevant decision context. The costs of programme implementation amounted to €48,700. Adding the costs for developing the programme design of €48,800 results in total costs of €97,500; adding on top of that the costs of asset assessment running to €35,600 would total €133,100. These four different cost figures match four different types of potentially relevant decisions contexts. Depending on the decision context the total costs, and hence the incremental cost-effectiveness ratio of a health promotion intervention, could differ considerably. Therefore, a detailed cost assessment and the identification of the decision context are of crucial importance.
Advances in Preventive Medicine

Vogl, M.; Wenig, C.M.; Leidl, R.; Pokhrel, S.
Smoking and health-related quality of life in English general population: Implications for economic evaluations.
BMC Public Health 12:203 (2012)
BACKGROUND: Little is known as to how health-related quality of life (HRQoL) when measured by generic instruments such as EQ-5D differ across smokers, ex-smokers and never-smokers in the general population; whether the overall pattern of this difference remain consistent in each domain of HRQoL; and what implications this variation, if any, would have for economic evaluations of tobacco control interventions. METHODS: Using the 2006 round of Health Survey for England data (n = 13,241), this paper aims to examine the impact of smoking status on health-related quality of life in English population. Depending upon the nature of the EQ-5D data (i.e. tariff or domains), linear or logistic regression models were fitted to control for biology, clinical conditions, socio-economic background and lifestyle factors that an individual may have regardless of their smoking status. Age- and gender-specific predicted values according to smoking status are offered as the potential 'utility' values to be used in future economic evaluation models. RESULTS: The observed difference of 0.1100 in EQ-5D scores between never-smokers (0.8839) and heavy-smokers (0.7739) reduced to 0.0516 after adjusting for biological, clinical, lifestyle and socioeconomic conditions. Heavy-smokers, when compared with never-smokers, were significantly more likely to report some/severe problems in all five domains - mobility (67%), self-care (70%), usual activity (42%), pain/discomfort (46%) and anxiety/depression (86%) -. 'Utility' values by age and gender for each category of smoking are provided to be used in the future economic evaluations. CONCLUSION: Smoking is significantly and negatively associated with health-related quality of life in English general population and the magnitude of this association is determined by the number of cigarettes smoked. The varying degree of this association, captured through instruments such as EQ-5D, may need to be fed into the design of future economic evaluations where the intervention being evaluated affects (e.g. tobacco control) or is affected (e.g. treatment for lung cancer) by individual's (or patients') smoking status.
BMC Public Health

Varga, O.; Soini, S.; Kääriäinen, H.; Cassiman, J.-J.; Nippert, I.; Rogowski, W.H.; Nys, H.; Kristoffersson, U.; Schmidtke, J.; Sequeiros, J.
Definitions of genetic testing in European legal documents.
J. Community Genet. 3, 125-141 (2012)
The definition of "genetic testing" is not a simple matter, and the term is often used with different meanings. The purpose of this work was the collection and analysis of European (and other) legislation and policy instruments regarding genetic testing, to scrutinise the definitions of genetic testing therewith contained the following: 60 legal documents were identified and examined-55 national and five international ones. Documents were analysed for the type (context) of testing and the material tested and compared by legal fields (privacy and confidentiality, data protection, biobanks, insurance and labour law, forensic medicine); some instruments are very complex and deal with various legal fields at the same time. There was no standard for the definitions used, and different approaches were identified (from wide general, to some very specific and technically based). Often, legal documents did not contain any definitions, and many did not distinguish between genetic testing and genetic information. Genetic testing was more often defined in non-binding legal documents than in binding ones. Definitions are core elements of legal documents, and their accuracy and harmonisation (particularly within a particular legal field) is critical, not to compromise their enforcement. We believe to have gathered now the evidence for adopting the much needed differentiation between (a) "clinical genetics testing", (b) "genetics laboratory-based genetic testing" and (c) "genetic information", as proposed before.
Journal of Community Genetics

Häfner, S.; Baumert, J.J.; Emeny, R.T.; Lacruz, M.E.; Bidlingmaier, M.; Reincke, M.; Kuenzel, H.; Holle, R.; Rupprecht, R.; Ladwig, K.-H.; MONICA/KORA Study Investigators ()
To live alone and to be depressed, an alarming combination for the renin-angiotensin-aldosterone-system (RAAS).
Psychoneuroendocrinology 37, 230-237 (2012)

INTRODUCTION: The renin-angiotensin-aldosterone-system (RAAS) is one of the most important systems involved in the pathogenesis of cardiovascular diseases. Its role in stress response has been generally neglected, although the progression of cardiovascular disease is considerably increased in the presence of stress and especially in the presence of depression risk. With the present analysis we aimed to evaluate whether the activity of the RAAS correlates with depressive symptomatology and with chronic stress. Moreover, we aimed to analyse whether stress response is altered in the presence of depressed symptomatology. We chose "living alone" to be our paradigm of chronic stress. METHODS AND RESULTS: Aldosterone and renin levels were assessed in 1743 (829 men, 914 women) from the population-based KORA study (Cooperative Health Research in the Region of Augsburg). The relationship between aldosterone, renin levels and the different combinations of living alone and depressive symptomatology was examined in three different multiple linear regression models adjusted for age, sex, creatinine levels, potassium levels, body mass index (BMI) and bio-behavioural factors. Neither "living alone" nor depressive symptomatology alone were associated with an activation of the RAAS, but the combination of living alone and depressive symptomatology yielded a highly significant increase in the aldosterone ($p<0.01$) and renin level ($p=0.03$). CONCLUSION: Our findings show that depressive symptomatology is associated with a hyper-responsiveness to chronic stress. Under the condition of chronic stress depressed individuals have an activated RAAS. Activation of the RAAS might explain the known increased risk of negative cardiovascular disease outcomes in this group.
Psychoneuroendocrinology

Schipf, S.; Werner, A.; Tamayo, T.; Holle, R.; Schunk, M.; Maier, W.; Meisinger, C.; Thorand, B.; Berger, K.; Mueller, G.; Moebus, S.; Bokhof, B.; Kluttig, A.; Greiser, K.H.; Neuhauser, H.; Ellert, U.; Icks, A.; Rathmann, W.; Völzke, H.
Regional differences in the prevalence of known type 2 diabetes mellitus in 45-74 years old individuals: Results from six population-based studies in Germany (DIAB-CORE consortium).
Diabetic Med. 29, E88-E95 (2012)
Aim: In Germany, regional data on the prevalence of Type 2 diabetes mellitus are lacking for health-care planning and detection of risk factors associated with this disease. We analysed regional variations in the prevalence of Type 2 diabetes and treatment with antidiabetic agents. Methods: Data of subjects aged 45-74 years from five regional population-based studies and one nationwide study conducted between 1997 and 2006 were analysed. Information on self-reported diabetes, treatment, and diagnosis of diabetes were compared. Type 2 diabetes prevalence estimates (95% confidence interval) from regional studies were directly standardized to the German population (31 December 2007). Results: Of the 11 688 participants of the regional studies, 1008 had known Type 2 diabetes, corresponding to a prevalence of 8.6% (8.1-9.1%). For the nationwide study, a prevalence of 8.2% (7.3-9.2%) was estimated. Prevalence was higher in men (9.7%; 8.9-10.4%) than in women (7.6%; 6.9-8.3%). The regional standardized prevalence was highest in the east with 12.0% (10.3-13.7%) and lowest in the south with 5.8% (4.9-6.7%). Among persons with Type 2 diabetes, treatment with oral antidiabetic agents was more frequently reported in the south (56.9%) and less in the northeast (46.0%), whereas treatment with insulin alone was more frequently reported in the northeast (21.6%) than in the south (16.4%). Conclusion: The prevalence of known Type 2 diabetes mellitus showed a southwest-to-northeast gradient within Germany, which is in accord with regional differences in the distribution of risk factors for Type 2 diabetes. Furthermore, the treatment with antidiabetic agents showed regional differences.
Diabetic Medicine

Huber, J.; Lampert, T.; Mielck, A.
Unterschiede bei Gesundheitsrisiken, Morbidität und gesundheitlicher Versorgung zwischen Kindern GKV- bzw. PKV-versicherter Eltern: Ergebnisse aus dem Kinder- und Jugendgesundheitssurvey (KiGGS).
Gesundheitswesen 74, 627-638 (2012)
Hintergrund: Die wenigen Studien zum Vergleich zwischen GKV- und PKV-versicherten Erwachsenen zeigen, dass die GKV-Versicherten zumeist kränker sind und öfter zu einem Allgemeinarzt gehen. Die Vermutung liegt nahe, dass vergleichbare Unterschiede auch bei ihren Kindern vorhanden sind; empirisch untersucht wurde dies offenbar jedoch noch nicht. Die folgende Arbeit will dazu beitragen, diese Forschungslücke zu schließen. Zugleich sollen einige Empfehlungen für weiterführende Analysen zu GKV/PKV-Unterschieden abgeleitet werden. Methoden: Aus den bevölkerungsrepräsentativen Daten der KiGGS-Studie (n=17 641; Responserate: 66,6%) wurden 3 Gruppen abhängiger Variablen ausgewählt: Variablen zu Gesundheitsrisiken, zur Morbidität und zur gesundheitlichen Versorgung. Die abhängigen Variablen, bei denen sich nach Durchführung von Chi-Quadrat-Tests ein signifikanter Unterschied zwischen GKV- bzw. PKV-versicherten Kindern zeigte, sind anschließend in die multivariate Analyse aufgenommen worden (logistische Regression; statistische Kontrolle von Alter, Geschlecht, Migrationshintergrund und sozioökonomischer Status (SES)). Zudem wurden nach Geschlecht und Sozialschicht stratifizierte Analysen durchgeführt Ergebnisse: Die bivariate Betrachtung zeigt, dass in jeder der 3 Gruppen abhängiger Variablen signifikante Unterschiede zwischen GKV- bzw. PKV-versicherten Kindern gefunden werden können. Im logistischen Modell reduzieren sich diese Unterschiede zum Teil erheblich, und sie sind nur noch bei einigen Variablen aus den Themenbereichen ‚Gesundheitsrisiken' und ‚gesundheitliche Versorgung' signifikant. Verglichen mit PKV-versicherten Kindern werden GKV-versicherte Kinder beispielsweise häufiger nicht voll gestillt (OR=1,17; 95%-CI 1,03-1,34), sie rauchen häufiger (OR=1,41; 95%-CI 1,04-1,91), und sie gehen öfter zu einem Kinderarzt oder zu einem Arzt für Allgemeinmedizin (OR=1,27; 95%-CI 1,05-1,54). Schlussfolgerung: GKV-versicherte Kinder und Jugendliche sind zumeist größeren gesundheitlichen Belastungen ausgesetzt als PKV-versicherte. Die Unterschiede beim Gesundheitszustand sind offenbar vor allem auf den Einfluss von Migrationshintergrund und sozioökonomischem Status zurückführen. Maßnahmen zur Verringerung dieser gesundheitlichen Unterschiede sollten daher vor allem bei den Risiken ansetzen, die mit Migrationshintergrund und niedrigem sozioökonomischen Status verbunden sind. Hinzu kommt, dass die größere Exposition GKV-versicherter Kinder und Jugendlicher bei gesundheitlichen Risiken wie Rauchen nicht durch Unterschiede bei Migrationshintergrund und sozioökonomischem Status erklärt werden kann. Hier besteht in der GKV also ganz allgemein (d. h. unabhängig von

Migrationshintergrund und sozioökonomischem Status) ein erhöhter Präventionsbedarf.
Gesundheitswesen, Das

Nagel, J.M.; Bücker, S.; Wood, M.; Stark, R.G.; Göke, B.; Parhofer, K.G.; Allgayer, H.
Less advanced stages of colon cancer in patients with type 2 diabetes mellitus: An unexpected finding?
Exp. Clin. Endocrinol. Diabet. 120, 224-228 (2012)
Epidemiological studies have found an increased risk for colon cancer and faster disease progression in patients with type 2 diabetes mellitus (T2DM). We aimed to determine whether patients with T2DM are diagnosed with more advanced stages of colorectal cancer, i. e., metastasized disease (UICC III and IV), at the time of diagnosis, since such a finding may have an impact on future guidelines for patients with T2DM.A cross-sectional analysis of colorectal cancer patients was performed. Stages at diagnosis in patients with (18.0%) or without (82%) T2DM were compared using logistic regression analysis to correct for confounders.Patients with T2DM were older, more obese, and more often male (each p<0.05). Unexpectedly, patients with T2DM had a lower risk for metastasized disease at diagnosis (p=0.023). Correction for age, gender, BMI, smoking and aspirin intake in a multiple logistic regression analysis did not change the result (OR=0.57, p=0.037). When looking at individual cancer stages rather than collapsed categories, there was a trend for less advanced stages in patients with T2DM (p=0.093). Excluding stage I because of potential screening bias due to the introduction of (insurance-covered) colonoscopy screening improved model fit, and confirmed less advanced cancer stages (p=0.0246).Possibly because of earlier detection, patients with T2DM may be at lower risk for advanced stages of colon cancer at diagnosis. Further studies are warranted to confirm our results and to investigate the impact of closer medical surveillance in patients with type 2 diabetes mellitus.
Experimental and Clinical Endocrinology & Diabetes

Mielck, A.; Helmert, U.
Soziale Ungleichheit und Gesundheit.
In: Hurrelmann, K.*; Razum, O.* [Eds.]: Handbuch Gesundheitswissenschaften. Landsberg: BELTZ, 2012. 493-515
no Abstract
Kuznetsov, L.; Maier, W.; Hunger, M.; Meyer, M.; Mielck, A.
Regional deprivation in Bavaria, Germany: Linking a new deprivation score with registry data for lung and colorectal cancer.
Int. J. Public Health 57, 827-835 (2012)
OBJECTIVE: This study aimed to examine the differences in cancer risk by regional deprivation in Bavaria, Germany. METHODS: Multilevel Poisson regression analysis was used to evaluate the association between lung and colorectal cancer risk and community deprivation level based on data from the Cancer Registry of Bavaria (2003-2006). The communities (n = 1,408) were classified according to the Bavarian Index of Multiple Deprivation (BIMD), differentiated into quintiles ranging from lowest to highest deprivation. RESULTS: Increased lung cancer risk in men and colorectal cancer risk in both genders were associated with increasing BIMD. Comparing the most deprived with the least deprived communities, the relative risk for lung cancer incidence in men was 1.39 (95% CI 1.29-1.49), for mortality risk 1.54 (95% CI 1.41-1.68). The relative risk for colorectal cancer incidence in men was 1.30 (95% CI 1.22-1.38) and in women 1.19 (95% CI 1.11-1.27); for mortality risk we found 1.57 (95% CI 1.40-1.76) in men and 1.34 (95% CI 1.19-1.51) in women. CONCLUSION: Area-based deprivation is significantly associated with cancer risk in Bavaria.
International Journal of Public Health

Maier, W.; Fairburn, J.; Mielck, A.
Regionale Deprivation und Mortalität in Bayern. Entwicklung eines 'Index Multipler Deprivation' auf Gemeindeebene.
Gesundheitswesen 74, 416-425 (2012)
Einleitung: Deprivationsindizes stellen wertvolle Instrumente zur Analyse regionaler Effekte auf die Gesundheit der Bevölkerung dar. Bei fehlenden sozioökonomischen Individualdaten können diese Indizes auch als Surrogat verwendet werden. Im Vereinigten Königreich sind derartige regionale Deprivationsindizes fester Bestandteil der Public Health - Diskussion, in Deutschland dagegen steht diese Entwicklung erst am Anfang. Unser Ziel war es, auf Grundlage einer etablierten britischen Methode einen kleinräumigen und mehrdimensionalen Index Multipler Deprivation (IMD) für Deutschland zu entwickeln Methodik: Als Modellregion wählten wir das Bundesland Bayern mit seinen n=2 056 Gemeinden. Unter Verwendung soziodemografischer, sozioökonomischer und umweltrelevanter Daten der amtlichen Statistik entwickelten wir hierfür einen Bayerischen Index Multipler Deprivation (BIMD). Um die Eignung dieses Index für epidemiologische Analysen zu prüfen, führten wir anschließend sowohl eine Korrelationsanalyse (Korrelationskoeffizient nach Spearman) als auch eine Poisson-Regression unter Verwendung von Daten zur vorzeitigen Mortalität (Altersgruppe < 65 Jahre) sowie zur Gesamtmortalität (alle Altersgruppen) durch. Ergebnisse: Die Korrelationsanalyse zeigte einen positiven signifikanten Zusammenhang zwischen regionaler Deprivation und Mortalität. Die Poisson-Regression ergab einen klaren Gradienten, d. h. das Mortalitätsrisiko stieg mit zunehmender regionaler Deprivation stufenweise an. Verglichen mit den Gemeinden im Quintil mit der niedrigsten Deprivation war das relative Risiko bei den Gemeinden mit der höchsten Deprivation deutlich größer, sowohl bei der vorzeitigen Mortalität [RR 1,49 (95% KI: 1,42 – 1,57)] als auch der Gesamtmortalität [RR 1,21 (95% KI: 1,18 – 1,25)] Diskussion: Unter Verwendung des neu gebildeten Index konnte am Beispiel Bayerns gezeigt werden, dass höhere regionale Deprivation mit höherer Mortalität assoziiert ist. Dieser Index stellt somit ein neues und potentiell sehr nützliches Werkzeug für gesundheitswissenschaftliche Studien in Deutschland dar.
Gesundheitswesen, Das

Malnati, M.S.; Heltai, S.; Cosma, A.; Reitmeir, P.; Allgayer, S.; Glashoff, R.H.; Liebrich, W.; Vardas, E.; Imami, N.; Westrop, S.; Nozza, S.; Tambussi, G.; Buttò, S.; Fanales-Belasio, E.; Ensoli, B.; Ensoli, F.; Tripiciano, A.; Fortis, C.; Lusso, P.; Poli, G.; Erfle, V.; Holmes, H.
A new antigen scanning strategy for monitoring HIV-1 specific T-cell immune responses.
J. Immunol. Methods 375, 46-56 (2012)
Delineation of the immune correlates of protection in natural infection or after vaccination is a mandatory step for vaccine development. Although the most recent techniques allow a sensitive and specific detection of the cellular immune response, a consensus on the best strategy to assess their magnitude and breadth is yet to be reached. Within the AIDS Vaccine Integrated

Project (AVIP http://www.avip-eu.org) we developed an antigen scanning strategy combining the empirical-based approach of overlapping peptides with a vast array of database information. This new system, termed Variable Overlapping Peptide Scanning Design (VOPSD), was used for preparing two peptide sets encompassing the candidate HIV-1 vaccine antigens Tat and Nef. Validation of the VOPSD strategy was obtained by direct comparison with 15mer or 20mer peptide sets in a trial involving six laboratories of the AVIP consortium. Cross-reactive background responses were measured in 80 HIV seronegative donors (HIV-), while sensitivity and magnitude of Tat and Nef-specific T-cell responses were assessed on 90 HIV+ individuals. In HIV-, VOPSD peptides generated background responses comparable with those of the standard sets. In HIV-1+ individuals the VOPSD pools showed a higher sensitivity in detecting individual responses (Tat VOPSD vs. Tat 15mers or 20mers: $p \leq 0.01$) as well as in generating stronger responses (Nef VOPSD vs. Nef 20mers: $p<0.001$) than standard sets, enhancing both CD4 and CD8 T-cell responses. Moreover, this peptide design allowed a marked reduction of the peptides number, representing a powerful tool for investigating novel HIV-1 candidate vaccine antigens in cohorts of HIV-seronegative and seropositive individuals.
Journal of Immunological Methods

Perna, L.; Mielck, A.; Lacruz, M.E.; Emeny, R.T.; Holle, R.; Breitfelder, A.; Ladwig, K.-H.
Socioeconomic position, resilience, and health behaviour among elderly people.
Int. J. Public Health 57, 341-349 (2012)
OBJECTIVES: Healthy psychological functioning, the ability to respond rapidly to environmental changes, has been associated with better health outcomes. Less work has examined the association with health behaviour. This study explores whether resilience (a specific expression of healthy psychological functioning) is positively associated with health behaviour in an elderly population aged ≥65 years and whether this association differs in different socioeconomic groups. METHODS: Resilience was measured in 3,942 elderly participating in a population-based cohort study (KORA-Age study) in Germany through a short version of the Resilience Scale developed by Wagnild and Young. Regression analyses were performed by socioeconomic position (low/high educational level or income) for two outcome variables, i.e. high consumption of fruit and vegetables and high/moderate physical activity. RESULTS: Resilient people were more likely to consume ≥5 servings of fruit and vegetables a day and to perform high/moderate physical activity as compared to non-resilient people (ORs ranging from 1.5 to 2.2), irrespective of socioeconomic position. CONCLUSIONS: Resilience could provide an important starting point for health promotion strategies, addressing resources rather than deficits and risk factors.
International Journal of Public Health

Hunger, M.; Sabariego, C.; Stollenwerk, B.; Cieza, A.; Leidl, R.
Validity, reliability and responsiveness of the EQ-5D in German stroke patients undergoing rehabilitation.
Qual. Life Res. 21, 1205-1216 (2012)
PURPOSE: To analyse the psychometric properties of the EQ-5D in German stroke survivors undergoing neurological rehabilitation. METHODS: The EQ-5D, the Hospital Anxiety and Depression Scale (HADS) and the Stroke Impact Scale (SIS) were completed before (210 subjects) and after (183 subjects) a patient education programme in seven rehabilitation clinics in Bavaria, Germany. A postal follow-up was conducted after 6 months. Acceptance, validity, reliability and responsiveness of the EQ-5D were tested. The SIS subscales were used as external anchors to classify the patients into change groups between the measurements. RESULTS: The proportion of missing answers ranged from 4.7 to 8.6%. Between 16 and 19% reported no problems in any EQ-5D dimension. At baseline, correlations between EQ-5D index and the SIS subscales ranged from 0.15 (communication) to 0.60 (mobility). Correlations with the EQ VAS were slightly smaller. All scores were reliable in test-retest with intraclass correlations ranging from 0.67 to 0.81. EQ-5D index and EQ VAS were consistently responsive only to improvements in health, showing small- to medium effect sizes (0.27-0.42). CONCLUSIONS: The EQ-5D has shown reasonable validity, reliability and, more limited, responsiveness in stroke patients with mild to moderate limitations of functional status, allowing it to be used in clinical trials in rehabilitation.
Quality of Life Research

Kowall, B.; Rathmann, W.; Heier, M.; Holle, R.; Peters, A.; Thorand, B.; Herder, C.; Strassburger, K.; Giani, G.; Meisinger, C.
Impact of weight and weight change on normalization of prediabetes and on persistence of normal glucose tolerance in an older population: The KORA S4/F4 study.
Int. J. Obes. 36, 826-833 (2012)
Background and aims:In a population-based cohort study with older subjects and without specific interventions, we investigated the impact of body mass index (BMI) and BMI change (as well as waist circumference and change of waist circumference) on reversion from prediabetes to normal glucose tolerance (NGT) and on long-term persistence of NGT.Materials and methods:Oral glucose tolerance tests were conducted at baseline and at follow-up in a cohort study in Southern Germany (KORA S4/F4; 1223 subjects without diabetes aged 55-74 years at baseline in 1999-2001; 887 subjects (73%), of whom 436 had prediabetes at baseline, participated in the follow-up 7 years later).Results:BMI reduction, but not initial BMI, predicted reversion from prediabetes to NGT. The odds ratio (OR) for returning to NGT was 1.43 (95% CI: 1.18-1.73) for a BMI decrease of 1 kg m(-2), after adjustment for age, sex, baseline glucose values and lifestyle factors. Initial BMI had no effect on reversion to NGT (OR=0.98, 95% CI: 0.91-1.06, per kg m(-2)). Persistence of NGT was associated with baseline BMI (OR=0.94, 95% CI: 0.88-0.998) and BMI reduction (OR=1.16, 95% CI: 1.02-1.33, per decrease by 1 kg m(-2)). For waist circumference and change of waist circumference similar results were obtained.Conclusion:In older adults, weight loss strongly increased the chances of returning from prediabetes to NGT irrespective of initial BMI. Long-term persistence of NGT depended both on initial BMI and on BMI change.
International Journal of Obesity

Menn, P.; Heinrich, J.; Huber, R.M.; Jörres, R.A.; John, J.; Karrasch, S.; Peters, A.; Schulz, H.; Holle, R.
Direct medical costs of COPD - an excess cost approach based on two population-based studies.
Respir. Med. 106, 540-548 (2012)

AIM: While it is known that severe COPD has substantial economic consequences, evidence on resource use and costs in mild disease is scarce. The objective of this study was to investigate excess costs of early stages of COPD. METHODS: Using data from two population-based studies in Southern Germany, current GOLD criteria were applied to pre-bronchodilator spirometry for COPD diagnosis and staging in 2255 participants aged 41 to 89. Utilization of physician visits, hospital stays and medication was compared between participants with COPD stage I, stage II+ (II or higher) and controls. Costs per year were calculated by applying national unit costs. In controlling for confounders, two-part generalized regression analyses were used to account for the skewed distribution of costs and the high proportion of subjects without costs. RESULTS: Utilization in all categories was significantly higher in COPD patients than in controls. After adjusting for confounders, these differences remained present in physician visits and medication, but not in hospital days. Adjusted annual costs did not differ between stage I (€ 1830) and controls (€ 1822), but increased by about 54% to € 2812 in stage II+. CONCLUSION: The finding that utilization and costs are considerably higher in moderate but not in mild COPD highlights the economic importance of prevention and of interventions aiming at early diagnosis and delayed disease progression.
Respiratory Medicine

Lacruz, M.E.; Emeny, R.T.; Haefner, S.; Zimmermann, A.-K.; Linkohr, B.; Holle, R.; Ladwig, K.-H.
Relation between depressed mood, somatic comorbidities and health service utilisation in older adults: Results from the KORA-Age study.
Age Ageing 41, 183-190 (2012)
BACKGROUND: prior literature suggests that comorbidity with depression significantly worsens the health state of people with chronic diseases. OBJECTIVE: the present study examines whether depressed mood increased medical care use for patients with a comorbid physical disease.Design, setting and subjects: the study was a population-based study (KORA-Age), with 3,938 participants aged 64-94. METHODS: we investigated differences in health services use in participants with and without depressed mood (Geriatric Depression Scale). A further adjustment for disease was done and differences were examined with the Mann-Whitney U test. The incidence rate ratios (IRRs) for doctors' appointments or the number of days in hospital were explored with (zero-inflated) negative binomial regression models. RESULTS: there are increased self-neglecting behaviours and medical comorbidities in participants with depressed mood. Depressed mood increased participants' use of medical services ($P < 0.0001$). Among participants who visited the doctor during the last 3 months, those with depressed mood had more visits than those without depressed mood, irrespective of somatic comorbidities ($P < 0.0001$ and $P < 0.05$ for ill and healthy, respectively). Additionally, patients with coexisting depressed mood and physical disease visited the doctor's practice significantly more often. Having depressed mood significantly increases the likelihood for more doctor visits (IRR = 1.5, CI = 1.3-1.7) and longer hospital stays (IRR = 1.9, CI = 1.6-2.3). In participants with somatic comorbidities the risk is even greater (IRR = 1.6, CI = 1.3-2, for the number of doctors visits and IRR = 2, CI = 1.4-2.9, for the number of days in the hospital). CONCLUSIONS: results suggest that patients with depressed mood had increased use of health-care services overall, particularly those with somatic comorbidities.
Age and Ageing

Haas, L.; Stargardt, T.; Schreyögg, J.
Cost-effectiveness of open versus laparoscopic appendectomy: A multilevel approach with propensity score matching.
Eur. J. Health Econ. 13, 549-560 (2012)
OBJECTIVE: To compare postoperative complications and cost of treatment of laparoscopic (LA) versus open appendectomy (OA) and to identify the most cost-effective treatment method METHODS: Patients treated for appendectomy in US veterans health administration (VHA) hospitals in 2005 were included into our study. Direct medical cost and postoperative complications during hospitalization were used as outcomes. Propensity score matching was employed to adjust for baseline imbalances between treatment groups. It was adjusted for the severity of appendicitis, comorbidities according to Charlson Comorbidity Index, and demographic variables. 1:1 optimal matching with replacement was performed. Based on the matched samples, we estimated generalized linear mixed regression models for costs (gamma model) and postoperative complications (logit model). Besides patients' covariates, predictors of hospital resource use and quality of care at the hospital level were considered as explanatory variables. RESULTS: The total study population comprised of 1,128 patients (370 LA, 758 OA) from 95 VHA hospitals. Type of appendectomy had a significant influence on total costs ($P = 0.005$), with predicted costs for LA being 17.1% lower in comparison to OA (OA: 10,851 US$ [95%CI: 9,707 US$; 12,131 US$] vs. LA: 8,995 US$ [95%CI: 8,073 US$; 10,022 US$]). Differences in the predicted overall postoperative complication were not significant between LA and OA ($P = 0.6311$). Severity of appendicitis had a significant impact on costs and postoperative complications. CONCLUSION: Predicted costs for LA were 1,856 US$ lower than for OA while the postoperative complication rate did not differ significantly. Thus, LA is the treatment of choice from a provider's perspective.
The European journal of health economics

Haas, L.; Stargardt, T.; Schreyögg, J.; Schlösser, R.; Danzer, G.; Klapp, B.F.
Inpatient costs and predictors of costs in the psychosomatic treatment of anorexia nervosa.
Int. J. Eating Disord. 45, 214-221 (2012)
Objective: In German inpatient psychosomatics per diem lump sums will be introduced as reimbursement rates by 2013. It was the aim to calculate total inpatient costs per case for the psychosomatic treatment of patients with anorexia nervosa and to identify cost predictors. Method: The sample comprised of 127 inpatients. Cost calculation was executed from the hospital's perspective, mainly using microcosting. Medical records provided data on patient characteristics and individual resource use. Two generalized linear models with gamma distribution and log link function were estimated to determine cost predictors by means of demographic data, comorbidities, and body-mass-index at admission. Results: Inpatient costs amounted to 4,647 e/6,831 US$ per case (standard deviation 3,714 e/5,460 US$).The admission BMI and "Disorders of Adult Personality and Behavior" were significant cost predictors (p�.05). Discussion: The formation of patient groups within the diagnosis

anorexia nervosa should be oriented towards the determined cost predictors.
International Journal of Eating Disorders

Leidl, R.; Reitmeir, P.; König, H.-H.; Stark, R.G.
The performance of a value set for the EQ-5D based on experienced health states in patients with inflammatory bowel disease.
Value Health 15, 151-157 (2012)
Objectives: To compare in patients with inflammatory bowel disease the performance of a value set for the EQ-5D based on experienced health states (EHSs) with value sets based on given health states (GHSs). Methods: A value set based on EHSs and valuation by the visual analogue scale (VAS) in the German general population was compared with a German and a UK value set, both based on GHSs and time-trade off valuation. Accuracy in the prediction of actual VAS ratings by patients was assessed using correlation and mean absolute error. Construct validity was tested by correlation with established disease activity indices and test-retest reliability by intraclass correlation between two measurements. Data originated from a survey of 270 patients with Crohn's disease and 232 patients with ulcerative colitis. Results: EHS-VAS correlates best with actual VAS ratings for all patients but not for all subgroups. EHS-VAS has the lowest mean absolute error for almost all analyzed groups except for measured differences between two time points. Regarding test-retest reliability in all patients, EHS-VAS correlations were closest to those of actual VAS ratings. Conclusion: EHS-VAS renders experience-based valuations but not decision utilities. GHS-based approaches cover severe health states more extensively, but study patients reported health states similar to those of a general population. Compared to GHS time-trade off value sets, the EHS-VAS value set predicted EQ-5D VAS valuations by patients with inflammatory bowel disease equally well and partly better. It performed partly better with respect to test-retest reliability and the same with respect to construct validity.
Value in Health

Wolfenstetter, S.B.
Future direct and indirect costs of obesity and the influence of gaining weight: Results from the MONICA/KORA cohort studies, 1995-2005.
Econ. Hum. Biol. 10, 127-138 (2012)
Over the last two decades, the prevalence of obesity has risen worldwide. As obesity is a confirmed risk factor for a number of diseases, its increasing prevalence nurtures the supposition that obesity may present a growing and significant economic burden to society. The objective of this study is to analyse the correlation between body mass index (BMI) and future direct and indirect costs, as well as the correlation between changing BMI and future in(direct) costs. Health care utilisation and productivity losses were based on data from 2581 participants aged 25-65years (1994/95) from two cross-sectional, population-representative health surveys (MONICA/KORA-survey-S3 1994/95 and follow-up KORA-survey-F3 2004/05) in Augsburg, Germany. The predicted average adjusted total direct costs per year and per user were estimated to be €1029-(healthy weight), €1093-(overweight) and €1040-(obesity). There are significantly greater future costs in the utilisation of general practitioners per user and per year at higher obesity levels (€72; €75; €96). The average total direct costs per person for those who stay in the same BMI class are €982, €1000 and €973. An overweight participant who becomes obese incurs significant costs of internists of €160 compared with those who remain overweight (€124). An overweight user incurs indirect costs of €2474, compared with €2136 for those who remain a healthy weight. There is a trend for higher predicted (in)direct costs when people are overweight or obese compared with healthy weight persons 10years earlier. Potential cost savings could be attained if preventive programs effectively targeted these individuals.
Economics and Human Biology

Hegar, R.; Döring, A.; Mielck, A.
Einfluss des subjektiven Sozialstatus auf gesundheitliche Risiken und Gesundheitszustand - Ergebnisse der KORA-F4-Studie.
Gesundheitswesen 74, 306-314 (2012)
OBJECTIVES: In public health research, social status is usually assessed by objective indicators such as educational level and income. Recent studies have shown the importance of including 'subjective social status (SSS)'. The aim of this study is to analyse the influence of SSS on health for the first time in Germany, and to find out if there is an effect over and above the objective indicators of social status. METHODS: The KORA F4 study took place in 2006-2008 in the region of Augsburg, Southern Germany, with a study population of 3 080 men and women aged 32-81 years. SSS was assessed by a single question with 6 possible responses. For the analyses, 3 SSS categories were differentiated: low, middle and high. The following dependent variables were included: self-rated health (SRH), hypertension (uncontrolled), diabetes, metabolic syndrome, hay fever, no participation in medical cancer prevention, obesity (assessed by body mass index and waist-hip-ratio), smoking, physical inactivity. Logistic regression models were used to estimate the influence of SSS (e. g. adjusted for educational level and income). RESULTS: About 25% of the participants group themselves into the lowest SSS-category. Without adjustment for educational level and income, SSS is negatively associated with SRH, hypertension, diabetes, metabolic syndrome, obesity, no participation in medical cancer prevention, smoking and physical inactivity; as expected the association with hay fever is positive. After adjustment for educational level and income, not all of these associations remain significant. Some of the adjusted odds ratios (OR) for SSS differ considerably when stratified by gender, for example concerning the variable 'physical inactivity': The comparison of 'SSS low' vs. 'SSS high' shows for men OR 2.35 (95% confidence interval (CI) 1.57-3.50) and for women OR 3.58 (95% CI 2.34-5.47). CONCLUSION: The results from this study strongly suggest that SSS is an important indicator of social status (to date largely disregarded in public health research). Thus, SSS should be applied in addition to other indicators of social status such as educational level and income. The associations with SSS depend on the health indicator studied. Also, sometimes there are large differences when stratified by gender. Further research is needed to fully understand the determinants of SSS and its impact on health.
Gesundheitswesen, Das

Kuznetsov, L.; Mielck, A.
Regionale Konzentration von sozialer Benachteiligung und von Risiken für Lungen- und Darmkrebs: Systematischer Review und Ableitung von Empfehlungen.
Gesundheitswesen 74, e42-e51 (2012)

OBJECTIVES: Individual health status is influenced by individual social characteristics (age, gender, income usw.) and by the social characteristics of the regional environment in which the person lives. This is true also for lung cancer and colon cancer, two of the most common cancer sites in Germany. No systematic review about the social and regional distribution of lung cancer and colon cancer has been published in German-speaking countries yet. However, it could allow us to deepen the discussion regarding explanations of cancer risks and potential interventions. METHODS: Lung cancer and colon cancer have been selected because they are the two most common gender-independent cancer sites in Germany. A systematic literature search has been conducted via the Medline database using PubMed. 2 groups of regional differences have been distinguished, first by socio-economic characteristics (e. g., average household income) and second by urban vs. rural characteristics. The publications have then been analysed in a systematic way. RESULTS: 17 publications could be found, just 2 of them are from a German-speaking country (one each from Germany and Switzerland). The results concerning incidence and mortality can be summarised in the following way: The risks for lung cancer increase with decreasing socio-economic status of the region, but no clear association could be found for colon cancer. Some studies include information on urban-rural differences. They show that the risks for lung cancer are higher in urban as compared to rural areas; for colon cancer, again, no clear associations could be found. CONCLUSION: The review shows that some studies have already looked at social and regional differences in lung cancer and colon cancer, and that these associations have hardly been discussed in German-speaking countries as yet. We still do not know why lung cancer risks are especially high in low status regions, even if individual smoking is accounted for. The answer could probably be provided by risks such as air pollution. Therefore, a balanced strategy for reducing health inequalities should not just focus on improving individual health behaviour, but also on reducing the regional risks factors.
Gesundheitswesen, Das

Zechmeister, I.; Ara, R.; Ward, S.; Stollenwerk, B.
Have statins met our expectations? A comparison of expected health gains from statins with epidemiological trends in Austria.
J. Public Health 20, 31-39 (2012)
Aim: As a consequence of the demonstrated efficacy in clinical studies, statins have increasingly been used in the secondary prevention of cardiovascular diseases (CVD). We aim to analyse whether expected health gains based on efficacy data can be confirmed by epidemiological trends in the Austrian population. Subjects and methods A Markov model that estimates clinical outcomes from statin treatment in secondary prevention was linked with Austrian data on statin prescription to estimate expected population health gains from 1997 to 2007. Model results are contrasted with epidemiological data on CVD mortality and morbidity. Results Among approximately 600,000 persons who took statins between 1996 and 2006, it was estimated that 860 fewer cases of unstable angina, 26,000 fewer myocardial infarcts (MIs), 1,100 fewer strokes, and roughly 25,000 more cases of stable angina occurred compared to non-medical prevention. In contrast, observed Epidemiological trends indicate an increase in CVD morbidity. Furthermore, the model demonstrated 10,300 avoided/postponed fatal CVD events in Austria. Decreasing coronary heart disease (CHD) and MI mortality rates in the model are congruent with the observed epidemiology. Conclusion Tentative evidence exists that statins may have contributed to decreasing CHD mortality in Austria, whereas the expected benefits with respect to CHD morbidity and related revascularisation interventions could not be verified.
Journal of Public Mental Health

Schad, M.; John, J.
Towards a social discount rate for the economic evaluation of health technologies in Germany: An exploratory analysis.
Eur. J. Health Econ. 13, 127-144 (2012)
Over the last decades, methods for the economic evaluation of health care technologies were increasingly used to inform reimbursement decisions. For a short time, the German Statutory Health Insurance makes use of these methods to support reimbursement decisions on patented drugs. In this context, the discounting procedure emerges as a critical component of these methods, as discount rates can strongly affect the resulting incremental cost-effectiveness ratios. The aim of this paper is to identify the appropriate value of a social discount rate to be used by the German Statutory Health Insurance for the economic evaluation of health technologies. On theoretical grounds, we build on the widespread view of contemporary economists that the social rate of time preference (SRTP) is the adequate social discount rate. For quantifying the SRTP, we first apply the market behaviour approach, which assumes that the SRTP is reflected in observable market interest rates. As a second approach, we derive the SRTP from optimal growth theory by using the Ramsey equation. A major part of the paper is devoted to specify the parameters of this equation. Depending on various assumptions, our empirical findings result in the range of 1.75-4.2% for the SRTP. A reasonable base case discount rate for Germany, thus, would be about 3%. Furthermore, we deal with the much debated question whether a common discount rate for costs and health benefits or a lower rate for health should be applied in health economic evaluations. In the German social health insurance system, no exogenously fixed budget constraint does exist. When evaluating a new health technology, the health care decision maker is obliged to conduct an economic evaluation in order to examine whether there is an economically appropriate relation between the value of the health gains and the additional costs which are given by the value of the consumption losses due to the additional health care expenditures. Therefore, a discount rate lower than the SRTP for consumption should be applied if an increase in the consumption value of health is expected. However, given the limited empirical evidence on the relationship between consumption and the value of health, it is hardly possible to make reliable forecasts of this value. Regarding the practice of the German evaluation authority, it is not recommended to use differential discounting in the base case. Instead, the issue of differential discounting should be addressed in sensitivity analyses. Reducing the discount rate for health compared to the rate for costs by a figure in the range between near 0% and 3% may be considered to be appropriate for Germany.
The European journal of health economics

Wenig, C.M.
The impact of BMI on direct costs in children and adolescents: Empirical findings for the German Healthcare System based on the KiGGS-study.
Eur. J. Health Econ. 13, 39-50 (2012)

To understand Latina mothers' definitions of health and obesity in their children and perceptions of physician weight assessments. 24 low-income Spanish speaking Mexican mothers of children ages 2–5 years were recruited to participate in 4 focus groups. Half of the mothers had overweight or obese children and half had healthy weight children. Focus group comments were transcribed and analyzed using grounded theory. Themes and supporting comments were identified independently by 3 reviewers for triangulation. A fourth reader independently confirmed common themes. Mothers define health as a function of their child's ability to play and engage in all aspects of life. Obesity was defined with declining physical abilities. Mothers state health care provider assessments help determine a child's overweight status. Causative factors of obesity included family role-modeling and psycho-social stress, physical inactivity, and high-fat foods consumed outside the home. Controlling food intake was the primary approach to preventing and managing obesity but mothers described family conflict related to children's eating habits. These findings held constant with mothers regardless of whether their children were overweight, obese, or at a healthy weight. Mothers utilize physical limitations and health care professional's assessment of their child's weight as indicators of an overweight status. These results highlight the importance of calculating and communicating body mass indices (BMI) for Latino children. Eliminating non-nutritive foods from the home, increasing physical activity, and involving family members in the discussion of health and weight maintenance are important strategies for the prevention and management of childhood obesity.
The European journal of health economics

2011
Voigtländer, S.; Mielck, A.; Razum, O.
Die Bedeutung des kleinräumigen Kontexts für Gesundheit: Entwurf eines Erklärungsmodells.
Gesundheitswesen 74, 702-709 (2011)
Hintergrund: Neuere empirische Arbeiten betonen, dass Merkmale des kleinräumigen Kontexts einen bedeutsamen und möglicherweise zunehmenden Einfl uss auf individuelle Gesundheit besitzen. Bisher fehlt es jedoch an einem einheitlichen Erklärungsmodell, welches die verschiedenen Arten solcher Merkmale integriert und als ein Zusammenspiel mit individuellen Merkmalen sozialer Ungleichheit konzeptualisiert. Methodik: Review theoretischer Arbeiten zum Zusammenhang von Lebenslage und Gesundheit sowie der bisherigen Modellvorschläge zum gesundheitlichen Einfl uss von Merkmalen des kleinräumigen Kontexts. Ergebnisse: Mit dem vorliegenden Artikel unterbreiten wir einen Vorschlag für ein Erklärungsmodell zur gesundheitlichen Bedeutung des kleinräumigen Kontexts. Dieses Modell konzeptualisiert den Wohnort von Individuen oder Familien als eine Dimension sozialer Ungleichheit, deren gesundheitliche Wirkung über die der Region und der Nachbarschaft innewohnenden Ressourcen und Belastungen vermittelt wird. Schlussfolgerung: Das beschriebene Erklärungsmodell bietet eine Orientierung für zukünftige empirische Untersuchungen und liefert eine Diskussionsgrundlage zur gesundheitlichen Relevanz des kleinräumigen Kontexts.
Gesundheitswesen, Das

Kuznetsov, L.; Maier, W.; Hunger, M.; Meyer, M.; Mielck, A.
Associations between regional socioeconomic deprivation and cancer risk: Analysis of population-based cancer registry data from Bavaria, Germany.
Prev. Med. 53, 328-330 (2011)
OBJECTIVE: Previous research from other countries shows a positive association between cancer risk and regional deprivation. This study explores this association for lung and colorectal cancers in Germany. METHOD: Regional deprivation was assessed by the 'Bavarian Index of Multiple Deprivation'. Cancer data were provided by the Cancer Registry of Bavaria (2003-2006). The association between cancer risk and regional deprivation was evaluated by multilevel Poisson regression analysis. RESULTS: Crude incidence and mortality rates (per 1000 people) in the least deprived areas were 1.46 and 0.92 for lung cancer, 2.82 and 0.69 for colorectal cancer. For lung cancer, the age-adjusted relative risk (RR) for incidence in the most deprived districts (compared with the least deprived) in men was 1.41 (95% CI: 1.28-1.54), for mortality 1.59 (95% CI: 1.40-1.80); in women, an elevated RR was seen for mortality (1.24, 95% CI: 1.06-1.46). For colorectal cancer, the RR for incidence (men: 1.31, 95% CI: 1.17-1.46; women: 1.25, 95% CI: 1.12-1.40) and mortality (men: 1.51, 95% CI: 1.28-1.80; women: 1.49, 95% CI: 1.26-1.77) was always highest in the most deprived districts. CONCLUSION: At the district level in Bavaria, the risk for lung and colorectal cancers mostly increases with increasing regional deprivation.
Preventive Medicine

Heidelberg, D.A.; Holle, R.; Lacruz, M.E.; Ladwig, K.-H.; von Lengerke, T.
Do diabetes and depressed mood affect associations between obesity and quality of life in postmenopause? Results of the KORA-F3 Augsburg population study.
Health Qual. Life Outcomes 9:97 (2011)
BACKGROUND: To assess associations of obesity with health-related quality of life (HRQL) in postmenopausal women, and whether depressed mood and diabetes moderate these associations. METHODS: Survey of 983 postmenopausal women aged 35-74, general population, Augsburg region/Germany, 2004/2005. Body weight/height and waist/hip circumference were assessed anthropometrically and classified via BMI ≥ 30 as obese, and WHR ≥ 0.85 as abdominally obese (vs. not). Depressed mood was assessed by the Depression and Exhaustion-(DEEX-)scale, diabetes and postmenopausal status by self-report/medication, and HRQL by the SF-12. RESULTS: General linear models revealed negative associations of obesity and abdominal obesity with physical but not mental HRQL. Both forms of excess weight were associated with diabetes but not depressed mood. Moderation depended on the HRQL-domain in question. In non-diabetic women, depressed mood was found to amplify obesity-associated impairment in physical HRQL (mean "obese"-"non-obese" difference given depressed mood: -6.4, p < .001; among those without depressed mood: -2.5, p = .003). Reduced mental HRQL tended to be associated with obesity in diabetic women (mean "obese"-"non-obese" difference: -4.5, p = .073), independent of depressed mood. No interactions pertained to abdominal obesity. CONCLUSIONS: In postmenopausal women, depressed mood may amplify the negative impact of obesity on physical HRQL, while diabetes may be a precondition for some degree of obesity-related impairments in mental HRQL.
Health and Quality of Life Outcomes

Wenig, C.M.; Knopf, H.; Menn, P.
Juvenile obesity and its association with utilisation and costs of pharmaceuticals - results from the KiGGS study.
BMC Health Serv. Res. 11:340 (2011)
BACKGROUND: According to a national reference, 15% of German children and adolescents are overweight (including obese) and 6.3% are obese. An earlier study analysed the impact of childhood overweight and obesity on different components of direct medical costs (physician, hospital and therapists). To complement the existing literature for Germany, this study aims to explore the association of body mass index (BMI) with utilisation of pharmaceuticals and related costs in German children and adolescents. METHODS: Based on data from 14,836 respondents aged 3-17 years in the German Interview and Examination Survey for Children and Adolescents (KiGGS), drug intake and associated costs were estimated using a bottom-up approach. To investigate the association of BMI with utilisation and costs, univariate analyses and multivariate generalised mixed models were conducted. RESULTS: There was no significant difference between BMI groups regarding the probability of drug utilisation. However, the number of pharmaceuticals used was significantly higher (14%) for obese children than for normal weight children. Furthermore, there was a trend for more physician-prescribed medication in obese children and adolescents. Among children with pharmaceutical intake, estimated costs were 24% higher for obese children compared with the normal weight group. CONCLUSIONS: This is the first study to estimate excess drug costs for obesity based on a representative cross-sectional sample of the child and adolescent population in Germany. The results suggest that obese children should be classified as a priority group for prevention. This study complements the existing literature and provides important information concerning the relevance of childhood obesity as a health problem.
BMC Health Services Research

Stark, R.G.; Schunk, M.; Holle, R.
Ergebnisse der KORA-Studien.
In: Günster, C.*; Klose, J.*; Schmacke, N.* [Eds.]: Versorgungsreport 2011. Schwerpunkt: Chronische Erkrankungen. Stuttgart: Schattauer, 2011. 78-82
no abstract

Bähr, I.N.; Tretter, P.; Krüger, J.; Stark, R.G.; Schimkus, J.; Unger, T.; Kappert, K.; Scholze, J.; Parhofer, K.G.; Kintscher, U.
High-dose treatment with telmisartan induces monocytic peroxisome proliferator-activated receptor-γ target genes in patients with the metabolic syndrome.
Hypertension 58, 725-732 (2011)
The present study aimed to explore the anti-inflammatory effects and peroxisome proliferator-activated receptor-γ (PPARγ)-activating properties of the angiotensin type 1 receptor blocker telmisartan by analysis of serum interleukin 6 levels and monocytic PPARγ target gene expression in drug-naïve patients with the metabolic syndrome. This was a 14-week, randomized, double-blind, placebo-controlled 2-center study with telmisartan 80 mg/d and telmisartan 160 mg/d in 54 patients with the metabolic syndrome. In addition to clinical laboratory measurements, peripheral monocytes were extracted by negative isolation using a Dynal Monocyte kit to evaluate ligand-activated PPARγ target gene expression (CD36 and CD163) at baseline and study end using quantitative real-time RT-PCR. In this low-risk patient population, telmisartan (80 and 160 mg) treatment did not significantly affect serum interleukin 6 levels. Expression of the PPARγ target gene CD36 in monocytes was markedly induced by telmisartan from baseline to study end (telmisartan 80 mg: 2.3±1.5-fold change versus placebo [P value not significant]; telmisartan 160 mg: 3.5±0.9-fold change versus placebo [P<0.05]). The recently reported PPARγ target gene CD163 was slightly induced by telmisartan (telmisartan 80 mg: 1.1±0.3-fold change versus placebo [P value not significant]; telmisartan 160 mg: 1.4±0.4-fold change versus placebo [P value not significant]), which did not reach statistical significance. This is the first clinical description of monocytic PPARγ target gene regulation with high-dose telmisartan treatment. These data implicate that the angiotensin type 1 receptor blocker telmisartan activates PPARγ in circulating monocytes of patients with the metabolic syndrome.
Hypertension

Peters, A.; Döring, A.; Ladwig, K.-H.; Meisinger, C.; Linkohr, B.; Autenrieth, C.; Baumeister, S.E.; Behr, J.; Bergner, A.; Bickel, H.; Bidlingmaier, M.; Dias, A.; Emeny, R.T.; Fischer, B.; Grill, E.; Gorzelniak, L.; Hänsch, H.; Heidbreder, S.; Heier, M.; Horsch, A.; Huber, D.; Huber, R.M.; Jörres, R.A.; Kääb, S.; Karrasch, S.; Kirchberger, I.; Klug, G.; Kranz, B.; Kuch, B.; Lacruz, M.E.; Lang, O.; Mielck, A.; Nowak, D.; Perz, S.; Schneider, A.E.; Schulz, S.; Müller, M.; Seidl, H.; Strobl, R.; Thorand, B.; Wende, R.; Weidenhammer, W.; Zimmermann, A.-K.; Wichmann, H.-E.; Holle, R.
Multimorbidität und erfolgreiches Altern. Ein Blick auf die Bevölkerung im Rahmen der KORA-Age-Studie.
Z. Gerontol. Geriatr. 44, Suppl. 2, 2, 41-54 (2011)
Hintergrund. Das KORA-Age-Verbundprojekt hat zum Ziel, die Determinanten und Folgen von Multimorbidität im Alter zu ermitteln und nach Faktoren des erfolgreichen Alterns in der Allgemeinbevölkerung zu suchen. Material und Methoden. Die KORA-Age-Kohorte besteht aus 9197 Personen, die 1943 oder früher geboren wurden und Teilnehmer der KORA-Kohorte (KORA: Kooperative Gesundheitsforschung in der Region Augsburg) zwischen 1984 und 2001 waren. In der randomisierten Interventionsstudie KORINNA (Koronarinfarktnachbehandlung im Alter) wurde ein von Krankenschwestern durchgeführtes Case-Management-Programm mit 338 Herzinfarktpatienten getestet und gesundheitsökonomisch bewertet. Ergebnisse. In der KORA-Age-Kohorte wurden 2734 Todesfälle registriert, 4565 Personen nahmen an einer schriftlichen Befragung und 4127 Personen an einem Telefoninterview teil (Teilnahme: 76,2% bzw. 68,9%). Zusätzlich wurde eine alters- und geschlechtsstratifizierte Stichprobe von 1079 Personen untersucht (Teilnahme: 53,8%). Schlussfolgerung. Das KORA-Age-Verbundprojekt untersuchte eine große bevölkerungsbezogene Stichprobe älterer Menschen, die Aufschluss über die Verteilung und Determinanten von Multimorbidität und erfolgreichem Altern gibt.
Zeitschrift für Gerontologie und Geriatrie

Mielck, A.
Für Sie gelesen - 20 Jahre: Arbeitslosigkeit und Suchtverhalten.
Suchttherapie 12, 146-147 (2011)
Es wird schon lange über die Frage diskutiert, inwiefern Arbeitslosigkeit und Suchtverhalten zusammenhängen. Fördert Arbeitslosigkeit das Suchtverhalten und/oder das Suchtverhalten die Arbeitslosigkeit? D. Henkel fasst die Studienergebnisse der

vergangenen 20 Jahre zusammen. Current Drug Abuse Reviews 2011; 4: 4-27 Es ist nicht einfach, die zum Teil sehr komplexe Diskussion nachzuvollziehen, auch und vor allem weil ein zusammenfassender Überblick über die Arbeiten der letzten 20 Jahre bisher gefehlt hat. Es ist daher ein großer Verdienst der hier vorliegenden Arbeit von D. Henkel, diese Lücke zu schließen. Die Fleißarbeit ist schon daran zu erkennen, dass der Beitrag insgesamt 24 Seiten, 4 große Tabellen und 207 Literaturstellen umfasst.
Suchttherapie
Rezension
Recension
Wenig, C.M.
Impact of obesity on healthcare utilisation and costs.
München: Verl. Dr. Hut, 2011, 156 S. (Zugl. München, Ludwig-Maximilians-Universität, Diss., 2011)
Obesity is a major public health concern, with a huge burden of directly and indirectly related diseases as well as economic implications for society. This thesis aims to contribute to current knowledge concerning the impact of obesity on utilisation of healthcare services and associated costs, particularly in Germany, and concerning the methodological development of cost-of-illness studies. The study objectives are: (1) to provide a systematic review of the international literature on the impact of childhood obesity on healthcare costs, analysing the methodologies used and the key findings; (2) to assess the effect of overweight and obesity in children and adolescents in Germany on the utilisation and costs of physician visits, non-physician therapists, hospitals and (3) pharmaceuticals; and (4) to analyse the impact of body mass index (BMI) and BMI change on future drug use and expenditures in German adults. Despite their limitations, these analyses add to existing literature providing important new information on the relevance of obesity as a health problem with implications for priority setting in research, policy and management.
von Reitzenstein, C.
Antecedents of individual research performance of surgeons - an empirical analysis of surgeons in US and German Academic Medical Centers.
Hamburg, Universität Hamburg, Fachbereich Betriebswirtschaftslehre, Diss., 2011, 158 S.
Based on findings that academic medical centers (AMCs) that strategically focus on research tend to perform well in the delivery of patient care as well as with respect to the overall performance, this dissertation empirically investigates antecedents of the research of physicians using the example of surgeons. Hypothesizing that antecedents can be found on individual, team and AMC levels of analysis the empirical analysis is based on multi-level modeling, conceptualizing influence factors with reference to organizational theories such as the resource based view, the diversity approach or the ambidexterity hypothesis. Data is collected accordingly on each analytical level on over 11.000 surgeons in the US and Germany. The analysis reveals that different resource types, forms of diversity and organizational strategies such as exploration, exploitation and ambidexterity have varying influence on individual research performance of surgeons. Managers of AMCs who aim to create a research-friendly environment should therefore pursue a comprehensive approach in consideration of individual-, team-, and organizational-level influence factors when implementing processes and strategies that aim to stimulate the research performance of their physicians.
Wolfenstetter, S.B.; Wenig, C.M.
Costing of physical activity programmes in primary prevention: A review of the literature.
Health Econ. Rev. 1:17 (2011)
This literature review aims to analyse the costing methodology in economic analyses of primary preventive physical activity programmes. It demonstrates the usability of a recently published theoretical framework in practice, and may serve as a guide for future economic evaluation studies and for decision making. A comprehensive literature search was conducted to identify all relevant studies published before December 2009. All studies were analysed regarding their key economic findings and their costing methodology. In summary, 18 international economic analyses of primary preventive physical activity programmes were identified. Many of these studies conclude that the investigated intervention provides good value for money compared with alternatives (no intervention, usual care or different programme) or is even cost-saving. Although most studies did provide a description of the cost of the intervention programme, methodological details were often not displayed, and savings resulting from the health effects of the intervention were not always included sufficiently. This review shows the different costing methodologies used in the current health economic literature and compares them with a theoretical framework. The high variability regarding the costs assessment and the lack of transparency concerning the methods limits the comparability of the results, which points out the need for a handy minimal dataset of cost assessment.
Health Economics Review

Hollmeyer, H.; Schreyögg, J.; Wahn, U.; Staab, D.
Staff costs of hospital-based outpatient care of patients with cystic fibrosis.
Health Econ. Rev. 1:10 (2011)
Background: This study identified per patient resource use and staff costs at a cystic fibrosis (CF outpatient unit from the health care provider's perspective. Methods: Personnel cost data were prospectively collected for all CF outpatients (n = 126) under routine conditions at the Charité Medical School Berlin in Germany over a six month study period. Patients were grouped according to age, sex and two severity categories. Ordinary least squares regression analysis was performed to determine the impact of various independent variables on personnel costs. Results: The mean staff costs were €142.3 per patient over six months of outpatient service. Services provided by physicians were the biggest contributor to staff costs. Patient age correlated significantly and negatively with mean total costs per patient. Conclusions: Age of patient is a significant determinant of staff costs for CF outpatient care. For a cost-covering remuneration of outpatient treatment it seems plausible to create separate reimbursement rates for two or three age groups and to consider additional costs due to tasks carried out by physicians without direct patient contact. The relatively low staff costs identified by our study reflect a staffing level not sufficient for specialist CF outpatient care.
Health Economics Review

Becker, C.; Langer, A.; Leidl, R.
The quality of three decision-analytic diabetes models: A systematic health economic assessment.

Expert Rev. Pharmacoecon. Outcomes Res. 11, 751-761 (2011)
Aims: Diabetes mellitus has important economic impacts worldwide. Interventions to prevent diabetes-related complications are often analyzed using model-based cost-effectiveness analyses. As model results are usually influenced by structural assumptions and by the data used, decision-makers should be able to assess the quality of diabetes models. The aim of this study was to assess the quality of selected diabetes models and to determine if modeling recommendations by the American Diabetes Association are considered. Methods: The quality of three selected diabetes models (Archimedes Model, CDC Model and Center for Outcomes Research [CORE] Diabetes Model) was assessed using systematic methods. Results: This systematic approach to assess model quality proved to be feasible and highlighted two areas for improvement: the rationale for model structure and methods to identify parameter values, which should be presented more transparently. Conclusions: Overall, the need for a quality assessment of diabetes models is emphasized.
Expert Review of Pharmacoeconomics and Outcomes Research

Stirbu, I.; Kunst, A.E.; Mielck, A.; Mackenbach, J.P.
Inequalities in utilisation of general practitioner and specialist services in 9 European countries.
BMC Health Serv. Res. 11:288 (2011)
BACKGROUND: The aim of this study is to describe the magnitude of educational inequalities in utilisation of general practitioner (GP) and specialist services in 9 European countries. In addition to West European countries, we have included 3 Eastern European countries: Hungary, Estonia and Latvia. To cover the gap in knowledge we pay a special attention to the magnitude of inequalities among patients with chronic conditions. METHODS: Data on the use of GP and specialist services were derived from national health surveys of Belgium, Estonia, France, Germany, Hungary, Ireland, Latvia, the Netherlands and Norway. For each country and education level we calculated the absolute prevalence and relative inequalities in utilisation of GP and specialist services. In order to account for the need for care, the results were adjusted by the measure of self-assessed health. RESULTS: People with lower education used GP services equally often in most countries (except Belgium and Germany) compared with those with a higher level of education. At the same time people with a higher education used specialist care services significantly more often in all countries, except in the Netherlands. The general pattern of educational inequalities in utilisation of specialist care was similar for both men and women. Inequalities in utilisation of specialist care were equally large in Eastern European and in Western European countries, except for Latvia where the inequalities were somewhat larger. Similarly, large inequalities were found in the utilisation of specialist care among patients with chronic diseases, diabetes, and hypertension. CONCLUSIONS: We found large inequalities in the utilisation of specialist care. These inequalities were not compensated by utilisation of GP services. Of particular concern is the presence of inequalities among patients with a high need for specialist care, such as those with chronic diseases.
BMC Health Services Research

Schunk, M.; Stark, R.G.; Reitmeir, P.; Rathmann, W.; Meisinger, C.; Holle, R.
Verbesserungen in der Versorgung von Patienten mit Typ-2-Diabetes? Gepoolte Analyse dreier bevölkerungsbasierter Studien (KORA) in der Region Augsburg zwischen 1999 und 2008.
Bundesgesundheitsbl.-Gesund. 54, 1187-1196 (2011)
Auf der Basis dreier bevölkerungsrepräsentativer Studien in der Region Augsburg (KORA) wurde die Qualität der primärmedizinischen Versorgung von Personen mit Typ-2-Diabetes im Quer- und Längsschnitt verglichen. Die Studien fanden in den Jahren 1999 bis 2001, 2003 bis 2005 und 2006 bis 2008 statt und enthielten medizinische Untersuchungen, einen Interviewteil und Selbstausfüllfragebogen. Für die Evaluation der Prozess- und Ergebnisqualität dienen Kriterien aus den Anforderungen für strukturierte Behandlungsprogramme. Die Auswertung erfolgte durch multiple Regressionsanalysen, in denen Geschlecht, Alter, Bildung, Diabetesdauer und kardiovaskuläre Komorbidität berücksichtigt wurden. Die Ergebnisse zeigen, dass die Zahl der Augen- (61% auf 71%) und Fußuntersuchungen (38% auf 55%) und die Einnahme von Medikamenten wie Blutdrucksenker, Lipidsenker und Thrombozytenaggregationshemmer im oben genannten Beobachtungszeitraum ansteigen. Bei den Selbstkontrollen und Schulungsteilnahmen waren keine Steigerungsraten festzustellen. Die Zielbereiche für Blutdruck und Cholesterin wurden häufiger erreicht. Zusammenfassend haben sich zwar die medizinische Kontrolle und die medikamentöse Therapie von Personen mit Typ-2-Diabetes verbessert, es wurden aber beim Einbezug der Patienten und bei ihrem Gesundheitsverhalten keine Erfolge erzielt.
Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz

Fischer, K.E.; Grosse, S.D.; Rogowski, W.H.
The role of health technology assessment in coverage decisions on newborn screening.
Int. J. Technol. Assess. Health Care 27, 313-321 (2011)
Objectives: The role and impact of health technology assessment (HTA) in health policy has been widely discussed. Researchers have started to analyze how decisions on coverage of new technologies are made. Although the involvement of HTA may be an indicator of a well established decision process, this hypothesis requires validation. Also, it is not known whether HTA involvement is associated with other characteristics of decision making like participation or transparency. The primary objective of this study was to develop and test statements on the association between the publication of an HTA and coverage decision making for newborn screening tests in European Union countries.Methods: Five statements were defined on the relative role of HTA during the steps of decision processes: trigger, participation, publication, assessment, and appraisal. For this purpose, data on twenty-two decision processes in the area of newborn screening across Europe were analyzed, defined as a coverage decision for a given disorder in a specific country. Decision processes were compared by whether the decision was accompanied by the publication of an HTA report. To test differences, nonparametric statistical tests were used.Results: The decision steps of trigger, participation and publication differed between the HTA and the non-HTA groups. No clear association between HTA and assessment methods in coverage decision making was identified.Conclusions: It appeared that there is an association between HTA and coverage decision processes that are more explicit, inclusive, and transparent. It is unclear whether HTA is associated with formal evidence reviews and economic evaluations.

International Journal of Technology Assessment in Health Care

Mielck, A.
Soziale Ungleichheit und Gesundheit/Krankheit.
In: Blümel, S.* [Eds.]: Leitbegriffe der Gesundheitsförderung und Prävention. Köln: Bundeszentrale für gesundheitliche Aufklärung (BZgA), 2011. 510-515
no Abstract

Graw, J.; Welzl, G.; Ahmad, N.; Klopp, N.; Heier, M.; Wulff, A.; Heinrich, J.; Döring, A.; Karrasch, S.; Nowak, D.; Schulz, S.; Rathmann, W.; Illig, T.; Peters, A.; Holle, R.; Meisinger, C.; Wichmann, H.-E.
The KORA eye study: A population-based study on eye diseases in Southern Germany (KORA F4).
Invest. Ophthalmol. Vis. Sci. 52, 7778-7786 (2011)
Purpose: The population-based KORA (Cooperative Health Research in the Region of Augsburg [Germany]) study was used to evaluate the prevalence of eye diseases and potential interactions with general health status, laboratory data, medication, and genetic background. Methods. In all, 2593 probands, ranging in age from 32 to 71 years (mean: 52 years), were asked in a standardized interview for the presence of cataracts, glaucoma, and corneal or retinal disorders; positive answers were validated and specified by treating ophthalmologists. Additional data came from a questionnaire or from laboratory data. Results. We validated 10 probands with corneal diseases (validation rate: 32%), 26 with retinal diseases (validation rate: 60%), 40 with glaucoma (validation rate: 75%), and 100 participants with cataracts (validation rate: 88%). Glaucoma was significantly associated with increasing age, diabetes and its treatment, and the use of drugs in airway diseases. Cataracts were significantly associated with increasing age, female sex, hypertension, and diabetes. In females, cataracts were particularly associated with the use of ophthalmological corticosteroids, some antihypertensives, and antidiabetics. In contrast, cataracts in males were associated only with the use of angiotensin-converting enzyme inhibitors. We also tested some polymorphic markers; two (GJA8, CRYBB3) were significantly associated with cataracts. Conclusions. Self-reported ocular diagnoses by questionnaire showed varying degrees of accuracy; this method of data collection is valid, providing confirmation is obtained from treating ophthalmologists. It revealed a similar profile of major risk factors for cataracts (age, female sex, and diabetes) in Germany like that of other international studies. The reported associations between medical treatment and genetic polymorphisms in early-onset cataract merit further functional study.
Investigative Ophthalmology & Visual Science, IOVS

Schwarzkopf, L.; Menn, P.; Kunz, S.; Holle, R.; Lauterberg, J.; Marx, P.; Mehlig, H.; Wunder, S.; Leidl, R.; Donath, C.; Graessel, E.
Costs of care for dementia patients in community setting: An analysis for mild and moderate disease stage.
Value Health 14, 827-835 (2011)
OBJECTIVE: Rising life expectancy is associated with higher prevalence rates of dementia disorders. When disease progresses the patients' call on formal health care services and on social support grows which imposes increasing costs of care. The aim of this study was to investigate the costs for patients with mild and moderate dementia in community setting in Germany. METHODS: We assessed total costs of care and individual cost components for 383 community-living dementia patients alongside a cluster-randomized trial from societal and health insurance perspective. Utilization of formal health care services was based on insurance claims data and time dedicated to informal care was assessed within caregiver interviews. We estimated costs using a two-part regression model adjusting for age, gender and cluster-effects. RESULTS: Costs of care equal €47,747 (Euros) from societal perspective which is almost the 4.7-fold of health insurance expenditures. Valued informal care covers 80.2% of societal costs and increases disproportionally when disease progresses. In moderate dementia the corresponding amount exceeds the one in mild dementia by 69.9%, whereas costs for formal health care services differ by 14.3%. CONCLUSION: Due to valued informal care, costs of care for community-living patients with moderate dementia are significantly higher than for patients with mild dementia. Informal care is a non-cash item saving expenditures for professional care. To relieve social security system and family caregivers as well as to allow dementia patients to stay at home as long as possible, concepts fostering community-based dementia care and support to family caregivers need to be further developed.
Value in Health

Meyer, T.; Reitmeir, P.; Brand, P.; Herpich, C.; Sommerer, K.; Schulze, A.; Scheuch, G.; Newman, S.
Effects of formoterol and tiotropium bromide on mucus clearance in patients with COPD.
Respir. Med. 105, 900-906 (2011)
BACKGROUND: Lung mucociliary clearance is impaired in patients with chronic obstructive pulmonary disease (COPD). Treatment guidelines recommend that patients with COPD receive maintenance therapy with long-acting beta-agonists and anticholinergic agents. METHODS: Twenty-four patients with mild to moderate COPD received formoterol (12 µg, twice daily from Turbuhaler® dry powder inhaler (DPI)) or tiotropium (18 µg, once daily from Handihaler® DPI) for 14 days. They also received single doses of formoterol, tiotropium, salbutamol (200 µg) and placebo. A radioaerosol technique was used to assess the effects on mucus clearance of 14 days treatment with formoterol or tiotropium, as well as single doses of these drugs. RESULTS: The 4 h whole lung retention of radioaerosol was significantly higher after 14 days treatment with tiotropium ($P = 0.016$), but not after 14 days treatment with formoterol. However, patients bronchodilated after 14 days treatment with both drugs, so that the deposited radioaerosol may have had an increased distance to travel in order to be cleared by mucociliary action. A single dose of formoterol enhanced radioaerosol clearance significantly compared to other single dose treatments ($P < 0.05$). CONCLUSION: Formoterol (12 µg) enhances mucus clearance in patients with mild to moderate COPD when given as a single dose, and may do so when given for 14 days. Studies of longer duration would be needed in order to assess the effects of the study drugs on mucus clearance when they are used for long-term maintenance therapy.
Respiratory Medicine

Wolfenstetter, S.B.
Conceptual framework for standard economic evaluation of physical activity programs in primary prevention.
Prev. Sci. 12, 435-451 (2011)

Economic evaluations of primary prevention physical activity programs have gained importance because of scarce resources in health-care-systems. A concept for economic evaluation should be based on the efficacy of physical activity, the standard methods of economic evaluation and the aims of public health. Previous publications have examined only parts of these components and have not developed a comprehensive conceptual framework; it is the objective of this article to develop such a framework. The derived method should aid decision makers and staff members of intervention programs in reviewing and conducting an economic evaluation. A literature search of articles was done using six electronic databases. Referenced works for standard methods and more comprehensive approaches for evaluation of preventive programs were studied. The newly developed conceptual framework for economic evaluation includes: (1) the type of physical activity program; (2) features of a selected study population; (3) the outcome dimension comprising exercise efficacy, reach, recruitment, response rate, maintenance, compliance and adverse health effects plus the social impact; and (4) the cost dimension consisting of program development costs, program implementation costs including the implementation, recruitment, program, participants' time costs and savings resulting from the health effects of the intervention. Cost-effectiveness also depends on the methodology, such as the chosen perspective, data collection, valuation methods and discounting. If an intervention is not considered cost-effective, it is necessary to check each dimension to find possible failures in order to learn for future interventions. A more detailed economic evaluation is of utmost importance for improved comparability and transferability.
Prevention Science

Stampfl, A.; Maier, M.; Radykewicz, R.; Reitmeir, P.; Göttlicher, M.; Niessner, R.
Langendorff heart: A model system to study cardiovascular effects of engineered nanoparticles.
ACS Nano 5, 5345-5353 (2011)
Engineered nanoparticles (ENPs) are produced and used in increasing quantities for industrial products, food, and drugs. The fate of ENPs after usage and impact on health is less known. Especially as air pollution, suspended nanoparticles have raised some attention, causing diseases of the lung and cardiovascular system. Human health risks may arise from inhalation of ENPs with associated inflammation, dispersion in the body, and exposure of vulnerable organs (e.g., heart, brain) and tissues with associated toxicity. However, underlying mechanisms are largely unknown. Furthermore future use of ENPs in therapeutic applications is being researched. Therefore knowledge about potential cardiovascular risks due to exposure to ENPs is highly demanded, but there are no established biological testing models yet. Therefore, we established the isolated beating heart (Langendorff heart) as a model system to study cardiovascular effects of ENPs. This model enables observation and analysis of electrophysiological parameters over a minimal time period of 4 h without influence by systemic effects and allows the determination of stimulated release of substances under influence of ENPs. We found a significant dose and material dependent increase in heart rate accompanied by arrhythmia evoked by ENPs made of flame soot (Printex 90), spark discharge generated soot, anatas ($TiO(2)$), and silicon dioxide ($SiO(2)$). However, flame derived $SiO(2)$ (Aerosil) and monodisperse polystyrene lattices exhibited no effects. The increase in heart rate is assigned to catecholamine release from adrenergic nerve endings within the heart. We propose the isolated Langendorff heart and its electrophysiological characterization as a suitable test model for studying cardiovascular ENP toxicity.
ACS Nano

Fischer, K.E.; Leidl, R.; Rogowski, W.H.
A structured tool to analyse coverage decisions: Development and feasibility test in the field of cancer screening and prevention.
Health Policy 101, 290-299 (2011)
OBJECTIVES: The comparison of fourth hurdle processes is challenging because they are heterogeneous and decision practice may deviate from formal process rules. This study applies a published framework consisting of key steps of coverage decision processes to the area of cancer prevention. METHODS: A research design was developed for analysis of case studies on past decision processes. Decisions were identified and information on the process steps was elicited by semi-structured telephone interviews with decision-makers and experts. The scheme was validated with experts from the areas of screening and prevention and fourth hurdle decision making. RESULTS: Indicators for a structured empirical comparison of coverage decisions were derived. Corresponding ordinal rankings were proposed. Details on six decisions about cancer screening (colorectal and prostate cancer) and vaccination against human papillomavirus in Sweden, Austria and Lithuania are presented. CONCLUSIONS: The development of the structured scheme for analysis of coverage decisions allows validation of official statements on decision processes and collection of larger data sets for empirical analysis. However, the semi-structured phone interviews were time-consuming for collecting information on a larger number of decisions. Further validation of the structured scheme and development of a research tool for large-scale empirical studies is still needed.
Health Policy

Hunger, M.; Baumert, J.J.; Holle, R.
Analysis of SF-6D index data: Is beta regression appropriate?
Value Health 14, 759-767 (2011)
BACKGROUND: Preference-weighted index scores of health-related quality of life are commonly skewed to the left and bounded at one. Beta regression is used in various disciplines to address the specific features of bounded outcome variables such as heteroscedasticity, but has rarely been used in the context of health-related quality of life measures. We aimed to examine if beta regression is appropriate for analyzing the relationship between subject characteristics and SF-6D index scores. METHODS: We used data from the population-based German KORA F4 study. Besides classical beta regression, we also fitted extended beta regression models by allowing a regression structure on the precision parameter. Regression coefficients and predictive accuracy of the models were compared to those from a linear regression model with model-based and robust standard errors. RESULTS: The beta distribution fitted the empirical distribution of the SF-6D index better than the normal distribution. Extended beta regression performed best in terms of predictive accuracy but confidence intervals of the fit measures suggested that no model was superior to the others. Age had a significant negative effect on the precision parameter indicating

higher variation of health utilities in older age groups. The observations reporting perfect health had a high influence on model results. CONCLUSIONS: Beta regression, especially with precision covariates is a possible supplement to the methods currently used in the analysis of health utility data. In particular, it accounted for the boundedness and heteroscedasticity of the SF-6D index. A pitfall of the beta regression is that it does not work well in handling one-valued observations.
Value in Health

Stark, R.G.; Schunk, M.; Meisinger, C.; Rathmann, W.; Leidl, R.; Holle, R.
Medical care of type 2 diabetes in German disease management programmes: A population-based evaluation.
Diabetes Metab. Res. Rev. 27, 383-391 (2011)
OBJECTIVE: Type 2 diabetes disease management programmes (DDMPs) are offered by German social health insurance to promote healthcare consistent with evidence-based medical guidelines. The aim of this study was to compare healthcare quality and medical endpoints between diabetes management programme participants and patients receiving usual care designated as controls. METHODS: All patients with type 2 diabetes (age range: 36-81) in a cross-sectional survey of a cohort study, performed by the Cooperative Health Research in the Region of Augsburg, received a self-administered questionnaire regarding their diabetes care. Physical examination and laboratory tests were also performed. The analysis only included patients with social health insurance and whose participation status in a diabetes disease management program was validated by the primary physician (n = 166). Regression analyses, adjusting for age, sex, education, diabetes duration, baseline waist circumference and clustering regarding primary physician were conducted. RESULTS: Evaluation of healthcare processes showed that those in diabetes disease management programmes (n = 89) reported medical examination of eyes and feet and medical advice regarding diet [odds ratio (OR): 2.39] and physical activity (OR: 2.87) more frequently, received anti-diabetic medications (OR: 3.77) and diabetes education more often (OR: 2.66) than controls. Both groups had satisfactory HbA(1c) control but poor low-density lipoprotein cholesterol control. Blood pressure goals (<140/90 mmHg) were achieved more frequently by patients in diabetes disease management programmes (OR: 2.21). CONCLUSIONS: German diabetes disease management programmes are associated with improved healthcare processes and blood pressure control. Low-density lipoprotein cholesterol control must be improved for all patients with diabetes. Further research will be required to assess the long-term effects of this diabetes disease management programme.
Diabetes/Metabolism Research and Reviews

Hunger, M.; Thorand, B.; Schunk, M.; Döring, A.; Menn, P.; Peters, A.; Holle, R.
Multimorbidity and health-related quality of life in the older population: Results from the German KORA-Age study.
Health Qual. Life Outcomes 9:53 (2011)
BACKGROUND: Multimorbidity in the older population is well acknowledged to negatively affect health-related quality of life (HRQL). Several studies have examined the independent effects of single diseases; however, little research has focused on interaction between diseases. The purpose of this study was to assess the impact of six self-reported major conditions and their combinations on HRQL measured by the EQ-5D. METHODS: The EQ-5D was administered in the population-based KORA-Age study of 4,565 Germans aged 65 years or older. A generalised additive regression model was used to assess the effects of chronic conditions on HRQL and to account for the nonlinear associations with age and body mass index (BMI). Disease interactions were identified by a forward variable selection method. RESULTS: The conditions with the greatest negative impact on the EQ-5D index were the history of a stroke (regression coefficient -11.3, $p < 0.0001$) and chronic bronchitis (regression coefficient -8.1, $p < 0.0001$). Patients with both diabetes and coronary disorders showed more impaired HRQL than could be expected from their separate effects (coefficient of interaction term -8.1, $p < 0.0001$). A synergistic effect on HRQL was also found for the combination of coronary disorders and stroke. The effect of BMI on the mean EQ-5D index was inverse U-shaped with a maximum at around 24.8 kg/m2. CONCLUSIONS: There are important interactions between coronary problems, diabetes mellitus, and the history of a stroke that negatively affect HRQL in the older German population. Not only high but also low BMI is associated with impairments in health status.
Health and Quality of Life Outcomes

Steinacker, J.M.; Liu, Y.; Muche, R.; Koenig, W.; Hahmann, H.; Imhof, A.; Kropf, C.; Brandstetter, S.; Schweikert, B.; Leidl, R.; Schiefer, D.H.
Long term effects of comprehensive cardiac rehabilitation in an inpatient and outpatient setting.
Swiss Med. Wkly. 141:w13141 (2011)
To compare the long-term effects of comprehensive outpatient versus inpatient rehabilitation with respect to morbidity and mortality, as well as to changes in physical performance and physical activity. DESIGN: A total of 163 consecutive patients were enrolled for comprehensive cardiac rehabilitation (CCR) following a recent coronary event, to outpatient or inpatient CCR according to treatment preference because randomisation was accepted by only 4 patients. CCR was six hours per day for 4 weeks and consisted of exercise training, education, psychological support, and nutritional and occupational advice. Examinations were before, after and 12 months after CCR. Primary outcome measures were event-free survival with or without interventions, EFS-I or EFS, respectively, 12 months after rehabilitation. RESULTS: Main patient characteristics were distributed equally in the cohorts. Results were adjusted by logistic regression for age, BMI, LV-function, exercise capacity and physical activity before the event. Adjusted EFS, EFS-I , overall survival and other morbidity outcome measures did not differ significantly. During CCR, physical activity was higher in outpatients, but this difference was not maintained in the follow up. Average physical activity was increased 12 month after CR with no difference between groups. CONCLUSION: Although influenced by patient preference, participation in either inpatient or outpatient CCR led to comparable results in terms of all-cause or cardiac overall survival, event-free survival and other secondary outcome measures like cardiac morbidity, physical performance and increased physical activity.
Swiss Medical Weekly

Leidl, R.; Reitmeir, P.
A value set for the EQ-5D based on experienced health states: Development and testing for the German population.

Pharmacoeconomics 29, 521-534 (2011)
BACKGROUND: Decision makers responsible for allocation of healthcare resources may require that health states are valued by the population for whom they are making decisions. To achieve this, health-state descriptions can be combined with a value set that reflects the valuations of the target population. In the decision-utility approach, such a value set is at least partly based on wants and expectations regarding given health states. This may reflect aspects different from the health state experienced and valued by a respondent. OBJECTIVES: To derive a value set that is completely based on experienced health states, emphasising the patient's perspective, and test its predictive performance in comparison with established approaches. METHODS: Problem descriptions and rating scale valuations of the EQ-5D were drawn from two representative German population surveys in 2006 and 2007. Two models based on given health states but differing in valuation method (1a, b) were analysed, along with three models based on experienced health states: (2) ordinary least squares regression; (3) scale-transformed regression; and (4) a generalized linear model with binomial error distribution and constraint parameter estimation. The models were compared with respect to issues in specification, and accuracy in predicting the actual valuations of experienced health states in a new data set, using correlation, mean error and ranking measures for the latter. In addition, the impact of standardizing experience-based index models for age and sex of the subjects was investigated. RESULTS: Models 1 (a, b), 2 and 3 partly led to plausible and comparable parameter estimates, but also led to problems of insignificance and inconsistencies in some of the estimates. Model 4 achieved consistency and featured partly equivalent and partly better predictive accuracy. Using this model, mean valuations of health states were much better predicted by the experience-based approach than by the decision-utility approach, especially for health states that frequently (>10) occurred in the population sample. Standardizing the experience-based index models for age and sex further improved predictive accuracy and strengthened the position of model 4. CONCLUSIONS: A value set for the EQ-5D can be plausibly estimated from experience-based valuations. The approach offers an alternative to decision makers who prefer experience-based valuation over decision utilities in the measurement of health outcome. Although usefulness in population samples was shown, use in a clinical context will first require indication-specific tests. Current limitations include use in a general population only, and a restricted range of health states covered.
PharmacoEconomics

Becker, F.; van El, C.G.; Ibarreta, D.; Zika, E.; Hogarth, S.; Borry, P.; Cambon-Thomsen, A.; Cassiman, J.J.; Evers-Kiebooms, G.; Hodgson, S.; Janssens, A.C.; Kääriäinen, H.; Krawczak, M.; Kristoffersson, U.; Lubinski, J.; Patch, C.; Penchaszadeh, V.B.; Read, A.; Rogowski, W.H.; Sequeiros, J.; Tranebjaerg, L.; van Langen, I.M.; Wallace, H.; Zimmern, R.; Schmidtke, J.; Cornel, M.C.
Genetic testing and common disorders in a public health framework: How to assess relevance and possibilities. Background Document to the ESHG recommendations on genetic testing and common disorders.
Eur. J. Hum. Genet. 19, S6-S44 (2011)
no Abstract
European Journal of Human Genetics

Kühn-Steven, A.; Gensch, K.; Haust, M.; Schneider, S.W.; Bonsmann, G.; Gaebelein-Wissing, N.; Lehmann, P.; Wons, A.; Reitmeir, P.; Ruland, V.; Luger, T.A.; Ruzicka, T.
Efficacy of tacrolimus 0.1% ointment in cutaneous lupus erythematosus: A multicenter, randomized, double-blind, vehicle-controlled trial.
J. Am. Acad. Dermatol. 65, 54-64 (2011)
BACKGROUND: Topical calcineurin inhibitors are licensed for the treatment of atopic dermatitis; however, the efficacy of tacrolimus in cutaneous lupus erythematosus (CLE) has only been shown in single case reports. OBJECTIVE: In a multicenter, randomized, double-blind, vehicle-controlled trial, we sought to evaluate the efficacy of tacrolimus 0.1% ointment for skin lesions in CLE. METHODS: Thirty patients (18 female, 12 male) with different subtypes of CLE were included, and two selected skin lesions in each patient were treated either with tacrolimus 0.1% ointment or vehicle twice daily for 12 weeks. The evaluation included scoring of clinical features, such as erythema, hypertrophy/desquamation, edema, and dysesthesia. RESULTS: Significant improvement ($P < .05$) was seen in skin lesions of CLE patients treated with tacrolimus 0.1% ointment after 28 and 56 days, but not after 84 days, compared with skin lesions treated with vehicle. Edema responded most rapidly to tacrolimus 0.1% ointment and the effect was significant ($P < .001$) in comparison to treatment with vehicle after 28 days. Clinical score changes in erythema also showed remarkable improvement ($P < .05$) after 28 days, but not after 56 and 84 days. Moreover, patients with lupus erythematosus tumidus revealed the highest degree of improvement. None of the patients with CLE demonstrated any major side effects. LIMITATIONS: The study was limited by the small sample size. CONCLUSION: Explorative subgroup analyses revealed that topical application of tacrolimus 0.1% ointment may provide at least temporary benefit, especially in acute, edematous, non-hyperkeratotic lesions of CLE patients, suggesting that calcineurin inhibitors may represent an alternative treatment for the various disease subtypes.
Journal of the American Academy of Dermatology : JAAD

Bäumer, A.; Pretzl, B.; Cosgarea, R.; Kim, T.S.; Reitmeir, P.; Eickholz, P.; Dannewitz, B.
Tooth loss in aggressive periodontitis after active periodontal therapy: Patient-related and tooth-related prognostic factors.
J. Clin. Periodontol. 38, 644-651 (2011)
To assess prognostic factors for tooth loss after active periodontal therapy (APT) in patients with aggressive periodontitis (AgP) at tooth level.MATERIAL AND METHODS: Eighty-four patients with AgP were re-evaluated after a mean period of 10.5 years of supportive periodontal therapy (SPT). Two thousand and fifty-four teeth were entered into the model. The tooth-related factors including baseline bone loss, tooth location and type, furcation involvement (FI), regenerative therapy, and abutment status, as well as time of follow-up and other patient-related factors were tested for their prognostic value at tooth level. Multilevel regression analysis was performed for statistical analysis to identify factors contributing to tooth loss. RESULTS: During SPT, 113 teeth (1.34 teeth per patient) were lost. Baseline bone loss, use as abutment tooth, tooth type, and maxillary location contributed significantly to tooth loss during SPT. Molars showed the highest risk for tooth loss after APT. Moreover, time of follow-up and the patient-related factor

"educational status" significantly accounted for tooth loss at tooth level. CONCLUSION: Baseline bone loss, abutment status, tooth location, and type as well as time of follow-up and educational status were detected as prognostic factors for tooth loss during SPT in patients with AgP at tooth level.
Journal of Clinical Periodontology

Bäumer, A.; El Sayed, N.; Kim, T.S.; Reitmeir, P.; Eickholz, P.; Pretzl, B.
Patient-related risk factors for tooth loss in aggressive periodontitis after active periodontal therapy.
J. Clin. Periodontol. 38, 347-354 (2011)
Evaluation of patient-related risk factors contributing to tooth loss and recurrence of periodontitis 10.5 years after initial therapy in patients with aggressive periodontitis (AgP). MATERIAL AND METHODS: Eighty-four of 174 patients were included. Re-examination consisted of patient's history, clinical examination and test for interleukin (IL)-1 composite genotype. Patients' charts were searched for regularity of maintenance and initial diagnosis. Statistical analysis was performed using Poisson and logistical regression analysis. RESULTS: The responder rate was 48%. Thirteen of 84 patients presented a localized AgP, 68 were females and 29 smoked. One hundred and thirteen teeth out of 2154 were lost after therapy (1.34 teeth/patient). Age ($p=0.0018$), absence of IL-1 composite genotype ($p=0.0091$) and educational status ($p=0.0085$) were identified as statistically significant risk factors for tooth loss. Twenty patients exhibited recurrence of periodontitis at re-examination. Smoking ($p=0.0034$) and mean Gingival Bleeding Index (GBI) ($p=0.0239$) contributed significantly to recurrence of disease. No patient participating regularly in supportive periodontal therapy (SPT) showed disease recurrence. CONCLUSION: Age, absence of IL-1 composite genotype and low social status are detected as risk factors for tooth loss. Smoking and high mean GBI are associated with an increased risk for recurrence of periodontitis, whereas regular SPT acts as a protective factor.
Journal of Clinical Periodontology

Krauth, C.; John, J.; Suhrcke, M.
Gesundheitsökonomische Methoden in der Prävention.
Präv. Gesundheitsf. 6, 85-93 (2011)
Die methodischen Grundlagen der gesundheitsökonomischen Evaluation sind weitgehend definiert und vereinheitlicht. Einige Besonderheiten bestehen jedoch bei der Evaluation von Primärprävention und Gesundheitsförderung (gegenüber medizinischen Interventionen). In dem vorliegenden Beitrag werden die spezifischen Anforderungen an die Evaluation von Präventionsprogrammen diskutiert: (1) Aus welcher Perspektive soll Prävention evaluiert werden? (2) Wie und in welchem Umfang sollen die Kosten von gewonnenen Lebensjahren durch Prävention in gesundheitsökonomischen Evaluationen berücksichtigt werden? (3) Soll der Zeitaufwand von Individuen für Präventionsaktivitäten in den Präventionskosten abgebildet werden? (4) Welche Effekte von Prävention sind aus gesundheitsökonomischer Perspektive relevant? (5) Sollen Auswirkungen auf die Verteilung von Gesundheit ausgewiesen werden, und wenn ja, wie können sie berücksichtigt werden?
Prävention und Gesundheitsförderung

Stark, R.G.; John, J.; Leidl, R.
Health care use and costs of adverse drug events emerging from outpatient treatment in Germany: A modelling approach.
BMC Health Serv. Res. 11:9 (2011)
BACKGROUND: This study's aim was to develop a first quantification of the frequency and costs of adverse drug events (ADEs) originating in ambulatory medical practice in Germany METHODS: The frequencies and costs of ADEs were quantified for a base case, building on an existing cost-of-illness model for ADEs. The model originates from the U.S. health care system, its structure of treatment probabilities linked to ADEs was transferred to Germany. Sensitivity analyses based on values determined from a literature review were used to test the postulated results. RESULTS: For Germany, the base case postulated that about 2 million adults ingesting medications have will have an ADE in 2007. Health care costs related to ADEs in this base case totalled 816 million Euros, mean costs per case were 381 Euros. About 58% of costs resulted from hospitalisations, 11% from emergency department visits and 21% from long-term care. Base case estimates of frequency and costs of ADEs were lower than all estimates of the sensitivity analyses. DISCUSSION: The postulated frequency and costs of ADEs illustrate the possible size of the health problems and economic burden related to ADEs in Germany. The validity of the U.S. treatment structure used remains to be determined for Germany. The sensitivity analysis used assumptions from different studies and thus further quantified the information gap in Germany regarding ADEs. CONCLUSIONS: This study found costs of ADEs in the ambulatory setting in Germany to be significant. Due to data scarcity, results are only a rough indication.
BMC Health Services Research

Stollenwerk, B.; Becker, C.; Leidl, R.
Gesundheitsökonomische Modellierung bei Diabetes mellitus.
Diabetologie 7, 99-104 (2011)
Die gesundheitsökonomische Evaluation gewinnt international sowie in Deutschland zunehmend an Bedeutung. In ihr kommen entscheidungsanalytische Modelle zum Einsatz, die die Evidenz unterschiedlicher Studien miteinander verknüpfen. Für eine chronische Erkrankung wie Diabetes mellitus sind derartige Modelle von hoher Relevanz: Allein für den Typ-2-Diabetes wurden mindestens 20 verschiedene Modelle entwickelt [19]. Entsprechend wurden von der Amerikanischen Diabetes Gesellschaft (ADA) bereits Modellierungsleitlinien erstellt. Viele Diabetesforscher sind jedoch nicht mit der gesundheitsökonomischen Modellierung vertraut. Daher werden ihre Grundprinzipien hier vorgestellt.
Diabetologie, Die

Rottenkolber, D.; Schmiedl, S.; Rottenkolber, M.; Farker, K.; Saljé, K.; Mueller, S.; Hippius, M.; Thuermann, P.A.; Hasford, J.; Net of Regional Pharmacovigilance Centers ()
Adverse drug reactions in Germany: Direct costs of internal medicine hospitalizations.
Pharmacoepidemiol. Drug Saf. 20, 626-634 (2011)
PURPOSE: German hospital reimbursement modalities changed as a result of the introduction of Diagnosis Related Groups (DRG) in 2004. Therefore, no data on the direct costs of adverse drug reactions (ADRs) resulting in admissions to departments of internal medicine are available. The objective was to quantify the ADR-related economic burden (direct costs) of hospitalizations in internal medicine wards in Germany. METHODS: Record-based study analyzing the patient records of about 57 000 hospitalizations between 2006 and 2007 of the Net of Regional

Pharmacovigilance Centers (Germany). All ADRs were evaluated by a team of experts in pharmacovigilance for severity, causality, and preventability. The calculation of accurate person-related costs for ADRs relied on the German DRG system (G-DRG 2009). Descriptive and bootstrap statistical methods were applied for data analysis. RESULTS: The incidence of hospitalization due to at least 'possible' serious outpatient ADRs was estimated to be approximately 3.25%. Mean age of the 1834 patients was 71.0 years (SD 14.7). Most frequent ADRs were gastrointestinal hemorrhage (n = 336) and drug-induced hypoglycemia (n = 270). Average inpatient length-of-stay was 9.3 days (SD 7.1). Average treatment costs of a single ADR were estimated to be approximately €2250. The total costs sum to €434 million per year for Germany. Considering the proportion of preventable cases (20.1%), this equals a saving potential of €87 million per year. CONCLUSIONS: Preventing ADRs is advisable in order to realize significant nationwide savings potential. Our cost estimates provide a reliable benchmark as they were calculated based on an intensified ADR surveillance and an accurate person-related cost application.
Pharmacoepidemiology and Drug Safety

Haucke, F.; Wichmann, H.-E.; Brüske, I.; Tschiersch, J.; Leidl, R.
Gesundheitsökonomische Betrachtung zu Radonsanierungsmaßnahmen. Abschlussbericht.
In: (Ressortforschungsberichte zur kerntechnischen Sicherheit und zum Strahlenschutz). Salzgitter: Bundesamt für Strahlenschutz, 2011. 157 S.
Stargardt, T.
Modelling pharmaceutical price changes in Germany: A function of competition and regulation.
Appl. Economics 43, 4515-4526 (2011)
In this article, price changes for pharmaceuticals in Germany are modelled as a function of regulation and competition. Changes in the regulatory environment, and in the competitive environment of a product, are taken into account. To follow the hierarchical structure, a four-level random intercept model was constructed. Price changes were allowed to vary randomly between drug classes, between different substances within a drug class, and between different manufacturers of a substance. This study provides evidence that two policy measures - reference pricing and temporary price freezes - succeeded in reducing prices in Germany between January 2004 and June 2006. For off-patent substances - depending on the competition faced by a drug - the effect of competition can be greater than the effect of regulation. The study, therefore, not only demonstrates the importance of competition between and within drug classes, it also provides evidence that generic entry has substantial effects on the prices of branded products.
Applied Economics

von Klot, S.; Cyrys, J.; Hoek, G.; Kühnel, B.; Pitz, M.; Kuhn, U.; Kuch, B.; Meisinger, C.; Hörmann, A.; Wichmann, H.-E.; Peters, A.
Estimated personal soot exposure is associated with acute myocardial infarction onset in a case-crossover study.
Prog. Cardiovasc. Dis. 53, 361-368 (2011)
The current study investigates the association of estimated personal exposure to traffic-related air pollution and acute myocardial infarction (AMI). Cases of AMI were interviewed in the Augsburg KORA Myocardial Infarction Registry from February 1999 through December 2003, and 960 AMI survivors were included in the analyses. The time-varying component of daily personal soot exposure (the temporally variable contribution due to the daily area level of exposure and daily personal activities) was estimated using a linear combination of estimated mean ambient soot concentration, time spent outdoors, and time spent in traffic. The association of soot exposure with AMI onset was estimated in a case-crossover analysis controlling for temperature and day of the week using conditional logistic regression analyses. Estimated personal soot exposure was associated with AMI (relative risk, 1.30 per 1.1 m(-1) × 10(-5) [95% confidence interval, 1.09-1.55]). Estimated ambient soot and measured ambient PM(2.5) particulate matter 2.5 μm and smaller in aerodynamic diameter were not significantly associated with AMI onset. Our results suggest that an increase in risk of AMI in association with personal soot exposure may be in great part due to the contribution of personal soot from individual times spent in traffic and individual times spent outdoors. As a consequence, estimates calculated based on measurements at urban background stations may be underestimations. Health effects of traffic-related air pollution may need to be updated, taking into account individual time spent in traffic and outdoors, to adequately protect the public.
Progress in Cardiovascular Diseases

Blankart, C.R.B.; Stargardt, T.; Schreyögg, J.
Availability of and access to orphan drugs: An international comparison of pharmaceutical treatments for pulmonary arterial hypertension, Fabry disease, hereditary angioedema and chronic myeloid leukaemia.
Pharmacoeconomics 29, 63-82 (2011)
BACKGROUND: Market authorization does not guarantee patient access to any given drug. This is particularly true for costly orphan drugs because access depends primarily on co-payments, reimbursement policies and prices. The objective of this article is to identify differences in the availability of orphan drugs and in patient access to them in 11 pharmaceutical markets: Australia, Canada, England, France, Germany, Hungary, the Netherlands, Poland, Slovakia, Switzerland and the US. METHODS: Four rare diseases were selected for analysis: pulmonary arterial hypertension (PAH), Fabry disease (FD), hereditary angioedema (HAE) and chronic myeloid leukaemia (CML). Indicators for availability were defined as (i) the indications for which orphan drugs had been authorized in the treatment of these diseases; (ii) the application date; and (iii) the date upon which these drugs received market authorization in each country. Indicators of patient access were defined as (i) the outcomes of technology appraisals; (ii) the extent of coverage provided by healthcare payers; and (iii) the price of the drugs in each country. For PAH we analysed bosentan, iloprost, sildenafil, treprostinil (intravenous and inhaled) as well as sitaxentan and ambrisentan; for FD we analysed agalsidase alfa and agalsidase beta; for HAE we analysed icatibant, ecallantide and two complement C1s inhibitors; for CML we analysed imatinib, dasatinib and nilotinib. RESULTS: Most drugs included in this study had received market authorization in all countries, but the range of indications for which they had been authorized differed by country. The broadest range of indications was found in Australia, and the largest variations in indications were found for PAH drugs. Authorization process speed (the time between application and market authorization) was fastest in the US, with an average of 362 days, followed by the EU (394 days). The highest prices for the included drugs were found in Germany and

the US, and the lowest in Canada, Australia and England. Although the prices of all of the included drugs were high compared with those of most non-orphan drugs, most of the insurance plans in our country sample provided coverage for authorized drugs after a certain threshold. CONCLUSIONS: Availability of and access to orphan drugs play a key role in determining whether patients will receive adequate and efficient treatment. Although the present study showed some variations between countries in selected indicators of availability and access to orphan drugs, virtually all of the drugs in question were available and accessible in our sample. However, substantial co-payments in the US and Canada represent important barriers to patient access, especially in the case of expensive treatments such as those analysed in this study. Market exclusivity is a strong instrument for fostering orphan drug development and drug availability. However, despite the positive effect of this instrument, the conditions under which market exclusivity is granted should be reconsidered in cases where the costs of developing an orphan drug have already been amortized through the use of the drug's active ingredient for the treatment of a common indication.
PharmacoEconomics

Kilinc, E.; Schulz, S.; Kuiper, G.J.; Spronk, H.M.H.; ten Cate, H.; Upadhyay, S.; Ganguly, K.; Stöger, T.; Semmler-Behnke, M.; Takenaka, S.; Kreyling, W.G.; Pitz, M.; Reitmeir, P.; Peters, A.; Eickelberg, O.; Wichmann, H.-E.
The procoagulant effects of fine particulate matter in vivo.
Part. Fibre Toxicol. 8:12 (2011)
Inhalation of fine particulate matter (<2.5 µm; fine PM) has been shown to increase the risk for cardiovascular events. In this letter, we reappraise the role of tissue factor (TF) antigen and we also summarize changes in measured coagulation proteins in humans and rodents by other studies with fine PM. By considering all studies including ours, we conclude that monitoring the overall coagulation state by measuring capacity assays such as thrombin generation, and quantification of TF activity would be more suitable than determining single coagulation proteins (such as TF antigen) in order to better assess the systemic prothrombotic effects of fine PM.
Particle and Fibre Toxicology
Letter to the Editor
Letter to the Editor
Breitfelder, A.; Wenig, C.M.; Wolfenstetter, S.B.; Rzehak, P.; Menn, P.; John, J.; Leidl, R.; Bauer, C.P.; Koletzko, S.; Roder, S.; Herbarth, O.; von Berg, A.; Berdel, D.; Krämer, U.; Schaaf, B.; Wichmann, H.-E.; Heinrich, J.; GINIplus Study Group (Wichmann, H.-E.; Heinrich, J.); LISAplus Study Group (Behrendt, H.; Grosch, J.)
Relative weight-related costs of healthcare use by children - results from the two German birth cohorts, GINI-plus and LISA-plus.
Econ. Hum. Biol. 9, 302-315 (2011)
Obesity among children and adolescents is a growing public health burden. According to a national reference among German children and adolescents aged 3-17 years, 15% are overweight (including obese) and 6.3% are obese. This study aims to assess the economic burden associated with overweight and obesity in children based on a cross-sectional survey from two birth cohort studies: the GINI-plus - German Infant Nutritional Intervention plus Non-Intervention study (3287 respondents aged 9 to <12 years) and the LISA-plus study - Influence of life-style factors on the development of the immune system and allergies in East and West Germany (1762 respondents aged 9 to <12 years). Using a bottom-up approach, we analyse direct costs induced by the utilisation of healthcare services and indirect costs emerging from parents' productivity losses. To investigate the impact of Body Mass Index (BMI) on costs, we perform various descriptive analyses and estimate a two-part regression model. Average annual total direct medical costs of healthcare use are estimated to be €418 (95% CI [346-511]) per child, split between physician (22%), therapist (29%), hospital (41%) and inpatient rehabilitation costs (8%). Bivariate analysis shows considerable differences between BMI groups: €469 (severely underweight), €468 (underweight), €402 (normal weight), €468 (overweight) and €680 (obese). Indirect costs make up €101 per year on average and tend to be higher for obese children, although this was not statistically significant. Drawing on these results, differences in healthcare costs between BMI groups are already apparent in children.
Economics and Human Biology

Gräßel, E.; Donath, C.; Kunz, S.; Menn, P.; Holle, R.
Versorgungsforschung bei Demenz im Projekt IDA: Vermittlung von angehörigenbezogenen Angeboten durch Hausärzte.
In: Stoppe, G.* [Eds.]: Die Versorgung psychisch kranker alter Menschen: Bestandsaufnahme und Herausforderung für die Versorgungsforschung. Köln: Dt. Ärzte-Verl., 2011. 151-159 (Report Versorgungsforschung; 3)
Angehörigenberatung und Angehörigengruppen gelten als niedrigschwellige Angebote, die insbesondere bei Demenz als hilfreich für die Angehörigen empfohlen werden. Im Projekt IDA, der Initiative Demenzversorgung in der Allgemeinmedizin, einer dreiarmigen clusterrandomisierten prospektiven Verlaufsstudie mit zweijährigem Beobachtungszeitraum wurden von 129 Hausärzten der Studienregion Mittelfranken 390 Demenzpatienten und ihre pflegenden Angehörigen rekrutiert. Die Hausärzte vermittelten in den Studienarmen B und C zu Beginn des Projekts den Angehörigen das Angebot zur Teilnahme an einer angeleiteten Angehörigengruppe. In Gruppe C wurde zusätzlich eine zugehende Angehörigenberatung durch geschulte Berater initiiert. Zugehende Angehörigenberatung bedeutet, das die Berater von sich aus mit den Angehörigen Kontakt aufnehmen, nachdem dies den Angehörigen vom Hausarzt angekündigt worden war. In Gruppe B fand dies zu Beginn des zweiten Studienjahres statt. Gruppe A fungierte als Kontrollgruppe. Auf der Grundlage der Angehörigeninterviews nach zwei Jahren zeigte sich eine Inanspruchannahme von Angehörigengruppen in B und C von 15% im Vergleich zu 3% in A. Angehörigenberatung wurde in B und C von 69% beziehungsweise 64% der Angehörigen in Anpruch genommen, in Studienarm A waren es 17%. Unter Berücksichtigung der Tatsche, dass die Inanspruchnahme auf freiwilliger Basis stattfand und kein Einschlusskriterium für die Teilnahme am Projekt IDA war, lässt sich feststellen, dass besonders Angehörigenberatung durch den Hausarzt erfolgreich vermittelt werden kann.
Karrasch, S.; Ernst, K.; Behr, J.; Heinrich, J.; Huber, R.M.; Nowak, D.; Wichmann, H.-E.; Baumeister, S.E.; Meisinger, C.; Ladwig, K.-H.; Holle, R.; Jörres, R.A.; Schulz, S.; KORA Study Group (Wichmann, H.-E.; Holle, R.; John, J.; Illig, T.; Peters, A.; Meisinger, C.; Ladwig, K.-H.)
Exhaled nitric oxide and influencing factors in a random population sample.

Respir. Med. 105, 713-718 (2011)
The aim of the current study was to determine the impact and interaction of important influencing factors on the fraction of exhaled nitric oxide (FeNO). FeNO was measured in a population-based sample of 1250 middle-aged subjects from the KORA F4 cohort (Augsburg, Germany). Analysis of covariance models was performed including the factors age, height, FVC, FEV(1), sex, current smoking status, recent respiratory tract infection, and respiratory allergy. Geometric mean (SD as factor; 95% confidence interval as factor) FeNO was 13.9 (1.9; 1.033) ppb. FeNO significantly depended on age, height, smoking, infection and allergy. Smoking reduced FeNO by 21%, while infection and allergy led to increases by 9 and 11%, respectively. Increases in age by 10 years and in height by 10 cm were associated with increases of FeNO by 15 and 10%, respectively. Non-smokers demonstrated independent multiplicative superposition of factors affecting FeNO while the effect of allergy was virtually eliminated in smokers without infection. We conclude that in middle-aged non-smokers the effects of infection, age and height can be easily taken into account and do not significantly disturb the effect of respiratory tract allergies on FeNO. In current smokers, however, effects were heterogeneous and information on smoking intensity seems to be useful for better adjustment.
Respiratory Medicine

Rottenkolber, D.
Discrete-Choice-Experimente zur Messung der Zahlungsbereitschaft für Gesundheitsleistungen - ein anwendungsbezogener Literaturreview
Gesundheitsökon. Qualitätsmanag. 16, 232-244 (2011)
Aim: Discrete choice experiments (DCE) are a method to assess willingness-to-pay (WTP) within the framework of cost-benefit analysis. Compared to traditional tools, DCE offer a broad application spectrum for the measurement of preferences. The objective of this paper was to evaluate the application of DCE in the measurement of willingness-to-pay for medical interventions. Method: A literature review was conducted in healthcare and economic databases (PubMed, EconLit), as well as manual search and citation-tracking in bibliographies for papers and books published in the period 01 / 1998 - 05 / 2010. Results: Compared to conventional methods, utility measurement using DCE provides two advantages. First, the experiment is less cognitive demanding for respondents. Second, willingness-to-pay and DCE are based on a valid theoretical basis. From the literature, validity, reliability, acceptance by respondents, practicability, and efficiency were evaluated as criteria for assessing DCE. These criteria proved to be of high methodological validity and reliability. Particularly, the results concerning internal consistency and theoretical validity are very encouraging. DCE provide an informative basis for identifying medical service features which create a higher benefit for patients, eliminating services for which no willingness-to-pay exists, and the conception of medical services offered to specific patient groups. Optimized results may be achieved if the respondents are familiar with the framing of the decision situation. Particularly in healthcare systems where respondents exhibit inadequate price sensitivity, this may be a difficulty. Conclusion: DCE are a versatile tool for WTP measurement in health economics, which enables researchers both to evaluate process attributes and to observe individual trade-offs between service attributes. By mimicking everyday decision-making situations the method is especially suitable for the evaluation of intervention-specific effects. However, numerous criteria require empirical examination. Focusing on WTP measurement, aside from experimental design aspects, particularly psychological aspects and cognitive problems of decision heuristics should be taken into consideration.
Gesundheitsökonomie & Qualitätsmanagement

Baumeister, S.E.; Fischer, B.; Döring, A.; Koenig, W.; Zierer, A.; John, J.; Heier, M.; Meisinger, C.
The Geriatric Nutritional Risk Index predicts increased healthcare costs and hospitalization in a cohort of community-dwelling older adults: Results from the MONICA/KORA Augsburg cohort study, 1994-2005.
Nutrition 27, 534-542 (2011)
OBJECTIVE: To determine if the Geriatric Nutritional Risk Index (GNRI), an index for the risk of nutrition-related complications, is associated with healthcare costs and risk of hospitalization at baseline and after 10 y. METHODS: Data from a German population-based cohort of 1999 subjects 55 to 74 y of age at baseline were used. Self-reported physician visits, length of hospital stay, and drug intake were used to estimate costs. The GNRI is based on serum albumin values and the discrepancy between real and ideal body weights. Low GNRI values were defined as mean minus 2 times standard deviation. Mean GNRI values were regarded as normal. RESULTS: Low baseline GNRI was consistently associated with increased total costs, probability of hospitalization, inpatient costs, and pharmaceutical costs at baseline and follow-up, after adjustment for socioeconomic characteristics, lifestyle factors, and coexisting conditions. Subjects with low GNRI at baseline had approximately 47% higher total costs, 50% higher risk of hospitalization, 62% higher inpatient costs and 27% higher pharmaceutical costs at follow-up than subjects with normal GNRI values. CONCLUSION: The GNRI risk predicted increased future healthcare costs and higher risk of hospitalization in independent-living older adults. The GNRI is a rapid and low-cost tool that might be routinely used in population-based settings.
Nutrition

Roll, K.; Stargardt, T.; Schreyögg, J.
Zulassung und Erstattung von Orphan Drugs im internationalen Vergleich
Gesundheitswesen 73, 504-514 (2011)
BACKGROUND: This paper analyses schemes to promote the authorisation of and reimbursement for orphan drugs. METHODS: 8 countries - Australia, Canada, Germany, Great Britain, France, Netherlands, Switzerland, USA - were studied to compare specific regulations for orphan drugs regarding drug admission, health technology assessment (HTA), decision-making for reimbursement, and off-label and compassionate use. Information was obtained by reviewing published and grey literature. Expert interviews were also conducted. RESULTS: The comparison of orphan drug legislation reveals that the EU and the USA offer the greatest incentives for the development of orphan drugs, whereas there is a tendency for Australia and Switzerland to profit from incentives in other countries. Although not explicitly stated, economic evaluation of orphan drugs takes the special circumstances for orphan drugs into account. In addition to common reimbursement practices, special schemes or programmes for the reimbursement of high-priced orphan

drugs exist in all countries that were analysed. Therefore access to orphan drugs seems to be warranted. However, due to co-payments of 5%, the USA may form an exception.
CONCLUSION: On the one hand, the use of special criteria for drug admission, HTA, and reimbursement promotes R&D for orphan drugs. On the other hand, high opportunity costs arise, because huge efforts are made for a minority of patients. A solution for this moral dilemma may be the application of "rule of rescue" or of "no cure, no pay" programmes.
Gesundheitswesen, Das

Drummond, M.; Jönsson, B.; Rutten, F.; Stargardt, T.
Reimbursement of pharmaceuticals: Reference pricing versus health technology assessment.
Eur. J. Health Econ. 12, 263-271 (2011)
Reference pricing and health technology assessment are policies commonly applied in order to obtain more value for money from pharmaceuticals. This study focussed on decisions about the initial price and reimbursement status of innovative drugs and discussed the consequences for market access and cost. Four countries were studied: Germany, The Netherlands, Sweden and the United Kingdom. These countries have operated one, or both, of the two policies at certain points in time, sometimes in parallel. Drugs in four groups were considered: cholesterol-lowering agents, insulin analogues, biologic drugs for rheumatoid arthritis and "atypical" drugs for schizophrenia. Compared with HTA, reference pricing is a relatively blunt instrument for obtaining value for money from pharmaceuticals. Thus, its role in making reimbursement decisions should be limited to drugs which are therapeutically equivalent. HTA is a superior strategy for obtaining value for money because it addresses not only price but also the appropriate indications for the use of the drug and the relation between additional value and additional costs. However, given the relatively higher costs of conducting HTAs, the most efficient approach might be a combination of both policies.
The European journal of health economics

Haas, L.
Präferenzmessung von Patienten in medizinischen Versorgungszentren (MVZ) - eine Gegenüberstellung der Behandlungsqualität von MVZ und niedergelassenen Haus- und Fachärzten.
Gesundheitswesen 73, 409-415 (2011)
Ziel der Studie: Besteht in der Präferenzmessung von Patienten zweier medizinischer Versorgungszentren (POLIKUM Gesundheitszentren) hinsichtlich der ambulanten Versorgungsformen medizinisches Versorgungszentrum (MVZ) und niedergelassene Ärzte (NÄ) aufgrund der jeweils dort erfahrenen Behandlungsqualität. Es wurden Determinanten der Präferenz zugunsten eines Versorgungssettings ermittelt. Methodik: 310 Fragebögen wurden in 2 MVZ an Patienten verteilt. Ein Qualitätsvergleich zwischen beiden ambulanten Versorgungsformen (MVZ vs. NÄ) erfolgte anhand von Qualitätsitems, welche der Literatur zur Qualitäts- und Zufriedenheitsforschung entnommen wurden. Das entwickelte und getestete Erhebungsinstrument bestand aus 17 Items mit 7-stufiger Antwortskala. T-Tests ermittelten inwieweit die erreichten Mittelwerte pro Item von einem theoretischen Testwert (MVZ ist im Vergleich zu NÄ in etwa gleich) abweichen. Die Determinanten der Präferenz wurden mithilfe einer schrittweisen multiplen Regressionsanalyse ermittelt. Ergebnisse: 310 Fragebögen wurden in beiden MVZ verteilt, die Rücklaufquote lag bei 92,3% (n=286). In 15 der 17 Items wurden die MVZ im Vergleich zu NÄ signifikant besser bewertet. Als Determinanten der Präferenz konnten folgende ermittelt werden (n=286, korrigiertes R2=0,29): (1) ausreichende Zeit des Arztes für die Behandlung des Patienten, (2) die fachliche Kompetenz der Ärzte, (3) Vorsorgeuntersuchungen, auf die Patienten aufmerksam gemacht werden. Schlussfolgerung: Die Präferenz zugunsten der MVZ könnte sich durch effizientere Organisationsstrukturen der Versorgungsform erklären lassen. Die ermittelten Determinanten der Präferenz der Patienten liefern praxisorientierte Ansätze zur Verbesserung der Präferenzposition medizinischer Leistungserbringer.
Gesundheitswesen, Das

Holzapfel, C.; Grallert, H.; Baumert, J.J.; Thorand, B.; Döring, A.; Wichmann, H.-E.; Hauner, H.; Illig, T.; Mielck, A.
First investigation of two obesity-related loci (TMEM18, FTO) concerning their association with educational level as well as income: The MONICA/KORA study.
J. Epidemiol. Community Health 65, 174-176 (2011)
Background Strong evidence exists for an association between socioeconomic status and body mass index (BMI) as well as between genetic variants and BMI. The association of genetic variants with socioeconomic status has not yet been investigated. The aim of this study was to investigate two obesity-related loci-the transmembrane 18 (TMEM18) and the fat mass and obesity-associated (FTO) gene-for their association with educational level and per capita income, and to test whether the detected genotype-BMI association is mediated by these social factors. Methods 12 425 adults from a large population-based study were genotyped for the polymorphism rs6548238 near TMEM18 and rs9935401 within the FTO gene. Data on educational level and per capita income were based on standardised questionnaires. Results High educational level and high per capita income were significantly associated with decreased BMI (-1.503 kg/m(2), p<0.0001/-0.820 kg/m(2), p<0.0001). Neither the polymorphism rs6548238 nor rs9935401 nor their combination were significantly associated with educational level (p=0.773/p=0.827/p=0.755) or income (p=0.751/p=0.991/p=0.820). Adjustment for social factors did not change the association between rs6548238 or rs9935401 and BMI. Conclusions As far as the authors know, this is the first study to investigate the association between polymorphisms and socioeconomic status. The polymorphisms rs6548238 and rs9935401 showed no association with educational level or income.
Journal of Epidemiology and Community Health

Schreyögg, J.; Stargardt, T.; Tiemann, O.
Costs and quality of hospitals in different health care systems: A multi-level approach with propensity score matching.
Health Econ. 20, 85-100 (2011)
Cross-country comparisons of costs and quality between hospitals are often made at the macro level. The goal of this study was to explore methods to compare micro-level data from hospitals in different health care systems. To do so, we developed a multi-level framework in combination with a propensity score matching technique using similarly structured data for patients receiving treatment for acute myocardial infarction in German and US Veterans Health Administration hospitals. Our case study shows important differences in results

between multi-level regressions based on matched and unmatched samples. We conclude that propensity score matching techniques are an appropriate way to deal with the usual baseline imbalances across the samples from different countries. Multi-level models are recommendable to consider the clustered structure of the data when patient-level data from different hospitals and health care systems are compared. The results provide an important justification for exploring new ways in performing health system comparisons.
Health Economics

Kowall, B.; Rathmann, W.; Strassburger, K.; Meisinger, C.; Holle, R.; Mielck, A.
Socioeconomic status is not associated with type 2 diabetes incidence in an elderly population in Germany: KORA S4/F4 Cohort Study.
J. Epidemiol. Community Health 65, 606-612 (2011)
Background An association between socioeconomic status (SES) and the incidence of type 2 diabetes mellitus (T2DM) has been found for younger and middle-aged individuals, but studies of this relationship in elderly populations are rare. Methods In a population-based cohort in southern Germany (KORA S4/F4: 1223 subjects aged 55-74 years at baseline, 887 subjects (73%) in the follow-up 7 years later) the identification of incident T2DM was based on oral glucose tolerance tests or on validated physician diagnoses. Regression models were fitted to predict incident T2DM and (pre)diabetes, respectively, with SES as the main independent variable. (Pre)diabetes here means incident T2DM or incident pre-diabetes. Results With five different SES measures (global Helmert index, income, educational level, occupational status, subjective social status), the diabetes risk of low SES groups was not significantly different from the risk of higher SES groups (ie, cumulative incidence 10% (low income), 9% (medium income), 13% (high income)). In subjects with normoglycaemia at baseline, (pre)diabetes incidence was more pronounced in lower SES groups, but almost all these associations were not significant. With measures of subjective SES stronger associations were found than with measures of objective SES. Conclusion There was no statistically significant association between objective SES and diabetes incidence in this elderly population. This might be due to a larger socioeconomic homogeneity of elderly populations and to a strong driving force for diabetes, which outweighed the influence of SES, and which was indicated by an adverse baseline metabolic profile in participants developing diabetes in the follow-up.
Journal of Epidemiology and Community Health

2010
Wenig, C.M.; Wolfenstetter, S.B.; John, J.
Recent economic findings on childhood obesity.
Sci. Newsl. 51, 4 (2010)
no Abstract
The Scientific Newsletter
Letter to the Editor
Letter to the Editor
Meisinger, C.; Heier, M.; von Scheidt, W.; Kirchberger, I.; Hörmann, A.; Kuch, B.
Gender-specific short and long-term mortality in diabetic versus nondiabetic patients with incident acute myocardial infarction in the reperfusion era (the MONICA/KORA Myocardial Infarction Registry).
Am. J. Cardiol. 106, 1680-1684 (2010)
The aim of this study was to investigate gender-specific short- and long-term mortalities after a first acute myocardial infarction (AMI) in patients with and without diabetes mellitus (DM). The study was based on 505 men and 196 women with DM and 1,327 men and 415 women without DM consecutively hospitalized with a first-ever AMI from January 1998 to December 2003 recruited from a population-based MI registry. Patients were followed until December 31, 2005 (median follow-up time 4.3 years). In men and women, no significantly independent association between DM and short-term mortality was observed. After multivariable adjustment odds ratios (95% confidence intervals [CIs]) for 28-day case fatality were 1.45 (95% CI 0.90 to 2.34) in men with DM compared to men without DM and 1.44 (95% CI 0.66 to 3.15) in women with DM compared to women without DM. Conversely, in 28-day AMI survivors DM was significantly associated with long-term mortality in age-adjusted analyses, in which men with DM had a hazard ratio (HR) of 1.57 (95% CI 1.18 to 2.10) for all-cause mortality compared to non-DM men; the corresponding HR in women with DM was 2.91 (95% CI 1.82 to 4.65). After multivariable adjustment the strong association in women with DM remained significant (HR 2.56, 95% CI 1.53 to 4.27); however, in men with DM it became borderline significant (HR 1.36, 95% CI 1.00 to 1.85). In conclusion, short-term mortality was not significantly increased in men and women with DM after a first-ever AMI, although estimates were relatively high, indicating a possible relation. However, long-term mortality was higher in patients with AMI and DM, particularly in women.
American Journal of Cardiology, The

Hegar, R.; Mielck, A.
'Subjektiver sozialer Status'. Stellenwert für die Untersuchung und Verringerung von gesundheitlicher Ungleichheit.
Präv. Gesundheitsf. 5, 389-400 (2010)
BackgroundSocial status is just about always assessed by 'objective' measures such as educational level, income or occupational status. In recent years, some studies have also included the assessment of 'subjective social status' (SSS). This new variable could be important for health promotion and prevention. In Germany, though, this discussion has hardly been recognized yet.MethodsBased on different databases, we conducted a systematic review of empirical studies which include an assessment of SSS. As far as we know, a similar review has not been published in German yet. We looked for associations with morbidity, mortality and health risks such as smoking or obesity. We finish with recommendations for further research and practice.ResultsWe were able to find 53 empirical studies. Most of them are from the USA; no study has been published from Germany, Austria or Switzerland. Most studies (46 of 53) were published in the last 5 years, clearly indicating that this discussion is still rather new. 'Subjective social status' is mostly assessed by the MacArthur Scale, i.e. a ladder where the respondents can mark their position between 'low' (low social status) and 'high' (high social status). The results of the studies often show increased health risks for people with low SSS, even if 'objective' measures such as educational level or income are controlled for statistically.Conclusion"Subjective social status" should also be included in German studies, in addition to 'objective' measures such as educational level or income. If people are to be reached in programmes for health promotion or prevention, it is important to know what social position they

believe they have; and this subjective perception does not just depend on 'objective' measures such as educational level or income. We would recommend that 'subjective social status' be assessed with a German version of the MacArthur Scale. The picture of a ladder is apparently able to capture the meaning of 'social status' very well and it is very easy to understand.
Prävention und Gesundheitsförderung

Leidl, R.
Economic modelling in public health: A tool of growing relevance.
Eur. J. Public Health 20, 365-366 (2010)
no Abstract
European Journal of Public Health
Editorial
Editorial
Rogowski, W.H.
What should public health research focus on? Comments from a decision analytic perspective.
Eur. J. Public Health 20, 484-485 (2010)
no Abstract
European Journal of Public Health
Editorial
Editorial
Stargardt, T.
The impact of reference pricing on switching behaviour and healthcare utilisation: The case of statins in Germany.
Eur. J. Health Econ. 11, 267-277 (2010)
This paper analyses (1) the impact of the inclusion of statins in the German reference pricing scheme in 2005 on the statin market, and (2) the effect of switching behaviour subsequent to the policy change on healthcare utilisation and costs. Patients with prescriptions for statins in 2004 were observed for 1 year before and 1 year after the policy change, which went into effect on 1 January 2005. Data on outpatient and inpatient visits, pharmaceutical consumption, and cost to the sickness fund were collected from a sickness fund with more than 5.8 million insured members in 2005. Compared to patients who were not affected by the policy change, patients treated previously with atorvastatin experienced higher non-adherence and increased discontinuation of treatment ($P < 0.0001$). Compared to patients who continued treatment with atorvastatin (non-switchers), patients who switched to another statin were hospitalised more often ($P = 0.0439$). However, difference-in-differences in hospitalisation due to coronary heart disease ($P = 0.8751$) and emergency visits ($P = 0.5624$) did not differ significantly between the two groups. Patients who switched more than once experienced a significant increase in hospital visits ($P = 0.0061$) and hospital visits due to cardiovascular disease ($P = 0.0096$) compared to non-switchers. Difference-in-differences in outpatient healthcare utilisation did not differ between non-switchers and switchers. Total savings resulting from the policy change ranged from 94.4 million to 108.7 million. Although manufacturers usually comply with reference pricing by reducing their retail prices to the reference price, regulators have to be aware of the consequences in cases where manufacturers react as in this situation.
The European journal of health economics

Schreyögg, J.; Weller, J.; Stargardt, T.; Herrmann, K.; Bluemel, C.; Dechow, T.; Glatting, G.; Krause, B.J.; Mottaghy, F.; Reske, S.N.; Buck, A.K.
Cost-effectiveness of hybrid PET/CT for staging of non-small cell lung cancer.
J. Nucl. Med. 51, 1668-1675 (2010)
Although the diagnostic effectiveness of integrated PET/CT for staging of non-small cell lung cancer (NSCLC) has already been proven, it remains to be determined if tumor staging with combined metabolic and anatomic imaging is also cost-effective. The objective of this study was to evaluate from a payers' perspective the cost-effectiveness of staging NSCLC with CT alone (representing the mainstay diagnostic test) and with integrated PET/CT. The study is based on 172 NSCLC patients from a prospective clinical study who underwent diagnostic, contrast-enhanced helical CT and integrated PET/CT. Imaging was performed at the University Hospital Ulm between May 2002 and December 2004. To calculate treatment costs, we differentiated among cost for diagnosis, cost for nonsurgical treatment according to the clinical diagnosis, and cost for surgical procedures according to the clinical tumor stage. The diagnostic effectiveness in terms of correct TNM staging was 40% (31/77) for CT alone and 60% (46/77) for PET/CT. For the assessment of resectability (tumor stages Ia-IIIa vs. IIIb-IV), 65 of 77 patients (84%) were staged correctly by PET/CT (CT alone, 70% [54/77]). The incremental cost-effectiveness ratios per correctly staged patient were $3,508 for PET/CT versus CT alone. The incremental cost-effectiveness ratios per quality-adjusted life year gained were $79,878 for PET/CT vs. CT alone, decreasing to $69,563 assuming a reduced loss of utility (0.10 quality-adjusted life years) due to surgical morbidity.Cost-effectiveness analyses showed that costs for PET/CT are within the commonly accepted range for diagnostic tests or therapies. Therefore, reimbursement of PET/CT for NSCLC staging can be also recommended from an economic point of view.
Journal of Nuclear Medicine

Rogowski, W.H.; Grosse, S.D.; John, J.; Kääriäinen, H.; Kent, A.; Kristofferson, U.; Schmidtke, J.
Points to consider in assessing and appraising predictive genetic tests.
J. Community Genet. 1, 185-194 (2010)
The use of predictive genetic tests is expanding rapidly. Given limited health care budgets and few national coverage decisions specifically for genetic tests, evidence of benefits and harms is a key requirement in decision making; however, assessing the benefits and harms of genetic tests raises a number of challenging issues. Frequently, evidence of medical benefits and harms is limited due to practical and ethical limitations of conducting meaningful clinical trials. Also, clinical endpoints frequently do not capture the benefit appropriately because the main purpose of many genetic tests is personal utility of knowing the test results, and costs of the tests and counseling can be insufficient indicators of the total costs of care. This study provides an overview of points to consider for the assessment of benefits and harms from genetic tests in an ethically and economically reflected manner. We discuss whether genetic tests are sufficiently exceptional to warrant exceptional methods for assessment and appraisal.
Journal of Community Genetics

Mielck, A.
Gesundheitspolitik und soziale Ungleichheit.
Pol. Bild. 4, 62-81 (2010)
Politische Bildung : PB

Schweikert, B.; John, J.; Ringborg, A.; Erhardt, W.; Bleckmann, A.; Neubauer, A.S.
Standards for the assessment of antidiabetic drugs-the IQWIG perspective.
Value Health 13, A300-A300 (2010)
Value in Health

Geiger-Gritsch, S.; Stollenwerk, B.; Miksad, R.; Guba, B.; Wild, C.; Siebert, U.
Safety of bevacizumab in patients with advanced cancer: A meta-analysis of randomized controlled trials.
Oncologist 15, 1179-1191 (2010)
Objective. We performed a meta-analysis on adverse events seen with bevacizumab to combine the existing evidence about its safety in patients with advanced cancer. Methods. A systematic literature search was conducted to identify published, randomized controlled trials of bevacizumab in cancer patients with data on adverse events available. The primary endpoint was "severe adverse event," a composite of grade 3 and 4 adverse events. Secondary endpoints for the exploratory analysis were individual adverse events. We used random-effects meta-analysis to combine data. Results. Thirteen eligible publications were identified and eight trials reported the primary endpoint. Compared with the control group, the bevacizumab group had a slightly higher risk for any severe adverse event (pooled relative risk, 1.10; 95% confidence interval [95% CI], 1.01-1.19). The pooled risk difference was 7% (95% CI, 1%-13%), with a number needed to harm of 14 treated patients. Exploratory analyses showed a statistically significant higher risk for eight of the 15 evaluated secondary endpoints: bevacizumab was associated with a fourfold higher risk for hypertension, epistaxis, and gastrointestinal hemorrhage/perforation; a threefold higher risk for any bleeding events; and a lower, but elevated risk for proteinuria, leukopenia, diarrhea, and asthenia. No statistically significant differences were found for any thrombotic event (arterial or venous), hemoptysis, cardiac event, thrombocytopenia, neutropenia, impaired wound healing, or death related to an adverse event. Conclusion. Treatment with bevacizumab was associated with a slightly higher risk for any severe (grade 3 or 4) adverse event in patients with cancer. The result may impact individual benefit-risk assessments and policy guidelines.
Oncologist, The

Wolfenstetter, S.B.
Economic aspects of obesity and physical inactivity.
München: Verl. Dr. Hut, 2010. 187 S.
no Abstract
Grander, W.; Dünser, M.; Stollenwerk, B.; Siebert, U.; Dengg, C.; Koller, B.; Eller, P.; Tilg, H.
C-reactive protein levels and post-ICU mortality in nonsurgical intensive care patients.
Chest 138, 856-862 (2010)
BACKGROUND: There are no data on the association between acute inflammation during critical illness and long-term mortality in ICU patients. METHODS: Nonsurgical patients with an ICU length of stay > 24 h surviving until ICU discharge were included into this prospective, observational, follow-up study. Demographics, chronic diseases, admission diagnosis, the Simplified Acute Physiology Score (SAPS) II, length of ICU stay, maximum C-reactive protein (CRP) levels during the ICU stay (CRPmax), and CRP levels at ICU discharge (CRPdis) were documented. After a follow-up time of 1.88 ± 1.16 years (range, 0.5-4 years), the survival status was determined. RESULTS: Seven hundred sixty-five patients were enrolled into the study protocol. One hundred fifty-eight patients (20.7%) died within 0.62 ± 0.88 years after ICU discharge. Cumulative survival rates differed between patients grouped into the CRPmax and CRPdis quartiles. Patients in the first and second CRPmax quartiles had better cumulative survival rates than those in higher CRPmax quartiles (all P < .001). Patients in the first CRPdis quartile had better cumulative survival rates than those in higher CRPdis quartiles (all P < .001). Using adjusted Cox proportional hazards models, both CRPmax and CRPdis were independently associated with post-ICU mortality (both P < .001). Furthermore, the number of chronic diseases (P < .001), age (P < .001), and the SAPS II (P = .03) were associated with post-ICU mortality in both Cox models. CONCLUSIONS: CRP levels during critical illness seem independently associated with post-ICU survival in nonsurgical ICU patients. Future research focusing on the association between acute systemic inflammation and post-ICU outcome is warranted in order to improve long-term survival of critically ill patients.
Chest

Wolfenstetter, S.B.
Zukünftige Kosten der Adipositas: Ergebnisse der 10-Jahresuntersuchung (1994/95-2004/05) in der KORA-Studienregion.
Obes. Facts 3, 27 (2010)
Obesity Facts
Meeting abstract

Breitfelder, A.; Wolfenstetter, S; Wenig, C.; Holle, R.; Leidl, R.
Economic assessment of obesity in children, adolescents and adults: Results from different surveys (KiGGS, GINI-plus/LISA-plus, KORA S3/F3).
Obes. Facts 3, 59 (2010)
Obesity Facts
Meeting abstract

Wenig, C.M.; Breitfelder, A.; Schaffrath-Rosario, A.
Zusammenhang zwischen BMI und Kosten der ambulanten Versorgung von Kindern und Jugendlichen in Deutschland-Ergebnisse aus der KiGGS-Studie.
Vortrag: 26. Jahrestagung der Deutschen Adipositas-Gesellschaft, 4-6 November 2010, Berlin. (2010)
Obesity Facts
Donath, C.; Gräßel, E.; Grossfeld-Schmitz, M.; Menn, P.; Lauterberg, J.; Wunder, S.; Marx, P.; Ruckdäschel, S.; Mehlig, H.; Holle, R.
Effects of general practitioner training and family support services on the care of home-dwelling dementia patients - results of a controlled cluster-randomized study.
BMC Health Serv. Res. 10:314 (2010)
BACKGROUND: More than 90% of dementia patients are cared for by their general practitioners, who are decisively involved in the diagnosis, therapy and recommendation of support services. Objective: To test whether special training of general practitioners alters the care of dementia patients through their systematic recommendation of caregiver counseling and support groups. METHOD: 129 general practitioners enrolled 390 dementia patients and their informal caregivers in a prospective,

three-arm cluster-randomized 2-year study. Arm A constituted usual care, in Arm B and C support groups and caregiver counseling (in Arm B one year after baseline, in Arm C at baseline) were recommended by the general practitioners. The general practitioners received arm-specific training. Diagnostic and therapeutic behavior of physicians was recorded at baseline. Informal caregivers were questioned in follow-up after 2 years about the utilization of support services. RESULTS: The diagnostic behavior of the general practitioners conforms to relevant guidelines. The procedure in newly-diagnosed patients does not differ from previously diagnosed patients with the exception of the rate of referral to a specialist. About one-third of the newly-diagnosed dementia patients are given an anti-dementia drug. The utilization of support groups and counseling increased five- and fourfold, respectively. Utilization of other support services remained low (< 10%), with the exception of home nursing and institutional short-term nursing. CONCLUSION: Trained general practitioners usually act in conformity with guidelines with respect to diagnosing dementia, and partly in conformity with the guidelines with respect to recommended drug therapy. Recommendations of support services for informal caregivers by the general practitioner are successful. They result in a marked increase in the utilization rate for the recommended services compared to offers which are not recommended by the general practitioner.
BMC Health Services Research

Bierwirth, R.A.; Kohlmann, T.; Moock, J.; Holle, R.; Landgraf, W.
Diabetesbezogene Kosten und Therapiezufriedenheit bei ICT-behandelten Typ-2-Diabetikern in der ambulanten Versorgung: Ergebnisse der LIVE-COM-Studie.
Med. Klin. Intensivmed. Notfmed. 105, 792-801 (2010)
Hintergrund und Ziel: Die Behandlung des Diabetes mellitus belastet die gesetzliche Krankenversicherung mit hohen Kosten. Ziel der LIVE-COMStudie (Long Acting Insulin Glargine versus Insulin Detemir Cost Evaluation Comparison) war es, den Einfluss einer auf Insulin glargin (GLA) oder Insulindetemir (DET) basierten, intensivierten konventionellen Therapie auf Diabeteskosten sowie Therapiezufriedenheit und Lebensqualität in einer zufälligen Stichprobe bei langjährigen Typ-2-Diabetikern zu ermitteln, die im hausärztlichen Bereich behandelt wurden. Patienten und Methodik: LIVE-COM ist eine nicht-interventionelle Querschnittsstudie, die zwischen April und September 2008 in 138 zufällig ausgewählten Hausarztpraxen durchgeführt wurde. Von 1731 gesetzlich krankenversicherten Typ-2-Diabetikern (GLA: n = 1150; DET: n = 581), die seit mindestens 6 Monaten eine Basal-Bolus-Therapie (ICT) mit GLA oder DET erhielten, wurden diabetesbezogene Therapiekosten (für Insuline, orale Antidiabetika, Blutzucker-Teststreifen, Nadeln, Lanzetten, Hypokits®) aus den Ressourcenverbräuchen der letzten 6 Monate aus GKV-Perspektive berechnet. Patientenbezogene Nutzenparameter wurden mit Hilfe der Fragebögen DTSQ, ITEQ und SF-12 erfasst. Ergebnisse: Die mittleren diabetesbezogenen Pro-Kopf-Gesamtkosten über 6 Monate waren bei Patienten mit GLA-Therapie geringer als bei jenen mit DET-Therapie (972 € ± 374 € vs. 1135 € ± 477 €, $p < 0{,}001$). Adjustiert auf alle relevanten Einflussfaktoren betrugen die Kosten 932 € (95% KI: 905, 957 €) vs. 1061 € (95% KI: 1025, 1099 €, $p < 0{,}001$). Die adjustierten mittleren Einzelkosten für Basalinsulin (223 € vs. 246 €), Bolusinsulin (241 € vs. 289 €), Teststreifen (347 € vs. 393 €) und Nadeln (67 € vs. 80 €) waren jeweils signifikant niedriger in der GLA-Gruppe ($p < 0.001$), während bei den Kosten für orale Antidiabetika (36 € vs. 35 €), Lanzetten (14 € vs. 15 €) und Hypokits® (1,9 € vs. 1,0 €) keine statistisch signifikanten Unterschiede bestanden. Bei niedrigerem Gesamtinsulinverbrauch (68 E/Tag vs. 79 E/Tag, $p < 0{,}01$) fand sich eine etwas bessere Stoffwechseleinstellung (HbA1c, Nüchternblutzucker) in der GLA-Gruppe, ebenso zeigten sich in der Therapiezufriedenheit etwas bessere Ergebnisse für die GLA-Gruppe. Schlussfolgerung: Innerhalb eines 6-monatigen Vergleichszeitraums war eine Glargin vs. Detemir basierte Basal-Bolus-Therapie bei Typ-2-Diabetikern aufgrund unterschiedlicher Ressourcenverbräuche Detemir mit niedrigeren diabetesbezogenen Kosten verbunden (Δ: –128 €/Patient). Weitere prospektivee Versorgungsstudien an größeren Patientenkollektiven wären hilfreich, um ökonomische Aspekte von Insulinanaloga, aber auch von anderen innovativen Therapiealternativen im Praxisalltag noch umfassender darzustellen.
Medizinische Klinik - Intensivmedizin und Notfallmedizin

Rogowski, W.H.; Carlsson, P.; Kristofferson, U.
The use of principles in allocating scarce health care resources for genetic tests.
In: Kristofferson, U.*; Schmidtke, J.*; Cassiman, J* [Eds.]: Quality Issues in Clinical Genetic Services. Houten: Springer, 2010. 173-182
Given limited health care resources also for genetic tests, it needs to be considered how we can meet health needs fairly if we cannot meet them all. Frequently, health care decision making involves the explicit or implicit use of principles. The four basic principles for ethical decision making autonomy, non-maleficience, beneficience and justice provide an example of an elaborated bioethical framework by Beauchamp and Childress. The qualitative use of such principles for allocating health resources within genetic testing is a fruitful starting point, but it should be complemented by health economic techniques and procedural fairness in a pragmatic manner.
von Lengerke, T.
Ambulante Versorgungsnutzung adipöser Erwachsener: psychisch bedingt?
In: Verhaltensepidemiologie und Ergebnisse der kooperativen Gesundheitsforschung in der Region Augsburg. Saarbrücken: SVH Südwestdt. Verl. für Hochsch.-Schr., 2010. 53-64
Die Annahme des Gesundheitswesens, Menschen nähmen nur dann gesundheitsbezogene Versorgung in Anspruch, wenn sie krank sind, stimmt so nicht. Dies gilt auch für die Adipositas, zumal sie als Krankheit sui generis umstritten ist. Der Autor entwickelt ein verhaltensepidemiologisches Inanspruchnahmemodell, das frühere Ansätze um psychische Einflüsse erweitert. Daten der Kooperativen Gesundheitsforschung in der Region Augsburg zeigen, dass die bei adipösen Erwachsenen erhöhte Inanspruchnahme von Allgemeinärzten, Physiotherapie und Heilpraktikern weder durch Gefühle der Verstehbarkeit, Bedeutsamkeit und Handhabbarkeit des eigenen Lebens noch durch Überzeugungen erklärt wird, die eigene Gesundheit sei Folge von Selbstverantwortlichkeit, Selbstverschulden, einflussreichen Anderen oder Zufall. Dagegen erklärt Unzufriedenheit mit dem eigenen Körpergewicht die erhöhte Inanspruchnahme von Physiotherapie und Heilpraktikern. Dies legt nahe, dass adipöse Erwachsene zum Arzt gehen, weil sie krank sind, zu nichtärztlichen Versorgern jedoch wegen negativem Körperbild. Die Arbeit unterstreicht die Rolle biopsychosozialer Analysen von Inanspruchnahme.

Mielck, A.
Socio-epidemiological and ethical approaches for the appraisal of health inequalities.
Ethik Med. 22, 235-248 (2010)
Definition of the problem Low socio-economic status is often associated with increased morbidity and mortality. In this paper, an appraisal of these health inequalities is offered from a social-epidemiological point of view, focussing on the question: who is responsible for the increased health risks of people in low status groups? Arguments Health behavior can explain just a small part of these health inequalities, making it even more important to look at other causes. Important are, for example, the social differences concerning harmful living conditions (noise, etc.), harmful working conditions, and also concerning access to health care. These social-epidemiological results can be well integrated into the ethical discussion. Conclusion Who is responsible for what part of the health inequalities? This question is often the starting point of heavy disputes. They can be solved only if the social-epidemiological and ethical discussions are better linked to one another.
Ethik in der Medizin

Findeisen, H.M.; Weckbach, S.; Stark, R.G.; Reiser, M.F.; Schoenberg, S.O.; Parhofer, K.G.
Metabolic syndrome predicts vascular changes in whole body magnetic resonance imaging in patients with long standing diabetes mellitus.
Cardiovasc. Diabetol. 9:44 (2010)
BACKGROUND: Although diabetic patients have an increased rate of cardio-vascular events, there is considerable heterogeneity with respect to cardiovascular risk, requiring new approaches to individual cardiovascular risk factor assessment. In this study we used whole body-MR-angiography (WB-MRA) to assess the degree of atherosclerosis in patients with long-standing diabetes and to determine the association between metabolic syndrome (MetS) and atherosclerotic burden. METHODS: Long standing (> or = 10 years) type 1 and type 2 diabetic patients (n = 59; 31 males; 63.3 +/- 1.7 years) were examined by WB-MRA. Based on the findings in each vessel, we developed an overall score representing the patient's vascular atherosclerotic burden (MRI-score). The score's association with components of the MetS was assessed. RESULTS: The median MRI-score was 1.18 [range: 1.00-2.41] and MetS was present in 58% of the cohort (type 2 diabetics: 73%; type 1 diabetics: 26%). Age (p = 0.0002), HDL-cholesterol (p = 0.016), hypertension (p = 0.0008), nephropathy (p = 0.0093), CHD (p = 0.001) and MetS (p = 0.0011) were significantly associated with the score. Adjusted for age and sex, the score was significantly (p = 0.02) higher in diabetics with MetS (1.450 [1.328-1.572]) compared to those without MetS (1.108 [0.966-1.50]). The number of MetS components was associated with a linear increase in the MRI-score (increase in score: 0.09/MetS component; r2 = 0.24, p = 0.038). Finally, using an established risk algorithm, we found a significant association between MRI-score and 10-year risk for CHD, fatal CHD and stroke. CONCLUSION: In this high-risk diabetic population, WB-MRA revealed large heterogeneity in the degree of systemic atherosclerosis. Presence and number of traits of the MetS are associated with the extent of atherosclerotic burden. These results support the perspective that diabetic patients are a heterogeneous population with increased but varying prevalence of atherosclerosis and risk.
Cardiovascular Diabetology

Grossfeld-Schmitz, M.; Donath, C.; Holle, R.; Lauterberg, J.; Ruckdaeschel, S.; Mehlig, H.; Marx, P.; Wunder, S.; Gräßel, E.
Counsellors contact dementia caregivers - predictors of utilisation in a longitudinal study.
BMC Geriatr. 10:24 (2010)
BACKGROUND: Counselling of family members is an established procedure in the support of dementia patients' relatives. In absence of widespread specialised dementia care services in most countries, however, counselling services are often not taken up or only very late in the course of the disease. OBJECT: In order to promote acceptance of this service, a new counselling concept was implemented where general practitioners recommended family counsellors, who then actively contacted the family caregivers to offer counselling ("Counsellors Contact Caregivers", CCC). The research questions were: To what extent can the rate of family counselling be increased by CCC? What are the predictors for usage of this form of family counselling? METHODS: The study started in June 2006 in Middle Franconia for patients with mild to moderate dementia. At baseline, 110 family caregivers were offered counselling based on the CCC guideline. Data was analysed from 97 patient-caregiver dyads who received counselling for one year. The mean age of the patients with dementia (67 women and 30 men) was 80.7 years (SD = 6.2). The mean age of their primary family caregivers (68 women, 23 men) was 60.8 years (SD = 13.8). RESULTS: 35 family members (36%) made use of more extensive counselling (more than one personal contact). By contrast, 29 family members (30%) had no personal contact or only one personal contact (33 cases, 34%). The factors "spouse" (p = .001) and "degree of care" (p = .005) were identified as significant predictors for acceptance of extensive counselling. CONCLUSIONS: Actively contacting patients and their caregivers is a successful means of establishing early and frequent contact with family members of patients with mild to moderate dementia. Use of extensive counselling is made especially by spouses of patients requiring intensified care.
BMC Geriatrics

Kowall, B.; Mielck, A.
Soziale Ungleichheit und Diabetes: Trifft es Arme öfter?
Diabetologie 6, 196-202 (2010)
Die Prävalenz der wichtigsten Risikofaktoren für den Typ-2-Diabetes ist in Deutschland in den unteren Statusgruppen besonders hoch, entsprechend steigen auch Inzidenz und Prävalenz des Typ-2-Diabetes mit abnehmendem sozialem Status. Beim Typ-1-Diabetes ist der Zusammenhang mit dem sozioökonomischen Status bisher kaum untersucht, dennoch gibt es auch hier Hinweise auf einen inversen Zusammenhang zwischen dem sozialen Status und der Inzidenz. Der Einfluss des sozialen Status auf die Gesundheit macht auch bei Patienten mit Diabetes nicht Halt, so dass Diabetespatienten mit niedrigem sozialen Status beispielsweise öfter unter Komplikationen leiden. Die Faktoren, die die genannten Zusammenhänge zumindest teilweise erklären können, sind vielfältig: Sie reichen vom Gesundheitsverhalten und der Gesundheitskompetenz der Patienten über den Zugang zum Gesundheitssystem bis zu Merkmalen des Behandlungsprozesses. Auf Grundlage dieser Faktoren werden abschließend einige Empfehlungen für die Gesundheitspolitik und für niedergelassene Ärzte formuliert.
Diabetologie, Die

Parhofer, K.G.; Zeymer, U.; Stark, R.G.; Binz, C.; Schwertfeger, M.; Bhatt, D.L.; Steg, P.G.; Röther, J.
In Germany diabetic patients with coronary artery disease are treated more intensively than diabetic patients with other manifestations of atherothrombosis - results from the REACH registry.
Exp. Clin. Endocrinol. Diabet. 118, 51-56 (2010)
Atherothrombosis can present as coronary artery disease (CAD) cerebrovascular disease (CVD) and peripheral arterial disease (PAD). It is unknown whether diabetics with CAD differ from those with other manifestations of atherothrombosis such as CVD or PAD regarding clinical characteristics, biochemical parameters, or medications. MATERIAL AND METHODS: The REACH (REduction of Atherothrombosis for Continued Health) registry evaluated 67 888 patients with established atherothrombosis or risk factors. Of 5 646 recruited German patients, 2 381 (42%) are diabetic. Of these 1 438 (60%) have CAD (either only CAD or in combination with CVD and/or PAD - CAD group) and 520 (22%) have other manifestations of atherothrombosis (either CVD or PAD or both - other manifestation group) and 18% have only risk factors. Differences between diabetics with CAD and diabetics with other manifestations of atherothrombosis were evaluated with multivariate models (79% male, 69+/-9 years, BMI 29+/-5 kg/m (2)) (SAS9.1). RESULTS: After correcting for age, sex and BMI, CAD patients receive (OR; 95% CI) more aspirin (1.5; 1.2-1.9; p=0.0002), statins (3.1; 2.6-3.7), beta-blockers (4.0; 3.8-4.8), diuretics (1.4; 1.2-1.6), ACE-inhibitors/ARBs (1.4; 1.2-1.7) and nitrates (8.8; 6.7-11.7) and significantly less often metformin (0.75; 0.61-0.93; p=0.01) with no differences concerning other antidiabetics. This resulted in significantly (p<0.05) lower blood-pressure (CAD 142/81 mmHg, other manifestations 145/82 mmHg) and LDL-cholesterol levels (CAD 108+/-37 mg/dl, other manifestations 123+/-37 mg/dl). Therefore more CAD patients reach LDL and blood-pressure-goals (CAD 47%/33%; other manifestations 30%/24%, respectively). Only few patients (CAD 7.1%, other manifestations 4.1%) reach all treatment goals. Furthermore, less CAD patients than patients with other manifestations of atherothrombosis are current smokers (11% vs. 22%). DISCUSSION: These data indicate considerable treatment differences between diabetics with CAD and those with other manifestations of atherothrombosis such as CVD or PAD. CAD patients are treated more intensively and therefore reach lower lipid and blood-pressure values.
Experimental and Clinical Endocrinology & Diabetes

Meyer, E.; Mielck, A.
Möglichkeiten und Gefahren der prädiktiven Diagnostik.
Forum DKG 25, 15-19 (2010)
Im Mittelpunkt des im Februar 2010 in Kraft getretenen Gendiagnostikgesetzes (GenDG) steht das Prinzip der informationellen Selbstbestimmung. Danach bestimmt jeder Bürger grundsätzlich selbst über die Verwendung seiner persönlichen Daten. Laut GenDG dürfen prädiktive genetische Untersuchungen nicht ohne Einwilligung der Betroffenen durchgeführt werden, wobei zuvor eine fachärzliche Beratung vorgesehen ist. Auch werden der Nutzung von Testergebnissen durch Arbeitgeber und Versicherer enge Grenzen gesetzt, um Benachteiligungen aufgrund genetischer Eigenschaften zu verhindern. Das GenDG kann somit als Antwort auf Befürchtungen verstanden werden, wonach soziale Ungleichheiten durch die wachsenden Möglichkeiten der genetischen Diagnostik zunehmen könnten. Ziel des vorliegenden Beitrags ist es daher, eine Einführung in das Thema "Soziale Ungleichheit und Gesundheit" zu geben und mögliche Probleme im Zusammenhang mit der prädiktiven Diagnostik aufzuzeigen.
Forum : Das Offizielle Magazin der Deutschen Krebsgesellschaft e.V.

Mielck, A.
Welche sozialen Unterschiede im Gesundheitszustand sind 'ungerecht'?
In: Marckmann, G.*; Strech, D.*; Wasem, J.* [Eds.]: Public Health Ethik. Berlin: LIT-Verl., 2010. 79-96 (Public Health Ethik; 1)
Im Alltagsverständnis werden unter dem Begriff 'soziale Ungleichheit' zumeist Unterschiede hinsichtlich Bildung, Einkommen und Beruf verstanden. Etwas präziser formuliert handelt es sich hierbei um Merkmale der 'vertikalen' sozialen Ungleichheit. Mit Hilfe von Angaben zu Bildung, Einkommen und Beruf lässt sich der soziale Status einer Person bestimmen; der Begriff 'Status' impliziert bereits die Einordnung in eine vertikale (d.h. hierarchische) Skala. Die Bevölkerung lässt sich aber auch nach weiteren Merkmalen wie Alter und Geschlecht in Gruppen unterteilen, und auch zwischen diesen Gruppen kann soziale Ungleichheit bestehen. Der vorliegende Beitrag konzentriert sich jedoch auf die 'vertikale soziale Ungleichheit', d.h. auf die Unterschiede nach Bildung, Einkommen und Beruf.
Public Health Ethik
Haucke, F.
The cost effectiveness of radon mitigation in existing German dwellings - a decision theoretic analysis.
J. Environ. Manage. 91, 2263-2274 (2010)
Radon is a naturally occurring inert radioactive gas found in soils and rocks that can accumulate in dwellings, and is associated with an increased risk of lung cancer. This study aims to analyze the cost effectiveness of different intervention strategies to reduce radon concentrations in existing German dwellings. The cost effectiveness analysis (CEA) was conducted as a scenario analysis, where each scenario represents a specific regulatory regime. A decision theoretic model was developed, which reflects accepted recommendations for radon screening and mitigation and uses most up-to-date data on radon distribution and relative risks. The model was programmed to account for compliance with respect to the single steps of radon intervention, as well as data on the sensitivity/specificity of radon tests. A societal perspective was adopted to calculate costs and effects. All scenarios were calculated for different action levels. Cost effectiveness was measured in costs per averted case of lung cancer, costs per life year gained and costs per quality adjusted life year (QALY) gained. Univariate and multivariate deterministic and probabilistic sensitivity analyses (SA) were performed. Probabilistic sensitivity analyses were based on Monte Carlo simulations with 5000 model runs. The results show that legal regulations with mandatory screening and mitigation for indoor radon levels >100 Bq/m(3) are most cost effective. Incremental cost effectiveness compared to the no mitigation base case is 25,181 euro (95% CI: 7371 euro-90,593 euro) per QALY gained. Other intervention strategies focussing primarily on the personal responsibility for screening and/or mitigative actions show considerably worse cost effectiveness ratios. However, targeting radon intervention to radon-prone areas is significantly more cost

effective. Most of the uncertainty that surrounds the results can be ascribed to the relative risk of radon exposure. It can be concluded that in the light of international experience a legal regulation requiring radon screening and, if necessary, mitigation is justifiable under the terms of CEA.
Journal of Environmental Management

Langer, A.
A systematic review of PET and PET/CT in oncology: A way to personalize cancer treatment in a cost-effective manner?
BMC Health Serv. Res. 10:283 (2010)
Background: A number of diagnostic tests are required for the detection and management of cancer. Most imaging modalities such as computerized tomography (CT) are anatomical. However, positron emission tomography (PET) is a functional diagnostic imaging technique using compounds labelled with positron-emitting radioisotopes to measure cell metabolism. It has been a useful tool in studying soft tissues such as the brain, cardiovascular system, and cancer. The aim of this systematic review is to critically summarize the health economic evidence of oncologic PET in the literature. Methods: Eight electronic databases were searched from 2005 until February 2010 to identify economic evaluation studies not included in previous Health Technology Assessment (HTA) reports. Only full health economic evaluations in English, French, or German were considered for inclusion. Economic evaluations were appraised using published quality criteria for assessing the quality of decision analytic models. Given the variety of methods used in the health economic evaluations, the economic evidence has been summarized in qualitative form. Results: From this new search, 14 publications were identified that met the inclusion criteria. All publications were decision analytic models and evaluated PET using Fluorodeoxyglucose F18 (FDG-PET). Eight publications were cost-effectiveness analyses; six were cost-utility analyses. The studies were from Australia, Belgium, Canada, France, Italy, Taiwan, Japan, the Netherlands, the United Kingdom, and the United States. In the base case analyses of these studies, cost-effectiveness results ranged from dominated to dominant. The methodology of the economic evaluations was of varying quality. Cost-effectiveness was primarily influenced by the cost of PET, the specificity of PET, and the risk of malignancy. Conclusions: Owing to improved care and less exposure to ineffective treatments, personalized medicine using PET may be cost-effective. However, the strongest evidence for the cost-effectiveness of PET is still in the staging of non-small cell lung cancer. Management decisions relating to the assessment of treatment response or radiotherapy treatment planning require further research to show the impact of PET on patient management and its cost-effectiveness. Because of the potential for increased patient throughput and the possible greater accuracy, the cost-effectiveness of PET/CT may be superior to that of PET. Only four studies of the cost-effectiveness of PET/CT were found in this review, and this is clearly an area for future research.
BMC Health Services Research

Langer, A.
Cost-effectiveness of diagnostic interventions: Non-small cell lung cancer.
Onkologe 16, 992-1002 (2010)
The present article is intended as an introduction to health economic evaluation as well as a review of economic evaluations of positron emission tomography (PET and PET/CT) in the diagnosis and management of non-small cell lung cancer. Furthermore, the transferability of the results of economic evaluations in other countries to the German health care context is assessed. With the help of a literature search 13 full health economic evaluations of staging (12 studies) and follow-up (1 study) of non-small cell lung cancer were identified. The primary health benefit measure was life years gained or quality-adjusted life years gained. All of these evaluations were based on modeling studies. Due to differences in assumptions and methodological heterogeneity, the incremental cost-effectiveness ratios varied widely. Because of the complexity of the diagnostic and therapeutic process, the transferability of international study results to the German situation is limited. The cost-effectiveness of PET for other management decisions in non-small cell lung cancer (e.g. radiotherapy planning) is still to be assessed.
Onkologe, Der

Upadhyay, S.; Ganguly, K.; Stöger, T.; Semmler-Behnke, M.; Takenaka, S.; Kreyling, W.G.; Pitz, M.; Reitmeir, P.; Peters, A.; Eickelberg, O.; Wichmann, H.-E.; Schulz, S.
Cardiovascular and inflammatory effects of intratracheally instilled ambient dust from Augsburg, Germany, in spontaneously hypertensive rats (SHRs).
Part. Fibre Toxicol. 7:27 (2010)
RATIONALE: Several epidemiological studies associated exposure to increased levels of particulate matter in Augsburg, Germany with cardiovascular mortality and morbidity. To elucidate the mechanisms of cardiovascular impairments we investigated the cardiopulmonary responses in spontaneously hypertensive rats (SHR), a model for human cardiovascular diseases, following intratracheal instillation of dust samples from Augsburg. METHODS: 250 µg, 500 µg and 1000 µg of fine ambient particles (aerodynamic diameter <2.5 µm, $PM_2(.)_5$-AB) collected from an urban background site in Augsburg during September and October 2006 ($PM_2(.)_5$ 18.2 µg/m³, 10,802 particles/cm3) were instilled in 12 months old SHRs to assess the inflammatory response in bronchoalveolar lavage fluid (BALF), blood, lung and heart tissues 1 and 3 days post instillation. Radio-telemetric analysis was performed to investigate the cardiovascular responses following instillation of particles at the highest dosage based on the inflammatory response observed. RESULTS: Exposure to 1000 µg of $PM_2(.)_5$-AB was associated with a delayed increase in delta mean blood pressure (ΔmBP) during 2(nd)-4(th) day after instillation (10.0 ± 4.0 vs. -3.9 ± 2.6 mmHg) and reduced heart rate (HR) on the 3rd day post instillation (325.1 ± 8.8 vs. 348.9 ± 12.5 bpm). BALF cell differential and inflammatory markers (osteopontin, interleukin-6, C-reactive protein, and macrophage inflammatory protein-2) from pulmonary and systemic level were significantly induced, mostly in a dose-dependent way. Protein analysis of various markers indicate that $PM_2(.)_5$-AB instillation results in an activation of endothelin system (endothelin1), renin-angiotensin system (angiotensin converting enzyme) and also coagulation system (tissue factor, plasminogen activator inhibitor-1) in pulmonary and cardiac tissues during the same time period when alternation in ΔmBP and HR have been detectedd. CONCLUSIONS: Our data suggests that high concentrations of $PM_2(.)_5$-AB exposure triggers low grade PM mediated inflammatory effects in the lungs but disturbs vascular homeostasis in pulmonary tissues and on a systemic level by affecting the renin angiotensin system, the endothelin system

and the coagulation cascade. These findings are indicative for promotion of endothelial dysfunction, atherosclerotic lesions, and thrombogeneis and, thus, provide plausible evidence that susceptible-predisposed individuals may develop acute cardiac events like myocardial infarction when repeatedly exposed to high pollution episodes as observed in epidemiological studies in Augsburg, Germany.
Particle and Fibre Toxicology

Stock, S.; Schmidt, H.; Büscher, G.; Gerber, A.; Drabik, A.; Graf, C.; Lüngen, M.; Stollenwerk, B.
Financial incentives in the German Statutory Health Insurance: New findings, new questions.
Health Policy 96, 51-56 (2010)
OBJECTIVES: This paper presents findings of a mandatory three-year evaluation of a prevention bonus scheme offered in the German Statutory Health Insurance (SHI). Its objective is to describe the rationale behind the programs, analyze their financial impact and discuss their implications on potentially conflicting goals on solidarity and competition. METHODS: The analysis included 70,429 insured enrolled in a prevention bonus program in a cohort study. The intervention group and their matched controls were followed for a three-year period. Matching was performed as nearest neighbor matching. The economic analysis comprised all costs relevant for Sickness Funds (SF) in the SHI and was carried out from a SHI perspective. Differences in cost trends between the intervention and the control group were examined applying the paired t-test. RESULTS: Regarding mean costs there was a significant difference between the two groups of euro177.48 (90% CI [euro149.73; euro205.24]) in favor of the intervention group. If program costs were considered cost reductions of euro100.88 (90% CI [euro73.12; euro128.63]) were obtained. CONCLUSIONS: The uptake of a prevention bonus program led to cost reductions in the intervention group compared to the control group even when program costs were considered. However, the results must be interpreted with caution as in addition to financial aspects, socio-economic and health-status, selection bias and the function and use of bonus programs as marketing tools, as well as their long-term sustainability should be considered in future assessments.
Health Policy

Dembek, C.J.; Kutscher, S.; Heltai, S.; Allgayer, S.; Biswas, P.; Ghezzi, S.; Vicenzi, E.; Hoffmann, D.; Reitmeir, P.; Tambussi, G.; Bogner, J.R.; Lusso, P.; Stellbrink, H.-J.; Santagostino, E.; Vollbrecht, T.; Goebel, F.D.; Protzer, U.; Draenert, R.; Tinelli, M.; Poli, G.; Erfle, V.; Malnati, M.; Cosma, A.
Nef-specific CD45RA+ CD8+ T cells secreting MIP-1β but not IFN-γ are associated with nonprogressive HIV-1 infection.
Aids Res. Ther. 7, 20 (2010)
BACKGROUND: Long-term survival of HIV-1 infected individuals is usually achieved by continuous administration of combination antiretroviral therapy (ART). An exception to this scenario is represented by HIV-1 infected nonprogressors (NP) which maintain relatively high circulating CD4+ T cells without clinical symptoms for several years in the absence of ART. Several lines of evidence indicate an important role of the T-cell response in the modulation of HIV-1 infection during the acute and chronic phase of the disease. RESULTS: We analyzed the functional and the differentiation phenotype of Nef- and Tat-specific CD8+ T cells in a cohort of HIV-1 infected NP in comparison to progressors, ART-treated seropositive individuals and individuals undergoing a single cycle of ART interruption. We observed that a distinctive feature of NP is the presence of Nef-specific CD45RA+ CD8+ T cells secreting MIP-1beta but not IFN-gamma. This population was present in 7 out of 11 NP. CD45RA+ IFN-gammaneg MIP-1beta+ CD8+ T cells were not detected in HIV-1 infected individuals under ART or withdrawing from ART and experiencing a rebounding viral replication. In addition, we detected Nef-specific CD45RA+ IFN-gammaneg MIP-1beta+ CD8+ T cells in only 1 out of 10 HIV-1 infected individuals with untreated progressive disease. CONCLUSION: The novel antigen-specific CD45RA+ IFN-gammaneg MIP-1beta+ CD8+ T cell population represents a new candidate marker of long-term natural control of HIV-1 disease progression and a relevant functional T-cell subset in the evaluation of the immune responses induced by candidate HIV-1 vaccines.
AIDS Research and Therapy

Meisinger, C.; Beck, J.; Heier, M.; Hörmann, A.; Kuch, B.; Sietas, G.; Koenig, W.
Myocardial infarction and incidence of type 2 diabetes mellitus. Is admission blood glucose an independent predictor for future type 2 diabetes mellitus?
Am. Heart J. 159, 258-263 (2010)
BACKGROUND: Although blood glucose levels in patients with acute myocardial infarction (AMI) are frequently elevated, studies investigating the future risk of type 2 diabetes mellitus (T2DM) in patients with AMI are scarce. We sought to investigate whether increased blood glucose levels on admission in nondiabetic patients with first AMI are predictive for future T2DM. METHODS: We used the KORA MI register database in Augsburg, Germany, and included 1,239 nondiabetic patients aged 25 to 74 years who were admitted to hospital between 1998 and 2003 with a diagnosis of a first AMI and who had survived at least 28 days. Incident cases of T2DM and the date of diagnosis were validated by hospital records or by contacting the patient's treating physician. RESULTS: A total of 108 cases of incident T2DM were registered during a mean follow-up of 4.7 years. Cox proportional hazards regression analysis was done, and admission blood glucose was divided into quartiles (Q). Compared to AMI patients with blood glucose on admission <111 mg/dL (Q1), patients with levels > or =153 mg/dL (Q4) showed an age and sex-adjusted relative risk of 2.76 (95% CI 1.61-4.75) for incident T2DM. This association was only slightly attenuated after multivariable adjustment (hazard ratio 2.59, 95% CI 1.49-4.49). CONCLUSIONS: Admission blood glucose in nondiabetic AMI patients could offer an initial screening tool during the short-term event to select those patients with high risk for future T2DM requiring a close monitoring of glucose metabolism.
American Heart Journal

Becker, C.; Leidl, R.; Stollenwerk, B.
Entscheidungsanalytische Modellierung in der ökonomischen Evaluation.
Gesundheitsökon. Qualitätsmanag. 15, 260-264 (2010)
In den letzten Jahren hat die Verwendung von entscheidungsanalytischen Modellen in der gesundheitsökonomischen Evaluation stark zugenommen. Modelle bieten eine zentrale Zugangsmethodik für Evaluationsstudien. Sie werden benötigt, wenn Daten aus klinischen Studien nicht verfügbar sind oder nicht direkt auf die aktuelle Forschungsfrage zutreffen. Für die

entscheidungsanalytische Modellierung steht eine Reihe von Modellierungsansätzen zur Verfügung. Dieser Artikel stellt mit Entscheidungsbäumen und Markov-Modellen die häufigsten Modelltypen dar und geht auf weitere - wie die diskrete Ereignissimulation - ein. Die Ergebnisse von Modellen sind mit Unsicherheit behaftet, welche mit dem Einsatz von Sensitivitätsanalysen abgeschätzt werden kann. Die verschiedenen Formen der Unsicherheit in Modellen und die Grundprinzipien einer Bearbeitung mit der Sensitivitätsanalyse werden präsentiert. Abschließend wird die Qualität von Modellierungen thematisiert, die von der verwendeten Struktur, den einfließenden Daten sowie der internen und externen Konsistenz abhängt. Zu qualitätssichernden Maßnahmen gehören z. B. das Einhalten von Richtlinien oder die Durchführung von Validierungen. Aktueller Forschungsbedarf besteht in der Weiterentwicklung von Modellierungsmethoden und von Richtlinien zur Beurteilung der Modellqualität.
Gesundheitsökonomie & Qualitätsmanagement

Rathmann, W.; Kowall, B.; Heier, M.; Herder, C.; Holle, R.; Thorand, B.; Strassburger, K.; Peters, A.; Wichmann, H.-E.; Giani, G.; Meisinger, C.
Prediction models for incident Type 2 diabetes mellitus in the older population: KORA S4/F4 cohort study.
Diabetic Med. 27, 1116-1123 (2010)
BACKGROUND: The aim was to derive Type 2 diabetes prediction models for the older population and to check to what degree addition of 2-h glucose measurements (oral glucose tolerance test) and biomarkers improves the predictive power of risk scores which are based on non-biochemical as well as conventional clinical parameters. METHODS: Oral glucose tolerance tests were carried out in a population-based sample of 1353 subjects, aged 55-74 years (62% response) in Augsburg (Southern Germany) from 1999 to 2001. The cohort was reinvestigated in 2006-2008. Of those individuals without diabetes at baseline, 887 (74%) participated in the follow-up. Ninety-three (10.5%) validated diabetes cases occurred during the follow-up. In logistic regression analyses for model 1, variables were selected from personal characteristics and additional variables were selected from routinely measurable blood parameters (model 2) and from 2-h glucose, adiponectin, insulin and homeostasis model assessment of insulin resistance (HOMA-IR) (model 3). RESULTS: Age, sex, BMI, parental diabetes, smoking and hypertension were selected for model 1. Model 2 additionally included fasting glucose, HbA(1c) and uric acid. The same variables plus 2-h glucose were selected for model 3. The area under the receiver operating characteristic curve significantly increased from 0.763 (model 1) to 0.844 (model 2) and 0.886 (model 3) (P<0.01). Biomarkers such as adiponectin and insulin did not improve the predictive abilities of models 2 and 3. Cross-validation and bootstrap-corrected model performance indicated high internal validity. CONCLUSIONS: This longitudinal study in an older population provides models to predict the future risk of Type 2 diabetes. The OGTT, but not biomarkers, improved discrimination of incident diabetes.
Diabetic Medicine

Lederbogen, F.; Kühner, C.; Kirschbaum, C.; Meisinger, C.; Lammich, J.; Holle, R.; Krumm, B.; von Lengerke, T.; Wichmann, H.-E.; Deuschle, M.; Ladwig, K.-H.
Salivary cortisol in a middle-aged community sample: Results from 990 men and women of the KORA-F3 Augsburg study.
Eur. J. Endocrinol. 163, 443-451 (2010)
OBJECTIVE: Analysis of salivary cortisol concentrations and derived indices is increasingly used in clinical and scientific medicine. However, comprehensive data on these parameters in the general population are scarce. The aim of this study was to evaluate the concentrations of salivary cortisol in a large middle-aged community sample and to identify major factors associated with altered hormone levels. DESIGN: We conducted a cross-sectional study within the Cooperative Health Research in the Region of Augsburg (KORA)-F3 study. A total of 1484 participants aged 50-69 years (52% women) had agreed to provide four saliva samples during a regular weekday. METHODS: We measured salivary cortisol concentrations at wake-up (F0), (1/2) h (F(1/2)), 8 h (F8), and 14 h (F14) after waking. We calculated cortisol awakening response (CAR), slope, and area under the curve (AUC(G)) of the circadian cortisol secretion. Sociodemographic and clinical characteristics were evaluated by interview and questionnaires, sampling conditions by protocol. In total, 1208 participants returned saliva samples, exclusion criteria left 990 subjects for final analyses. RESULTS: Salivary cortisol levels were (means+/-s.d.) F0=13.7+/-7.6, F(1/2)=20.5+/-9.8, F8=5.4+/-3.3, and F14=2.0+/-1.8 nmol/l. Earlier sampling times were associated with higher CAR and smaller slope. Cortisol secretion was also influenced by gender and smoking habits. Higher perceived social support was associated with lower AUC(G) and smaller slope. CONCLUSIONS: We provide data on salivary cortisol concentrations in a large middle-aged community sample. Gender, sampling time, smoking habits, and perceived social support appeared as determinants of cortisol secretion.
European Journal of Endocrinology

Kowall, B.; Rathmann, W.; Strassburger, K.; Heier, M.; Holle, R.; Thorand, B.; Giani, G.; Peters, A.; Meisinger, C.
Association of passive and active smoking with incident type 2 diabetes mellitus in the elderly population: The KORA S4/F4 cohort study.
Eur. J. Epidemiol. 25, 393-402 (2010)
Active smoking is a risk factor for type 2 diabetes (T2DM), but it is unclear whether exposure to environmental tobacco smoke (ETS) is also associated with T2DM. The effect of passive and active smoking on the 7-year T2DM incidence was investigated in a population-based cohort in Southern Germany (KORA S4/F4; 1,223 subjects aged 55-74 years at baseline in 1999-2001, 887 subjects at follow-up). Incident diabetes was identified by oral glucose tolerance tests or by validated physician diagnoses. Among never smokers, subjects exposed to ETS had an increased diabetes risk in the total sample (odds ratio (OR) = 2.5; 95% confidence interval (CI): 1.1, 5.6) and in a subgroup of subjects having prediabetes at baseline (OR = 4.4; 95% CI: 1.5, 13.4) after adjusting for age, sex, parental diabetes, socioeconomic status, and lifestyle factors. Active smoking also had a statistically significant effect on diabetes incidence in the total sample (OR = 2.8; 95% CI: 1.3, 6.1) and in prediabetic subjects (OR = 7.8; 95% CI: 2.4, 25.7). Additional adjustment for components of the metabolic syndrome including waist circumference did not attenuate any of these associations. This study provides evidence that both passive and active smoking is associated with T2DM.
European Journal of Epidemiology

Buck, A.K.; Herrmann, K.; Stargardt, T.; Dechow, T.; Krause, B.J.; Schreyögg, J.
Economic evaluation of PET and PET/CT in oncology: Evidence and methodologic approaches.
J. Nucl. Med. 51, 401-412 (2010)
PET and PET/CT have changed the diagnostic algorithm in oncology. Health care systems worldwide have recently approved reimbursement for PET and PET/CT for staging of non-small cell lung cancer and differential diagnosis of solitary pulmonary nodules because PET and PET/CT have been found to be cost-effective for those uses. Additional indications that are covered by health care systems in the United States and several European countries include staging of gastrointestinal tract cancers, breast cancer, malignant lymphoma, melanoma, and head and neck cancers. Regarding these indications, diagnostic effectiveness and superiority over conventional imaging modalities have been shown, whereas cost-effectiveness has been demonstrated only in part. This article reports on the current knowledge of economic evaluations of PET and PET/CT in oncologic applications. Because more economic evaluations are needed for several clinical indications, we also report on the methodologies for conducting economic evaluations of diagnostic tests and suggest an approach toward the implementation of these tests in future clinical studies.
Journal of Nuclear Medicine

Mielck, A.
Konzepte sozialer Gerechtigkeit im Kontext nachhaltiger Gesundheitsförderung.
In: Nachhaltige Gesundheitsförderung - Gesundheit gemeinsam gestalten. Bd. 4. Frankfurt: Mabuse-Verl., 2010. 110-124
In der letzten Zeit häufen sich in Deutschland nicht nur die Armutsberichte, sondern auch die Berichte über den Zusammenhang zwischen der sozialen Ungleichheit einerseits und dem Gesundheitszustand andererseits. In einer kaum mehr überschaubaren Vielzahl von Arbeiten ist immer wieder gezeigt worden, dass Personen mit niedrigem sozialen Status zumeist einen besonders schlechten Gesundheitszustand aufweisen, dass sie kränker sind und früher sterben als Personen mit höherem sozialen Status (Mielck 2005, Richter/Hurrelmann 2009). In der wissenschaftlichen Diskussion wird dieser Zusammenhang zwischen Sozialstatus und Morbidität bzw. Mortalität als "gesundheitliche Ungleichheit" bezeichnet.
von Lengerke, T.
Inanspruchnahme gesundheitsbezogener Versorgung. Forschungsstand in Deutschland und Implikationen für Prävention.
In: Hurrelmann, K.*; Pfaff, H.*; Razum, O.*; Schaeffer, D.* [Eds.]: Adipositas Public Health. Weinheim [u.a.]: Juventa, 2010. 65-81
Kirchberger, I.; Meisinger, C.; Seidl, H.; Wende, R.; Kuch, B.; Holle, R.
Nurse-based case management for aged patients with myocardial infarction: Study protocol of a randomized controlled trial.
BMC Geriatr. 10:29 (2010)
BACKGROUND: Aged patients with coronary heart disease (CHD) have a high prevalence of co-morbidity associated with poor quality of life, high health care costs, and increased risk for adverse outcomes. These patients are often lacking an optimal home care which may result in subsequent readmissions. However, a specific case management programme for elderly patients with myocardial infarction (MI) is not yet available. The objective of this trial is to examine the effectiveness of a nurse-based case management in patients aged 65 years and older discharged after treatment of an acute MI in hospital. The programme is expected to influence patient readmission, mortality and quality of life, and thus to reduce health care costs compared with usual care. In this paper the study protocol is described. METHODS/DESIGN: The KORINNA (Koronarinfarkt Nachbehandlung im Alter) study is designed as a single-center randomized two-armed parallel group trial. KORINNA is conducted in the framework of KORA (Cooperative Health Research in the Region of Augsburg). Patients assigned to the intervention group receive a nurse-based follow-up for one year including home visits and telephone calls. Key elements of the intervention are to detect problems or risks, to give advice regarding a broad range of aspects of disease management and to refer to the general practitioner, if necessary. The control group receives usual care. Twelve months after the index hospitalization all patients are re-assessed. The study has started in September 2008. According to sample size estimation a total number of 338 patients will be recruited. The primary endpoint of the study is time to first readmission to hospital or out of hospital death. Secondary endpoints are functional status, participation, quality of life, compliance, and cost-effectiveness of the intervention. For the economic evaluation cost data is retrospectively assessed by the patients. The incremental cost-effectiveness ratio (ICER) will be calculated. DISCUSSION: The KORINNA study will contribute to the evidence regarding the effectiveness of case management programmes in aged people with MI. The results can be an important basis for clinicians, administrators and health policy makers to decide on the provision of high-quality care to older patients with CHD.
BMC Geriatrics

Mielck, A.; Maier, W.; Perna, L.; Bolte, G.; Koller, D.
Gesundheitszustand von Kindern in München: Soziale und räumliche Unterschiede.
In:. München: Referat für Gesundheit und Umwelt der Landeshauptstadt München, 2010. 66 S. (Stadt-Gesundheit, Gesundheitsberichterstattung der Landeshauptstadt München)
Gesundheitsrelevante Verhaltensweisen und viele Risikofaktoren für schwer wiegende Erkrankungen im Erwachsenenalter bilden sich bereits im frühen Lebensalter. Aktuelle Studien belegen die Zunahme gesundheitsschädigender Verhaltensweisen und gesundheitlicher Beeinträchtigungen bei Kindern und Jugendlichen. Dabei sind deutliche Zusammenhänge mit sozialen Einflüssen belegt: Ein niedriger sozialer Status (gemessen z. B. an Bildung und Einkommen der Eltern) birgt höhere gesundheitliche Risiken. Neben individuellen Indikatoren wie Schulbildung, Einkommen, Migrationshintergrund und anderen kommt den regionalen Einflüssen eine besondere Bedeutung zu: das heißt, das Wohnen in einer sozial benachteiligten Region ist ein gesundheitlicher Risikofaktor an sich und mit großen gesundheitlichen Belastungen für alle Bewohnerinnen und Bewohner verbunden. Der Frage der regionalen Unterschiede unter der Fragestellung der 'Umweltgerechtigkeit sowie der sozialen Einflussgrößen auf die Gesundheit hat sich die Gesundheitsberichterstattung der LHM bereits in mehreren Publikationen gewidmet (siehe www.muenchen.de/gbe). Das Wohnen in einer Region, in der sich Umweltbelastungen, Infrastrukturdefizite und soziale Benachteiligungen summieren, ist mit gesundheitlichen Risiken für alle Bewohnerinnen und Bewohner verbunden. Diese

Schwerpunktsetzung wird auch von der im Herbst 2009 im Rahmen der „Perspektive München" beschlossenen - Leitlinie Gesundheit" aufgegriffen, die neben gesundheitlicher Chancengleichheit die Schaffung einer gesundheitsförderlichen Umwelt als zentrales Handlungsfeld benennt. Der Öffentliche Gesundheitsdienst der Landeshauptstadt stellt sich seit Jahren dieser Herausforderung. Bereits 2001 fand eine Gesundheitskonferenz zum Thema - Armut und Gesundheit - Chancengleichheit für Kinder und Jugendliche in München" statt, auf der dien sogenannte - Münchner Erklärung" verabschiedet wurde und Handlungsempfehlungen zur Verringerung der gesundheitlichen Ungleichheit vorgeschlagen wurden. 2005 beschloss der Stadtrat der LH München das maßgebliche Ziel, das heute nach wie vor verfolgt wird: - Das Referat für Gesundheit und Umwelt erreicht verstärkt Kinder und Jugendliche mit einer Häufung von gesundheitlichen Benachteiligungen durch esundheitsförderung, Gesundheitsberatung und Präventionsprogramme". Der Öffentliche Gesundheitsdienst der LH München fokussiert und entwickelt daher seine Angebote vor allem im Hinblick auf sozial benachteiligte Kinder und Jugendliche weiter, da diese, insbesondere wenn sie von Armut betroffen sind, mit höheren gesundheitlichen Risiken leben. In diesem Zusammenhang ist besonders der Hausbesuchsdienst der Kinderkrankenschwestern für Familien mit Säuglingen und Kleinkindern hervorzuheben. Dieses niederschwellige aufsuchende Beratungsangebot kommt besonders den benachteiligten oder gefährdeten Kindern aus Familien mit und ohne Migrationshintergrund zu Gute. Der Hausbesuchsdienst steht grundsätzlich allen Münchner Familien mit Kindern bis 3 Jahre offen. Bevorzugt werden jedoch Familien in schwierigen Lebenslagen aufgesucht, z.B. in Asylbewerberheimen oder in solchen Straßenzügen, in denen Familien mit erhöhtem Beratungsbedarf zu vermuten sind. Die Beratung durch die Kinderkrankenschwester dient sowohl der gesundheitlichen Prävention als auch dem präventiven Kinderschutz. Im Rahmen eines Leitprojektes zur Leitlinie Kinder- und Familienpolitik der LHM wurde eine Evaluation des Hausbesuchsdienstes durchgeführt. Eine ausführliche Darstellung der Evaluationsergebnisse aus Elternbefragung, Befragung der Kinderkrankenschwestern, Hausbesuchsprotokollen und Befragung einiger Kooperationspartner wurde im März 2010 dem Stadtrat bekannt gegeben. Weitere wesentliche Ansätze sind das Münchner Modell der Frühen Hilfen sowie die Ausweitung der Hausbesuche auf Kinder von 3-6 Jahren ohne Kindertagesbetreuung, beide vom Stadtrat beschlossen im Dezember 2007. Auch im schulärztlichen Bereich sind benachteiligte Kinder und Jugendliche unsere vorrangige Zielgruppe, in Förderschulen, Übergangsklassen und einigen Hauptschulen konnten in den letzten Jahren schwerpunktmäßig schulärztliche Untersuchungen, Sprechstunden und Gesundheitsunterricht angeboten werden, die jedoch den Bedarf bei weitem nicht decken. Im Rahmen der bereits erwähnten - Leitlinie Gesundheit" hat der Stadtrat 2009 ein Leitprojekt beschlossen, mit dem die Schulärztinnen des RGU gemeinsam mit der Münchner Ärzteschaft neue Wege für die Gesundheitsvorsorge in den Hauptschulen beschreiten wollen. Bei der Entwicklung gesundheitsfördernder und präventiver Ansätze profitieren wir von den langjährigen praktischen Erfahrungen der städtischen Gesundheitsberatungsstelle Hasenbergl, die seit vielen Jahren niederschwellig, wohnortnah und unbürokratisch Leistungen für die Gesundheitsvorsorge benachteiligter Kinder, Jugendlicher und Familien erbringt. Den stadträumlichen Unterschieden gesundheitlicher Chancengleichheit wird vor Allem im Projekt „Gesundheit in der Sozialen Stadt" Rechnung getragen, das ebenfalls ein Leitprojekt im Rahmen der - Leitlinie Gesundheit" ist Der vorliegende Bericht basiert auf den Daten des Schuleingangsscreenings unserer Kinderkrankenschwestern, an denen jedes Jahr bis 12.000 Kinder teilnehmen sowie auf der Auswertung der Fragebögen, die im Rahmen der Gesundheitsmonitoring-Einheiten des Bayrischen Landesamtes für Gesundheit und Lebensmittelsicherheit von den Eltern der Einschulkinder einiger Schulsprengel ausgefüllt wurden. Wir freuen uns ganz besonders, dass wir für die Auswertung der Daten den bundesweit anerkannten Experten auf diesem Gebiet, Herrn Dr. Andreas Mielck vom Helmholtz Zentrum München gewinnen konnten. Ihm und seinen Ko-Autorinnen und Ko-Autoren möchten wir an dieser Stelle ausdrücklich für die geleistete Arbeit danken. Insgesamt zeigt die vorliegende Auswertung auch für München deutliche Zusammenhänge zwischen Sozialstatus, einzelnen Parametern der Gesundheit und regionalen Gegebenheiten, teilweise unterschiedlich ausgeprägt bei Jungen und Mädchen. Eine kurze Zusammenfassung der Ergebnisse findet sich in Kapitel D. Ich bin sicher, mit dem vorliegenden Bericht der Münchner Gesundheitsberichterstattung allen im Münchner Gesundheitswesen Tätigen sowie der interessierten Öffentlichkeit weitere interessante und nützliche Informationen und Denkanstöße für ihre Arbeit zur Verfügung stellen zu können. Unser Referat wird auch weiterhin der Thematik der gesundheitlichen Chancengleichheit besonders für Kinder große Bedeutung beimessen und die eingeschlagenen Wege zu deren Verbesserung stärken, ausbauen und gezielt fördern.

John, J.

Economic perspectives on pediatric obesity: Impact on health care expenditures and cost-effectiveness of preventive interventions.

In: Koletzko, B.*; Koletzko, S.*; Ruemmele, F.* [Eds.]: Drivers of innovation in pediatric nutrition (Nestle Nutr. Workshop Ser. Pediatr. Program). Basel: Karger, 2010. 111-124 (Nestlé Nutrition Institute Workshop Series: Pediatric Program; 66)

This chapter surveys two segments of the economic literature on pediatric obesity: first, research regarding the impact of childhood obesity on health care expenditure, and second, research evaluating the cost-effectiveness of programs to prevent pediatric obesity. Evidence in support of the hypothesis that obese children and adolescents have higher health care costs than their otherwise similar healthy-weight peers has been found for female adolescents. Studies trying to calculate the complete lifetime health care costs attributable to childhood obesity are missing. Only a small number of studies assessing the cost-effectiveness of preventive obesity interventions among children have been published until now. The results call for the inclusion of nutrition behavior as an intervention target. There is some evidence that childhood obesity prevention might be successful in combining health gains with cost savings. However, it is not possible to rank the interventions according to their cost-effectiveness or to assess the generalizability of their results. Cost-effectiveness increasingly will be a major consideration in public reimbursement decisions. Therefore, evaluation research has to pay more attention to the economic aspects of new health technologies. Without providing good value for money, those technologies probably will not turn from

inventions to innovations in health care. Moreover, future research should address various methodological and conceptual challenges and limitations which economic evaluations of preventive interventions into childhood obesity are faced with.

Huber, J.; Mielck, A.

Morbidität und Gesundheitsversorgung bei GKV- und PKV-Versicherten: Forschungsstand empirischer Studien.

Bundesgesundheitsbl.-Gesund. 53, 925-938 (2010)

In Deutschland wurde bisher nur selten explizit untersucht, ob es zwischen GKV- und PKV-Versicherten neben den sozioökonomischen Unterschieden auch Unterschiede in der Morbidität und gesundheitlichen Versorgung gibt. Zudem sind die hierzu vorhandenen Forschungsergebnisse sehr verstreut, und ein zusammenfassender Überblick liegt bisher noch nicht vor. Die folgende Arbeit will dazu beitragen, diese Lücke zu schließen. Zugleich sollen Empfehlungen für die künftige wissenschaftliche Analyse dieser Unterschiede zwischen GKV- und PKV-Versicherten abgeleitet werden.

Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz

Haag, C.; Marx, P.; Ruckdäschel, S.; Mehlig, H.; Gräßel, E.; Wunder, S.; Holle, R.; Lauterberg, J.; Sitte, M.

Initiative Demenzversorgung in der Allgemeinmedizin (IDA) - Modellprojekt zur besseren Versorgung Demenzkranker und ihrer pflegenden Angehörigen in Mittelfranken.

In: Amelung, V.E.* [Eds.]: Innovative Konzepte im Versorgungsmanagement von ZNS-Patienten. Berlin: Mwv Medizinisch Wissenschaftliche Verl.-Ges., 2010. 101-111

Wolfenstetter, S.B.; Wenig, C.M.

Economic evaluation and transferability of physical activity programmes in primary prevention: A systematic review.

Int. J. Environ. Res. Public Health 7, 1622-1648 (2010)

This systematic review aims to assess the characteristics of, and the clinical and economic evidence provided by, economic evaluations of primary preventive physical exercise interventions, and to analyse their transferability to Germany using recommended checklists. Fifteen economic evaluations from seven different countries met eligibility criteria, with seven of the fifteen providing high economic evidence in the special country context. Most of the identified studies conclude that the investigated intervention provide good value for money compared with alternatives. However, this review shows a high variability of the costing methods between the studies, which limits comparability, generalisability and transferability of the results.

International Journal of Environmental Research and Public Health

Schnell-Inderst, P.; Schwarzer, R.; Göhler, A.; Grandi, N.; Grabein, K.; Stollenwerk, B.; Manne, J.; Klauss, V.; Siebert, U.; Wasem, J.

Prognostic value, clinical effectiveness, and cost-effectiveness of high-sensitivity C-reactive protein as a marker for major cardiac events in asymptomatic individuals: A health technology assessment report.

Int. J. Technol. Assess. Health Care 26, 30-39 (2010)

OBJECTIVES: The aim of this study was to compare the predictive value, clinical effectiveness, and cost-effectiveness of high-sensitivity C-reactive protein (hs-CRP)-screening in addition to traditional risk factor screening in apparently healthy persons as a means of preventing coronary artery disease. METHODS AND RESULTS: The systematic review was performed according to internationally recognized methods. Seven studies on risk prediction, one clinical decision-analytic modeling study, and three decision-analytic cost-effectiveness studies were included. The adjusted relative risk of high hs-CRP-level ranged from 0.7 to 2.47 ($p < .05$ in four of seven studies). Adding hs-CRP to the prediction models increased the areas under the curve by 0.00 to 0.027. Based on the clinical decision analysis, both individuals with elevated hs-CRP-levels and those with hyperlipidemia have a similar gain in life expectancy following statin therapy. One high-quality economic modeling study suggests favorable incremental cost-effectiveness ratios for persons with elevated hs-CRP and higher risk. However, many model parameters were based on limited evidence. CONCLUSIONS: Adding hs-CRP to traditional risk factors improves risk prediction, but the clinical relevance and cost-effectiveness of this improvement remain unclear.

International Journal of Technology Assessment in Health Care

Menn, P.; Weber, N.; Holle, R.

Health-related quality of life in patients with severe COPD hospitalized for exacerbations - comparing EQ-5D, SF-12 and SGRQ.

Health Qual. Life Outcomes 8:39 (2010)

BACKGROUND: The aim of this study was to measure HrQoL during acute exacerbations of COPD using generic and disease-specific instruments, and to assess completeness, proportion with best or worst health state, sensitivity to change and discriminative ability for each instrument. METHODS: EQ-5D, SF-12 and SGRQ were obtained from COPD patients with GOLD stage III and IV hospitalized for an acute exacerbation both at admission and discharge. To assess the instruments' properties, utility values were calculated for EQ-5D and SF-12, and a total score was derived from the SGRQ. RESULTS: Mean utilities ranged from 0.54 (SF-12, stage IV) to 0.62 (EQ-5D, stage III) at admission, and from 0.58 (SF-12, stage IV) to 0.84 (EQ-5D, stage III) at discharge. Completeness was best for EQ-5D and SGRQ, while no utility value for the SF-12 could be calculated for more than 30%. For SGRQ subscales, the minimal score occurred in up to 11% at admission, while full health was observed for the EQ-5D at discharge in 13%. Sensitivity to change was generally good, whereas discrimination between COPD stages was low for the EQ-5D. CONCLUSIONS: Acute exacerbations seriously impair health status and quality of life. The EQ-5D is generally suitable to measure HrQoL in exacerbations of severe COPD, although the high proportion of patients reporting full health at discharge poses a problem. The main issue with the SF-12 is the high proportion of missing values in a self-assessed setting. Properties of the SGRQ were satisfactory. However, since no utility values can be derived from this disease-specific instrument, it is not suitable for cost-utility analyses in health-economic evaluations.

Health and Quality of Life Outcomes

Perna, L.; Bolte, G.; Mayrhofer, H.; Spies, G.; Mielck, A.

The impact of the social environment on children's mental health in a prosperous city: An analysis with data from the city of Munich.

BMC Public Health 10:199 (2010)

BACKGROUND: Children with a low socioeconomic position are more affected by mental difficulties as compared to children with a higher socioeconomic position. This paper explores whether

this socioeconomic pattern persists in the prosperous German city of Munich which features high quality of life and coverage of children mental health specialists that lies well above the national average and is among the highest in Europe. METHODS: 1,265 parents of preschool children participated in a cross-sectional health survey. They were given a self-administered questionnaire (including socioeconomic variables) and the 'Strengths and Difficulties Questionnaire (SDQ)', a well-established method to identify mental difficulties among children and adolescents. Prevalence estimates for the 'SDQ-Total Difficulties Score' were calculated, with a special focus on differences by parental (resp. household) socioeconomic position. The association between parental education, household income, single parenthood, nationality, and parental working status on one hand, and their children's mental health on the other, was explored using multivariable logistic regression models. The coverage of mental health specialists per 100,000 children aged 14 or younger in the city of Munich was also calculated. RESULTS: In Munich, the distribution of mental health difficulties among children follows the same socioeconomic pattern as described previously at the national level, but the overall prevalence is about 30% lower. Comparing different indicators of socioeconomic position, low parental education and household income are the strongest independent variables associated with mental difficulties among children (OR = 2.7; CI = 1.6 - 4.4 and OR = 2.8; CI = 1.4 - 5.6, respectively). CONCLUSIONS: Socioeconomic differences in the prevalence of childhood mental difficulties are very stable. Even in a city such as Munich, which is characterized by high quality of life, high availability of mental health specialists, and low overall prevalence of these mental difficulties, they are about as pronounced as in Germany as a whole. It can be concluded that the effect of several characteristics of socioeconomic position 'overrules' the effect of a health promoting regional environment.
BMC Public Health

Genz, J.; Haastert, B.; Meyer, G.; Steckelberg, A.; Müller, H.; Verheyen, F.; Cole, D.; Rathmann, W.; Nowotny, B.; Roden, M.; Giani., G.; Mielck, A.; Ohmann, C.; Icks, A.
Blood glucose testing and primary prevention of diabetes mellitus type 2 - evaluation of the effect of evidence based patient information.
BMC Public Health 10:15 (2010)
BACKGROUND: Evidence-based patient information (EBPI) has been recognised as important tool for informed choice in particular in the matter of preventive options. An objective, on the best scientific evidence-based consumer information about subthreshold elevated blood glucose levels (impaired fasting glucose and impaired glucose tolerance) and primary prevention of diabetes, is not available yet. Thus we developed a web-based EBPI and aim to evaluate its effects on informed decision making in people 50 years or older. METHODS/DESIGN: We conduct a web-based randomised-controlled trial to evaluate the effect of information about elevated blood glucose levels and diabetes primary prevention on five specific outcomes: (i) knowledge of elevated blood glucose level-related issues (primary outcome); (ii) attitudes to a metabolic testing; (iii) intention to undergo a metabolic testing; (iv) decision conflict; (v) satisfaction with the information. The intervention group receives a specially developed EBPI about subthreshold elevated blood glucose levels and diabetes primary prevention, the control group information about this topic, available in the internet.The study population consists of people between 50 and 69 years of age without known diabetes. Participants will be recruited via the internet page of the cooperating health insurance company, Techniker Krankenkasse (TK), and the internet page of the German Diabetes Centre. Outcomes will be measured through online questionnaires. We expect better informed participants in the intervention group. DISCUSSION: The design of this study may be a prototype for other web-based prevention information and their evaluation. TRIAL REGISTRATION: Current Controlled Trial: ISRCTN22060616.
BMC Public Health

Kunz, S.
Psychometric properties of the EQ-5D in a study of people with mild to moderate dementia.
Qual. Life Res. 19, 425-434 (2010)
PURPOSE: Due to their cognitive impairment, the health-related quality of life (HRQoL) of patients with dementia is often rated by proxies. This study aims to analyse the psychometric properties of the EQ-5D applied to patients with mild to moderate dementia and their family caregivers. METHODS: Three hundred and ninety patients and their caregivers were asked to assess the patients' HRQoL using the EQ-5D. The German population-based time trade-off values were used to calculate utility weights. Acceptance, discriminative ability, construct validity, inter-rater agreement and responsiveness were tested. Factors that could have an impact on inter-rater agreement were analysed using a multivariate regression. RESULTS: Five per cent of patients did not fill out the EQ-5D. The response rate of caregivers and of patients with mild dementia was higher than that of patients with moderate dementia. There were no floor or ceiling effects. The test results of the caregivers concerning construct validity and responsiveness were better than those of the patients. The inter-rater reliability was not satisfactory either on the dimension level or on the utility score level. Caregivers gave the patients' HRQoL significantly lower ratings than did the patients themselves. Better abilities of the patient to perform activities of daily living and a lower subjective burden of the caregiver were associated with a higher inter-rater agreement. CONCLUSIONS: The study showed that the EQ-5D is especially applicable to patients with mild dementia and their caregivers as proxies. However, there are important differences between patient and proxy ratings, even in cases of mild dementia, at the dimension level as well as utility score level, which should be considered in the interpretation of quality of life scores
Quality of Life Research

Reincke, M.; Meisinger, C.; Holle, R.; Quinkler, M.; Hahner, S.; Beuschlein, F.; Bidlingmaier, M.; Seissler, J.; Endres, S.
Is primary aldosteronism associated with diabetes mellitus? Results of the German Conn's Registry.
Horm. Metab. Res. 42, 435-439 (2010)
Aldosterone excess in the context of primary aldosteronism (PA) has been associated with impaired glucose tolerance and diabetes mellitus. We retrospectively assessed the prevalence of diabetes mellitus in patients from the German Conn's Register and compared the data with those from hypertensive subjects of a population-based survey. In a case-control study, we have compared 638 patients with PA from the German Conn's registry who were treated in 6 German centers with 897 hypertensive control subjects from the population-based F3 survey of the Cooperative Health Research in the Region of Augsburg

(KORA). The samples were matched for age, sex, and blood pressure in a 1:1 ratio. Risk factors associated with the presence of diabetes mellitus were calculated in 638 patients with PA and 897 hypertensive controls. In the case control study, the diabetes prevalence was calculated in 338 cases and controls. In patients with primary aldosteronism, age, BMI, and a higher number of antihypertensive drugs (lowest tertile vs. highest tertile) were variables associated with diabetes mellitus. In contrast, serum potassium and plasma aldosterone concentrations were not associated with higher diabetes prevalence, whereas diastolic blood pressure was inversely associated with diabetes mellitus. Diabetes mellitus was more prevalent in patients with PA than in 338 matched controls (23 vs. 10% in controls). Our data for the German population show that diabetes mellitus is more prevalent in patients with primary aldosteronism than in hypertensive controls.
Hormone and Metabolic Research

Koller, D.; Spies, G.; Bayerl, B.; Mielck, A.
Soziale Unterschiede bei Wohnzufriedenheit und gesundheitlichen Risiken.
Präv. Gesundheitsf. 5, 129-135 (2010)
Hintergrund: Bei Gesundheitsförderung und Prävention in sozial benachteiligten Wohngebieten muss beachtet werden, dass auch innerhalb dieser Wohngebiete soziale Unterschiede vorhanden sein können. Bisher liegen dazu jedoch kaum empirische Studien vor. Material und Methoden: Grundlage ist eine im Jahr 2004 durchgeführte Bewohnerbefragung bei 668 Erwachsenen im Münchner APUG-Projekt ("Aktionsprogramms für Umwelt und Gesundheit"). Der Sozialstatus wird mit 4 Variablen erfasst: Schulabschluss, Pro-Kopf-Einkommen, Arbeitslosigkeit, Art der Wohnung. Abhängige Variablen sind die Zufriedenheit mit der Wohnsituation und das Gesundheitsverhalten. Ergebnisse: Innerhalb dieses Gebiets gibt es große soziale Unterschiede. Die Bewohnerinnen und Bewohner mit niedrigem sozialem Status sind besonders unzufrieden mit der Wohnsituation, sie treiben weniger Sport und sie verbringen mehr Zeit vor dem Fernseher. Schlussfolgerungen: Die "soziale Binnendifferenzierung" in dieser APUG-Region ist groß. Vor der Implementierung eines Interventionsprogramms muss daher gezielt gefragt werden, welche Gruppe von Bewohnerinnen und Bewohnern welche Maßnahmen benötigt.
Prävention und Gesundheitsförderung

Tamayo, T.; Icks, A.; Holle, R.; Berger, K.; Meisinger, C.; Moebus, S.; Greiser, K.H.; Mielck, A.; Neuhauser, H.; Schipf, S.; Rathmann, W.
Der Zusammenschluss von populationsbasierten Studien ermöglicht regionale Vergleiche zum Diabetes mellitus in Deutschland.
Med. Welt 61, 94-96 (2010)
Für Planungen im Gesundheitswesen zum Typ-2-Diabetes sind Informationen über die Prävalenz und Inzidenz, regionale und kleinräumige Unterschiede, die Verteilung von Risikofaktoren und Kostenschätzungen unerlässlich. Bislang liegen diese Informationen nur in begrenztem Umfang und insbesondere nicht auf kleinräumiger Ebene für Deutschland vor. Im Rahmen des BMBF-Kompetenznetzes Diabetes haben sich sechs populationsbasierte Kohortenstudien zu einer Meta-Analyse zusammengeschlossen, um über das „Poolen" von individuellen Daten aus verschiedenen Regionen Deutschlands eine Datengrundlage zu schaffen, die nun erstmals die Bearbeitung epidemiologischer Themenfelder zum Typ-2-Diabetes auf regionaler und kleinräumiger Ebene ermöglicht.
Medizinische Welt, Die

von Lengerke, T.; John, J.; Mielck, A.
Excess direct medical costs of severe obesity by socioeconomic status in German adults.
GMS Psycho-Social-Medicine 7:Doc01 (2010)
Objective: Excess direct medical costs of severe obesity are by far higher than of moderate obesity. At the same time, severely obese adults with low socioeconomic status (SES) may be expected to have higher excess costs than those with higher SES, e.g. due to more comorbidities. This study compares excess costs of severe obesity among German adults across different SES groups.Methods: In a subsample (N=947) of the KORA-Survey S4 1999/2001 (a cross-sectional health survey in the Augsburg region, Germany; age group: 25-74 years), visits to physicians, inpatient days in hospital, and received and purchased medication were assessed via computer-assisted telephone interviews (CATI) over half a year. Body mass index (BMI in kg/m(2)) was measured anthropometrically. SES was determined via reports of education, income, and occupational status from computer-assisted personal interviews (CAPI) (used both as single indicators, and as indexed by the Helmert algorithm); due to small subsample sizes all were median-split. Data of respondents in normal weight (18.5 /= 35) range were analysed by generalized linear models with mixed poisson-gamma (Tweedie) distributions. Physician visits and inpatient days were valuated as recommended by the Working Group Methods in Health Economic Evaluation (AG MEG), and drugs were valuated by actual costs. Sex, age, kind of sickness fund (statutory/private) and place of residence (urban/rural) were adjusted for, and comorbidities were considered by the Physical Functional Comorbidity Index (PFCI).Results: Excess costs of severe obesity were higher in respondents with high SES, regardless of the SES indicator used. For instance, annual excess costs were almost three times higher in those with an above-median SES-Index as compared with those with a median or lower SES-Index (plus euro 2,966 vs. plus euro 1,012; contrast significant at p<.001). Mediation of excess costs of severe obesity by physical comorbidities pertained to the low SES-Index and the low occupational status groups: differences in costs between severe obesity and normal weight were still positive, but statistically insignificant, in the lower status groups after adjusting for the PFCI, but still positive and significant given higher SES. For example, severe obesity's excess costs were euro 2,406 after PFCI-adjustment in the high SES-Index group (p<.001), but euro 539 in the lower status group (p=.17). At the same time, physical comorbidities as defined by the PCFI increased with BMI and decreased with SES, however the factors BMI and SES did not significantly interact in this context.Conclusions: To our knowledge, this is the first study to show in Germany that excess direct medical costs of severe obesity are not distributed equitably across different SES groups, do not reflect comorbidity status, and are significantly higher in those with high SES than in those with lower SES. Thus, allocation of health care resources spent on severely obese adults seems to be in need of readjustment towards an equitable utilization across all socioeconomic groups.
GMS Psycho-Social Medicine

Welte, R.; Leidl, R.; Greiner, W.; Postma, M.
Health economics of infectious diseases.
In: Krämer, A.*; Kretzschmar, M.*; Krickeberg, K.* [Eds.]: Modern Infectious Disease Epidemiology : Concepts, Methods, Mathematical Models, and Public Health. New York, NY: Springer, 2010. 249-275 (Statistics for Biology and Health)
Due to technical innovations and demographic changes, many industrialized countries are facing problems in financing health-care costs. One way to guide decision maker in the allocation of their limited health-care budget is the use of economic evaluation . The economic evaluation of health technologies is a special discipline of health economics, which compares the technical efficiency of technologies in the health-care sector. The term technology covers everything from drugs to medical equipment to the design of intervention programs. Technical efficiency is achieved if with a minimum input (of resources) a given output is produced or if with a specific input a maximum of output (e.g., life years) is produced. Hence, technical efficiency considers both effectiveness and resource utilization. Only an effective technology can be efficient. Typically, in economic evaluations the incremental cost-effectiveness ratio (ICER) of a technology is estimated. The ICER is a measure for the technical efficiency of a technology and can be expressed, for example, as € 30,000 per life year gained (LYG) or US $ 15,000 per quality-adjusted life year (QALY) gained, reflecting the net costs (costs minus savings) of gaining one life year or QALY, respectively.
Perna, L.; Thien-Seitz, U.; Ladwig, K.-H.; Meisinger, C.; Mielck, A.
Socio-economic differences in life expectancy among persons with diabetes mellitus or myocardial infarction: Results from the German MONICA/KORA study.
BMC Public Health 10:135 (2010)
BACKGROUND: Differences in life expectancy (LE) between social groups in a specific country are a fundamental measure of health inequalities within that country. Constant monitoring of these differences provides important information on the population's general health. The purpose of the present study is to explore and quantify the socio-economic differences in LE in Germany, focussing on a topic rarely assessed in other studies, the dependency of these LE differences on the presence of myocardial infarction or diabetes mellitus. METHODS: The dataset consists of 13,427 participants (6,725 men, 6,702 women) aged 25-74 years, recruited in the region of Augsburg in Germany through three independent cross-sectional representative surveys conducted in 1984/85, 1989/90, 1994/95, with a mortality follow up in 1998 and 2002. We use a parametric model for the survival function based on the Weibull distribution, in which the hazard function is described in terms of two parameters. We estimate these parameters with a maximum likelihood method that takes into account censoring and data truncation. RESULTS: The difference in LE between the lowest and the highest socio-economic group is estimated to be 3.79 years for men and 4.10 years for women. Diabetes mellitus reduces LE of men from the upper three income quartiles by 4.88 years, and LE of men belonging to the lowest income quartile by 7.97 years. For women, the corresponding figures are 5.79 and 5.72 years. Myocardial infarction reduces LE of men and women from the upper three income quartiles by 3.65 and 3.75 years, respectively, and LE of men and women belonging to the lowest income quartile by 5.11 and 10.95 years, respectively. CONCLUSIONS: This study shows that in Germany the differences in LE by socio-economic status are comparable to those found in other European countries, and that these differences seem to increase when diabetes mellitus or myocardial infarction is present. The statistical method used allows estimates of LE with relatively small datasets.
BMC Public Health

von Lengerke, T.; Mielck, A.
Unzufriedenheit mit dem eigenen Körpergewicht nach Einkommensarmut: Eine Mehrebenenanalyse in der Region Augsburg.
In: Berth, H.* [Eds.]: Psychologie und Medizin - Traumpaar oder Vernunftehe?. Lengerich: Pabst Science Publishers, 2010. 69-80
John, J.; Wenig, C.M.; Wolfenstetter, S.B.
Recent economic findings on childhood obesity: Cost-of-illness and cost-effectiveness of interventions.
Curr. Opin. Clin. Nutr. Metab. Care 13, 305-313 (2010)
PURPOSE OF REVIEW: The rising prevalence of obesity amongst children and adolescents is a growing public health burden. This study reviews recent studies, first, examining the economic consequences of childhood obesity, and, second, evaluating the cost-effectiveness of programs to prevent and to manage childhood obesity. RECENT FINDINGS: Evidence of the impact of childhood obesity on healthcare costs for children is ambiguous. Although one study did not find increasing costs with increasing body mass index (BMI), in some other studies this effect was visible--partly only in subgroups. The evaluation studies show that in order to reach acceptable cost-effectiveness values, interventions cannot focus solely on physical activity, but must include nutrition as an intervention target. Moreover, there is some evidence supporting the expectation that childhood obesity prevention may be successful in combining health gains with net cost savings. SUMMARY: There is a need to estimate the costs of childhood obesity as an essential part of identifying cost-effective treatment and prevention measures. Given the diversity and shortcomings of the methodological approaches chosen in the existing evaluation studies, there is an urgent need both for more standardized economic evaluations of those measures and more methodological research.
Current Opinion in Clinical Nutrition & Metabolic Care

Hauke, F.; Brückner, U.
First approaches to the monetary impact of environmental health disturbances in Germany.
Health Policy 94, 34-44 (2010)
OBJECTIVES: This article aims to describe essential conditions and starting-points for the monetary evaluation of environmentally attributable diseases. Furthermore, a cost calculation within a scenario analysis is conducted for Germany. METHODS: To calculate the costs of environmental health effects we chose a disease-specific perspective. The national statistics of the Federal Statistical Office and the World Health Report burden of disease estimates were used to identify the most important disease categories for Germany. Based on an extensive literature research in computerized databases and the publications of national and international institutions, available costs of illness studies for Germany as well as environmental attributable fractions (EAFs) were identified. Based on these data environmental health costs were calculated with a top-down approach. RESULTS: Direct and indirect environmental costs of illness add up to 15-62 billion euro(2006) per year depending on the specific scenario. From our results a tentative scheme is deduced of how the monetary environmental burden of specific

diseases is composed and how it can be assigned to major environmental exposures and economic sectors which can be used in setting intervention priorities and evaluating intervention efficiency. CONCLUSION: Within this article, we were able to calculate environmental health costs for Germany based on available, easy to access data and deduce implications for environmental policy decision-making. However, there are restrictions in data quality, as the aetiology of some diseases with respect to environmental impacts is not very well documented and data has not been collected particularly for Germany.
Health Policy

Stark, R.G.; Reitmeir, P.; Leidl, R.; König, H.-H.
Validity, reliability, and responsiveness of the EQ-5D in inflammatory bowel disease in Germany.
Inflamm. Bowel Dis. 16, 42-51 (2010)
The EuroQol (EQ)-5D questionnaire is a generic instrument measuring health-related quality of life. Its validity, reliability, and responsiveness were assessed in a large sample of Crohn's disease (CD) and ulcerative colitis (UC) patients. METHODS: The EQ-5D was completed initially (270 CD and 232 UC subjects) and after 4 weeks (447 subjects) with a transition question rating health change. Responsiveness of EQ visual analog scale (EQ-VAS) and the United Kingdom (UK-index) and German EQ-5D index (EQ-index) scores to reported changes in health was evaluated by standardized response means (SRM) and meaningful differences (MDs). RESULTS: EQ-VAS and EQ-index scores correlated well with disease activity indices and differed significantly between active disease and remission groups. All scores were reliable in test-retest (ICC: EQ-VAS: 0.89; UK-index: 0.76; German EQ-index: 0.72). According to SRM, EQ-VAS was more responsive for deterioration in health than for improvement in health and was more responsive than index scores. Index scores were most responsive for deterioration in health in subjects in remission and for improved health in subjects with active disease. MDs for improved health (EQ-VAS: 10.9; UK EQ-index: 0.076; German EQ-index: 0.050) and deteriorated health (EQ-VAS: -14.4; UK EQ-index: -0.109; German EQ-index: -0.067) were significant, but MD of EQ-VAS also differed significantly according to disease activity. CONCLUSIONS: The EQ-5D generates valid, reliable, and responsive preference-based evaluations of health in CD and UC. EQ-VAS scores were more responsive than EQ-5D index scores. Thus, small health differences that are important from the patient's perspective may not be reflected in the EQ-index.
Inflammatory Bowel Diseases

Baumeister, S.E.; Böger, C.A.; Krämer, B.K.; Döring, A.; Eheberg, D.; Fischer, B.; John, J.H.; Koenig, W.; Meisinger, C.
Effect of chronic kidney disease and comorbid conditions on health care costs: A 10-year observational study in a general population.
Am. J. Nephrol. 31, 222-229 (2010)
Chronic kidney disease (CKD) is common, but the longitudinal effects of CKD and associated comorbidities on health care costs in the general population are unknown. Methods: Population-based cohort study of 2,988 subjects in Germany, aged 25-74 years at baseline, who participated both in the baseline and 10-year follow-up examination (1994/95-2004/05). Presence of CKD was based on serum creatinine and defined as an estimated glomerular filtration rate of <60 ml/min/1.73 m(2). Self-reported health services utilization was used to estimate costs. Results: Health care costs at baseline and follow-up were higher for subjects with CKD. Controlling for socio-economics, lifestyle factors and comorbid conditions, subjects with baseline CKD, in comparison to those without, exhibited 65% higher total costs 10 years after baseline examination, corresponding to a difference in adjusted costs of EUR 743. Incident CKD was related to 38% higher total costs. Costs for inpatient treatment and drug costs were the major costs components, while CKD revealed no effect on outpatient costs. The effect of CKD was strongly modified by angina, myocardial infarction, diabetes, and anemia. Conclusions: The direct effect of CKD on costs is modified by comorbid conditions. Therefore, early treatment of CKD and its precipitous factors may save future health care costs.
American Journal of Nephrology

Mielck, A.; Vogelmann, M.; Schweikert, B.; Leidl, R.
Gesundheitszustand bei Erwachsenen in Deutschland: Ergebnisse einer repräsentativen Befragung mit dem EuroQol 5D (EQ-5D).
Gesundheitswesen 72, 476-486 (2010)
OBJECTIVE OF THE STUDY: Over the past few years, the discussion on HEALTH-RELATED QUALITY OF LIFE (HRQL) has increased considerably in Germany as well. HRQL can be assessed by different dimensions of health, and it can be summarised by a single numerical value. This study intends to describe the HRQL of German adults based on individual valuations, to compare the results with those of an earlier study, to investigate the impact of using valuations based on given health states, and as an example of use to analyse socioeconomic differences using the EQ-5D. METHODS: The analyses are based on a representative survey in Germany, conducted by the Wort und Bild Verlag in 2006. HRQL has been assessed by the EuroQol 5D (EQ-5D). In the descriptive part, health was assessed by five descriptive questions. Next, valuations of overall health were elicited from survey participants using a visual analogue scale (VAS) and, alternatively, taken from a different sample based on the time trade off (TTO) method. Five independent variables were included in the analysis: age, sex, educational level, per capita income, employment status. The results are compared with previous German evidence from the ESEMeD study. RESULTS: Data were retrieved from 1 966 persons (aged 20 years or above); the response rate was 73%. In the descriptive part of the EQ-5D, the prevalence of SOME PROBLEMS was especially high in the dimension PAIN/DISCOMFORT (31.9%). In contrast, the prevalence of EXTREME PROBLEMS was very low in all five dimensions. The mean VAS value was 79.2. Considering the five dimensions, the VAS values and the TTO score, HRQL was mostly higher for men than for women, and mostly higher for the upper educational groups (as compared with the lower educational groups). Very similar associations were found when the independent variables are mutually controlled for, in logistic regressions (dependent variables: five dimensions) as well as in linear regressions (dependent variables: VAS value or TTO score). The linear regressions also showed that HRQL increases with increasing per capita income. DISCUSSION: The EQ-5D provides a simple instrument for assessing HRQL. It can well detect health inequalities, and the results can be replicated in different studies. More research is needed on the techniques to valuate HRQL in population studies. The EQ-5D provides a tool

to assess the HRQL of the German population. New reference figures have been presented for this, and it has been shown how health economic tools and research on health inequalities can be integrated.
Gesundheitswesen, Das

Schreyögg, J.; Grabka, M.M.
Copayments for ambulatory care in Germany: A natural experiment using a difference-in-difference approach.
Eur. J. Health Econ. 11, 331-341 (2010)
In response to increasing health expenditures and a high number of physician visits, the German government introduced a copayment for ambulatory care in 2004 for individuals with statutory health insurance (SHI). Because persons with private insurance were exempt from the copayments, this health-care reform can be regarded as a natural experiment. We used a difference-in-difference approach to examine whether the new copayment effectively reduced the overall demand for physician visits and to explore whether it acted as a deterrent to vulnerable groups, such as those with low income or chronic conditions. We found that there was no significant reduction in the number of physician visits among SHI members compared to our control group. At the same time, we did not observe a deterrent effect among vulnerable individuals. Thus, the copayment has failed to reduce the demand for physician visits. It is likely that this result is due to the design of the copayment scheme, as the copayment is low and is paid only for the first physician visit per quarter.
The European journal of health economics

Grosse, S.D.; Rogowski, W.H.; Friedman Ross, L.; Cornel, M.C.; Dondorp, W.; Khoury, M.J.
Population screening for genetic disorders in the 21st century: Evidence, economics, and ethics.
Public Health Genomics 13, 106-15 (2010)
Proposals for population screening for genetic diseases require careful scrutiny by decision makers because of the potential for harms and the need to demonstrate benefits commensurate with the opportunity cost of resources expended. METHODS: We review current evidence-based processes used in the United States, the United Kingdom, and the Netherlands to assess genetic screening programs, including newborn screening programs, carrier screening, and organized cascade testing of relatives of patients with genetic syndromes. In particular, we address critical evidentiary, economic, and ethical issues that arise in the appraisal of screening tests offered to the population. Specific case studies include newborn screening for congenital adrenal hyperplasia and cystic fibrosis and adult screening for hereditary hemochromatosis. RESULTS: Organizations and countries often reach different conclusions about the suitability of screening tests for implementation on a population basis. Deciding when and how to introduce pilot screening programs is challenging. In certain cases, e.g., hereditary hemochromatosis, a consensus does not support general screening although cascade screening may be cost-effective. CONCLUSION: Genetic screening policies have often been determined by technological capability, advocacy, and medical opinion rather than through a rigorous evidence-based review process. Decision making should take into account principles of ethics and opportunity costs.
Public Health Genomics

Stollenwerk, B.; Stock, S.; Siebert, U.; Lauterbach, K.W.; Holle, R.
Uncertainty assessment of input parameters for economic evaluation: Gauss's error propagation, an alternative to established methods.
Med. Decis. Making 30, 304-313 (2010)
In decision modeling for health economic evaluation, bootstrapping and the Cholesky decomposition method are frequently used to assess parameter uncertainty and to support probabilistic sensitivity analysis. An alternative, Gauss's error propagation law, is rarely known but may be useful in some settings. Bootstrapping, the Cholesky decomposition method, and the error propagation law were compared regarding standard deviation estimates of a hypothetic parameter, which was derived from a regression model fitted to simulated data. Furthermore, to demonstrate its value, the error propagation law was applied to German administrative claims data. All 3 methods yielded almost identical estimates of the standard deviation of the target parameter. The error propagation law was much faster than the other 2 alternatives. Furthermore, it succeeded the claims data example, a case in which the established methods failed. In conclusion, the error propagation law is a useful extension of parameter uncertainty assessment.
Medical Decision Making

Maier, W.; Mielck, A.
Environmental justice: Stand der empirischen Analyse und Ableitung von methodischen Empfehlungen.
Präv. Gesundheitsf. 5, 115-128 (2010)
Hintergrund Environmental justice (bzw. Umweltgerechtigkeit) thematisiert die sozial und räumlich ungleiche Verteilung von Umweltbelastungen, wie Luftverschmutzung oder Lärm, und deren Relevanz für Public Health. In Deutschland wird nach wie vor nur wenig über diesen Zusammenhang diskutiert, der jedoch für das Verständnis der sozialen Verteilung von Gesundheit von großer Bedeutung ist. Wichtig ist jetzt v. a. die Erstellung von methodisch gut abgesicherten empirischen Ergebnissen, denn nur auf dieser Grundlage lässt sich der Interventionsbedarf präzise definieren (Daten für Taten). Material und Methoden Systematische Übersichtsarbeiten über den Stand der empirischen Forschung sind bisher kaum vorhanden, sie bilden jedoch die Basis für die notwendige methodische und inhaltliche Weiterentwicklung dieses Forschungsthemas. Zur Erstellung eines systematischen Reviews wurde Primärliteratur systematisch und nach beschriebenen Methoden identifiziert und selektiert. Die ausgewählten Publikationen wurden kritisch bewertet, die relevanten Ergebnisse extrahiert und in Tabellen zusammengefasst. Ergebnisse Hier werden die Ergebnisse dieses systematischen Review vorgestellt, der 29 empirische Studien aus Westeuropa und Nordamerika beinhaltet. Aus inhaltlicher Sicht zeigen die meisten Studien eine erhöhte Belastung durch Luftverschmutzung und Lärm bei den unteren Statusgruppen. Aus methodischer Sicht wird die Aussagekraft der Studien jedoch eingeschränkt durch die Verwendung von sehr verschiedenen und mehr oder weniger adäquaten Studiendesigns und Analyseverfahren. Bewertung Aus dieser Erkenntnis heraus lassen sich hier auch einige Empfehlungen für weitere empirische Analysen ableiten. Ein vergleichbar umfangreicher Überblick über den Stand der empirischen Forschung zum Thema environmental justice ist u. W. im westeuropäischen Raum bisher noch nicht vorgelegt worden.
Prävention und Gesundheitsförderung

2009
Lehrke, M.; Becker, A.; Greif, M.; Stark, R.G.; Laubender, R.P.; von Ziegler, F.; Lebherz, C.; Tittus, J.; Reiser, M.; Becker, C.; Göke, B.; Leber, A.W.; Parhofer, K.G.; Broedl, U.C.
Chemerin is associated with markers of inflammation and components of the metabolic syndrome but does not predict coronary atherosclerosis.
Eur. J. Endocrinol. 161, 339-344 (2009)
Objectives: Chemerin is a recently discovered adipokine that regulates adipocyte differentiation and modulates chemotaxis and activation of dendritic cells and macrophages. Given the convergence of adipocyte and macrophage function, chemerin may provide an interesting link between obesity, inflammation and atherosclerosis in humans. We sought to examine the relationship of 1) chemerin and markers of inflammation, 2) chemerin and components of the metabolic syndrome, and 3) chemerin and coronary atherosclerotic plaque burden and morphology. Design: Serum chemerin levels were determined in 303 patients with stable typical or atypical chest pain who underwent dual-source multi-slice CT-angiography to exclude coronary artery stenosis. Atherosclerotic plaques were classified as calcified, mixed or non-calcified. Results: Chemerin levels were highly correlated with hsCRP (r=0.44, p<0.0001), IL-6 (r=0.18, p=0.002), TNF-{alpha} (r=0.24, p<0.0001), resistin (r=0.28, p<0.0001) and leptin (r=0.36, p<0.0001) concentrations. Furthermore, chemerin was associated with components of the metabolic syndrome including BMI (r=0.23, p=0.0002), triglycerides (r=0.29, p<0.0001), HDL-C (r=-0.18, p=0.003) and hypertension (p<0.0001). In bivariate analysis, chemerin levels weakly correlated with coronary plaque burden (r=0.16, p=0.006) and the number of non-calcified plaques (r=0.14, p=0.02). These associations, however, were lost after adjusting for established cardiovascular risk factors (OR 1.17, 95%CI 0.97 to 1.41, p=0.11 for coronary plaque burden; OR 1.06, 95%CI 0.96 to 1.17, p=0.22 for non-calcified plaques). Conclusions: Chemerin is strongly associated with markers of inflammation and components of the metabolic syndrome. Chemerin, however, does not predict coronary atherosclerosis.
European Journal of Endocrinology

Langer, A.; John, J.
Neugeborenenscreening im Spannungsfeld der Gesundheitsökonomie.
Mon.schr. Kinderheilkd. 157, 1230-1236 (2009)
Der vorliegende Beitrag gibt eine Einführung in die gesundheitsökonomische Evaluation sowie eine Übersicht zu ökonomischen Evaluationsstudien zum Neugeborenenscreening auf Medium-Chain-Acyl-CoA-Dehydrogenase-Störung (MCADD) mittels Tandemmassenspektrometrie (TMS). Mit Hilfe einer systematischen Literaturrecherche wurden 10 vollständige ökonomische Evaluationen identifiziert. Der primäre Outcomeparameter waren gewonnene Lebensjahre oder gewonnene qualitätsadjustierte Lebensjahre. Bei allen Evaluationen handelte es sich um modellbasierte Untersuchungen. Aufgrund der methodischen Heterogenität der ökonomischen Evaluationen zeigten die inkrementellen Kosten-Effektivitäts-Relationen eine breite Streuung. Diese war darüber hinaus auch auf Unterschiede in verschiedenen, den Evaluationen zugrunde liegenden Annahmen zurückzuführen. Im Vergleich zu konventionellen Screeningmethoden oder einer Praxis ohne Screening liegen die Kosten beim Neugeborenenscreenings mittels TMS in einem vielfach als akzeptabel eingeschätzten Verhältnis zu den Gesundheitsgewinnen. Um eine fundierte Aussage zum deutschen Kontext treffen zu können, wäre jedoch eine entsprechend zugeschnittene Modellierung notwendig.
Monatsschrift Kinderheilkunde

Rogowski, W.H.; Landauer, M.; John, J.
Decision-analytical modelling of costs per QALY in the context of the German Social Law.
Gesundheitswesen 71, 739-750 (2009)
PURPOSE: In 2007, a legal reform introduced formal health economic evaluation for selected reimbursement decisions by the statutory health insurance in Germany. The methods of evaluation are currently under discussion. This study assesses whether an approach based on decision-analytic cost per QALY modelling fits with the legal requirements set by Book Five of the German Social Code (SGB V). METHODS: It is based on a review of legal documents and the relevant literature. RESULTS: Key specifications for economic evaluation in Germany are the differential interpretations of "benefit" in the relevant legislation as well as the requirement that the methods follow "international standards of evidence-based medicine and health economics" (section sign section sign 35b, 139a SGB V). In German reimbursement decision practice, new interventions have undergone an assessment of (1) benefit, (2) necessity and (3) cost-effectiveness (prior to the legal reform only exclusion of dominated alternatives). While the establishment of benefit in step (1) is preferably based on clinical trials in current practice, also two different interpretations of "benefit" in steps (1) and (3) would be in accord with SGB V. Methods for establishing QALYs measure and evaluate different dimensions of health benefit based on transparent and theoretically justified methods. They also capture the dimensions specifically stated by section sign 35b SGB V, e. g., extension of life or improvement in quality of life. Compared to ad-hoc synthesis of the different measures of patient benefit from clinical trials, this is more consistent with the standards of evidence-based medicine and health economics. Decision analytical modelling provides a practical and theoretically sound method to integrate the condition-specific evidence for estimating the costs and benefits associated with a medical treatment in health care practice. CONCLUSIONS: Both the establishment of health effects in terms of QALYs and decision-analytical models for evidence synthesis meet the requirements of SGB V. Further methodological issues that need to be addressed include guidelines for QALY measures, and the choice of analytical perspective that fits best with German law. This notwithstanding, it remains an open question how the appropriateness of a cost-benefit ratio should be appraised and what role cost-effectiveness should play in health care decision making, compared with other principles potentially relevant to the decision.
Gesundheitswesen, Das

Eder-Debye, R.; Mielck, A.; Schunk, M.
Münchner Modell der Frühen Hilfe für psychosozial hochbelastete Familien - Evaluation und neue Formen der Kooperation.
In: Gerechtigkeit schafft mehr Gesundheit für alle (14. bundesweiter Kongress Armut und Gesundheit 5./6. Dezember 2008). Berlin: Gesundheit Berlin, 2009. 1-6
von Lengerke, T.

Psychische Determinanten gesundheitsrelevanten Verhaltens: Verhaltensspezifische Kernkonstrukte und sozialepidemiologische Forschungsperspektiven.
Hallesche Beitr. Gesundh.- u. Pflegewiss. 8, 3-39 (2009)
Vor dem Hintergund der verhaltensepidemiologischen Fragestellung, wie gesundheitsrelevante Verhaltensweisen entstehen und aufrechterhalten werden, gibt der vorliegenede Beitrag einen Überblick über die aus gesundheitspsychologischer Perspektive zentralen psychischen Determinanten gesundheitsrelevanter Verhaltensweisen auf der Mikroebene handelnder Individuen. Es handelt sich dabei um die verhaltensspezifischen Kernkonstrukte Risikowahrnehmungen, Konsequenz- und Selbstwirksamkeitserwartungen, Ziel- und Ausführungsintentionen sowie Verhaltensstadien und Gewohnheitsstärken. Die Verhaltensbereiche, für die Skalen zur Erfassung dieser Konstrukte beispielhaft vorgestellt werden, sind Raucherentwöhnung, Alkoholkonsum, körperliche Bewegung, Ernährung sowie die Inanspruchnahme von Früherkennungsuntersuchunge. Abschließend werden zentrale sozialepidemiologische Forschungsperspektiven bzgl. Der Rolle der genannten psychischen Konstrukte für die Erklärung sozioökonomisch bzw. sozial bedingter Ungleichheiten in gesundheitsrelevanten Verhaltensweisen skizziert. Diese beziehen sich vor allem auf die Analyse mediierender und moderierender Mechanismen sowie konzeptuell auf die "Sozialisierung" psychischer Verhaltensdeterminanten (entweder als Modellierung überindividueller Größen oder mittels der Berücksichtigung verhaltensrelevanter Aspekte der sozialen und /oder physischen Umwelt bei der Formulierung individueller, selbstbezogener Konstrukte). Praxisbezogen könnten damit durch Bereitstellung einer psycho-sozial-verhaltensepidemiologischen Datenbasis wichtige Erkenntnisse für die Prävention und Therapie von Erkrankungen durch die Entwicklung und Evaluation von Progammen zur Förderung gesunden Handeln und Verhaltens produziert werden.
Hallesche Beiträge zu den Gesundheits- und Pflegewissenschaften

Marrett, E.; Stargardt, T.; Mavros, P.; Alexander, C.M.
Patient-reported outcomes in a survey of patients treated with oral antihyperglycaemic medications: Associations with hypoglycaemia and weight gain.
Diabetes Obes. Metab. 11, 1138-1144 (2009)
Aim To examine the association between medication side-effects (SEs) and patient-reported outcomes (PROs) among patients with type 2 diabetes treated with oral antihyperglycaemic agents (OAHAs). Methods A total of 1984 participants responded to an internet-based survey in the United States. Data were collected on hypoglycaemia 6 months and weight gain 12 months prior to the survey. Health-related quality of life (HRQoL) was measured using the EuroQol-5D (EQ-5D). Also administered were the Treatment Satisfaction Questionnaire for Medication v.1.4 (TSQM) and the Hypoglycaemia Fear Survey II (HFS). Results Symptoms of hypoglycaemia were reported by 62.9% of participants, and 36.9% reported weight gain. For those reporting hypoglycaemia, mean scores were lower for TSQM and EQ-5D and higher for HFS when compared with those with no symptoms (TSQM: 69.7 vs. 75.1; EQ-5D: 0.78 vs. 0.86; HFS: 17.5 vs. 6.2; all $p < 0.0001$). The same remained true when accounting for symptom severity, where severity was monotonically related with PRO scores (all $p < 0.0001$). Similarly, reported weight gain was associated with lower treatment satisfaction (69.0 vs. 73.3) and HRQoL (0.77 vs. 0.83), and increased fear of hypoglycaemia (15.7 vs. 11.8) (all $p < 0.0001$). In mixed linear regression analysis, the associations between medication SEs and PROs remained significant after adjusting for patient and disease characteristics. Conclusions Among patients with type 2 diabetes treated with OAHAs, self-reported hypoglycaemia and weight gain were associated with decreased treatment satisfaction and HRQoL. In addition, the presence of these SEs was associated with increased fear of hypoglycaemia.
Diabetes, Obesity and Metabolism

Stargardt, T.; Gonder-Frederick, L.; Krobot, K.J.; Alexander, C.M.
Fear of hypoglycaemia: Defining a minimum clinically important difference in patients with type 2 diabetes.
Health Qual. Life Outcomes 7:91 (2009)
BACKGROUND: To explore the concept of the Minimum Clinically Important Difference (MID) of the Worry Scale of the Hypoglycaemia Fear Survey (HFS-II) and to quantify the clinical importance of different types of patient-reported hypoglycaemia. METHODS: An observational study was conducted in Germany with 392 patients with type 2 diabetes mellitus treated with combinations of oral anti-hyperglycaemic agents. Patients completed the HFS-II, the Treatment Satisfaction Questionnaire for Medication (TSQM), and reported on severity of hypoglycaemia. Distribution- and anchor-based methods were used to determine MID. In turn, MID was used to determine if hypoglycaemia with or without need for assistance was clinically meaningful compared to having had no hypoglycaemia. RESULTS: 112 patients (28.6%) reported hypoglycaemic episodes, with 15 patients (3.8%) reporting episodes that required assistance from others. Distribution- and anchor-based methods resulted in MID between 2.0 and 5.8 and 3.6 and 3.9 for the HFS-II, respectively. Patients who reported hypoglycaemia with (21.6) and without (12.1) need for assistance scored higher on the HFS-II (range 0 to 72) than patients who did not report hypoglycaemia (6.0). CONCLUSION: We provide MID for HFS-II. Our findings indicate that the differences between having reported no hypoglycaemia, hypoglycaemia without need for assistance, and hypoglycaemia with need for assistance appear to be clinically important in patients with type 2 diabetes mellitus treated with oral anti-hyperglycaemic agents.
Health and Quality of Life Outcomes

Stollenwerk, B.; Gerber, A.; Lauterbach, K.W.; Siebert, U.
The german coronary artery disease risk screening model: Development, validation, and application of a decision-analytic model for coronary artery disease prevention with statins.
Med. Decis. Making 29, 619-633 (2009)
Coronary artery disease (CAD) is a major cause of death in industrial countries, leading to high health-related costs and decreased quality of life. OBJECTIVE: To develop and validate a decision-analytic model for CAD risk screening in Germany (German Coronary Artery Disease Screening Model). DESIGN: . Markov model. Target POPULATION: Age- and gender-specific cohorts of the German population. Data Sources. Mortality rates posted by the German Federal Statistical Office, the German Health Survey, social health insurance institutions, the MONICA Augsburg study, and the literature. Time Horizon. Lifetime. Interventions. CAD risk screening for high-risk individuals using Framingham risk equation and use of statins as the primary

preventive measure, compared with a setting without screening. Outcome MEASURES: Life-years (LY) gained, quality-adjusted life-years (QALYs) gained. RESULTS: The model-based CAD incidence corresponds well with empirical data from the MONICA Augsburg study. Health outcomes depend on the screening threshold (cutoff value of Framingham 10-year risk) and on the age and gender of the cohort screened (0.03 to 0.26 LYs and 0.06 to 0.42 QALYs gained per person screened in cohorts of 50- and 60-year-old men and women, respectively). CONCLUSIONS: The model provides a valid tool for evaluating the long-term effectiveness of CAD risk screening in Germany. Using statins as a primary prevention intervention for CAD in high-risk individuals identified by screening could improve the long-term health of the German population.
Medical Decision Making

Stollenwerk, B.; Brunner, H.
Weiterführende Methoden.
In: Lauterbach, K.W.*; Stock, S.*; Brunner, H.* [Eds.]: Gesundheitsökonomie: Lehrbuch für Mediziner und andere Gesundheitsberufe. 2. Auflage. Bern: Huber, 2009. 315-336
Mielck, A.
Umwelt-Gerechtigkeit: Plädoyer für die Weiterentwicklung der empirischen Methoden und Ergebnisse aus der Münchner APUG-Region.
In: Hornberg, C.*; Pauli, A.* [Eds.]: Umweltgerechtigkeit - die soziale Verteilung von gesundheitsrelevanten Umweltbelastungen. Bielefeld: Universität Bielefeld, 2009. 99-110
Neubauer, S.; Holle, R.; Menn, P.; Grässel, E.
A valid instrument for measuring informal care time for people with dementia.
Int. J. Geriatr. Psychiatry 24, 275-282 (2009)
Objective An economic evaluation of dementia-related interventions from a societal perspective should take account of informal caregiving. We assessed informal caregiving time and report our findings on the validity and stability of our results. Methods Within the German IDA study ('Dementia Care Initiative in Primary Practice'), informal care time for people with dementia living at home is assessed. We applied a German adaptation of the Resource Utilization in Dementia (RUD) questions on informal care, which distinguishes three categories of informal care activities: Activities of Daily Living (ADL), Instrumental ADL, (IADL), and supervision. In contrast to the original version, we included the time of all informal caregivers who are involved in caring for the patient. The questionnaire was completed as a computer-assisted telephone interview at baseline and after 1 year. To test the plausibility of the questionnaire, we proposed seven hypotheses about the reported informal care time. Results Nearly all results confirmed our hypotheses. Informal care time as well as changes over tithe correlated with the physical and mental health status of the patient. Considering the time of other informal caregivers led to slightly higher correlations (not significant). The results indicate that interviewees seem to underestimate particularly the time of supervision of other informal caregivers. Conclusion In sum, the instrument gives plausible results and is suited for measuring informal care time, as well as changes over time. if it is not possible to directly interview each caregiver involved, it is of great importance to identify and interview the primary informal caregiver in order to prevent an underestimation of total informal care time.
International Journal of Geriatric Psychiatry

Schmidt, C.O.; Schweikert, B.; Wenig, C.M.; Schmidt, U.; Gockel, U.; Freynhagen, R.; Tölle, T.R.; Baron, R.; Kohlmann, T.
Modelling the prevalence and cost of back pain with neuropathic components in the general population.
Eur. J. Pain 13, 1030-1035 (2009)
Although there is increasing knowledge of the prevalence of neuropathic pain, little has been done to isolate the cost of neuropathic pain, especially with reference to the frequent complaint of back pain. AIMS: To estimate the prevalence of neuropathic components in back pain and associated costs. METHODS: We used available epidemiological data to model the prevalence of neuropathic back pain in the general adult population, combining three studies: painDETECT 1, painDETECT 2, and the German back pain research network (GBPRN) study, representing a total of 21,047 subjects. The painDETECT screening questionnaire was used in the former two surveys to assess neuropathic pain components. Costing data were obtained from 1718 participants in the GBPRN survey. RESULTS: According to our model, approximately 4% of the general adult population experienced back pain with a neuropathic component. Owing to the greater severity of neuropathic pain, its costs were found to be disproportionately high: among patients with persistent back pain, typical costs associated with a person suffering neuropathic back pain were higher than those of an average back pain patient, and as much as 67% higher than those of a patient with nociceptive back pain only. Approximately, 16% of the total costs associated with back pain were attributable to pain with a neuropathic component. CONCLUSIONS: Back pain with neuropathic components is likely to affect a relevant proportion of the general adult population and cause a disproportionately high share of back pain-related costs.
European Journal of Pain

Kuch, B.; von Scheidt, W.; Ehmann, A.; Kling, B.; Greschik, C.; Hoermann, A.; Meisinger, C.
Extent of the decrease of 28-day case fatality of hospitalized patients with acute myocardial infarction over 22 years: Epidemiological versus clinical view: The MONICA/KORA Augsburg infarction registry.
Circ.-Cardiovasc. Qual. Outcomes 2, 313-319 (2009)
BACKGROUND: No data exist regarding time trends of 28-day case fatality (CF) of patients with presumed acute myocardial infarction (AMI) using epidemiological criteria, clinical criteria, and AMI classification after validation of presumed in-hospital AMI-related deaths (gold-standard criteria). METHODS AND RESULTS: From 1985 to 2004, we prospectively examined all 9210 AMI patients consecutively hospitalized in a large teaching hospital by using a broad epidemiological AMI definition (WHO-MONICA). Twenty-eight-day CF decreased significantly from 32% in 1985-1986 to 18% in 2003-2004, mostly because of a reduction in early deaths (<24 hours). When applying the clinical AMI definition, most of the early deaths were not counted as AMI related. A retrospective validation process from a sample of all early deceased patients by the epidemiological AMI definition (388/2076) and a prospective validation of the complete cohort in 2005-2006 revealed that only about 50% of early deaths are reclassified as a real fatal AMI using newer criteria resulting in a 28-day CF of 23% in 1985-1986 and 11% in 2005-2006. The difference between the AMI 28-day CF by applying gold-standard criteria and the clinical AMI 28-day CF (18% in 1985-

1986 and 7% in 2005-2006) has decreased during recent years. CONCLUSIONS: The application of broad epidemiological criteria for AMI overestimates 28-day CF by almost 2-fold compared with gold-standard criteria (after validation of early deaths) and almost 3-fold compared to the clinical definition. The growing similarity in 28-day CF between the clinically based definition and the gold-standard criteria implies that recent clinical-based registries may represent a realistic picture of trends regarding in-hospital AMI mortality.
Circulation: Cardiovascular Quality and Outcomes

Schreyögg, J.; Bäumler, M.; Busse, R.
Balancing adoption and affordability of medical devices in Europe.
Health Policy 92, 218-224 (2009)
Dramatic increases in health expenditures have led to a substantial number of regulatory interventions in the markets for devices over the last years. However, little attention has been paid thus far to the regulation of medical devices and its effects. This article explores the policies pursued by European countries to find the right balance between improving access to new medical devices and restricting market forces to contain costs and ensure affordability. We outline the medical device policies of the four European countries with the largest expenditures on devices: Germany, France, Italy, and the UK. Subsequently, we discuss how these policies attempt to balance technological adoption and affordability by illustrating two case studies from Italy and Germany. We find that reference prices, if defined as maximum reimbursement levels, can help to achieve balance, because they are supposed to contain costs effectively, but do not necessarily act as a hurdle for the adoption of innovations. We also find that policy tools that encourage technological adoption should be used carefully since the benefits of a new technology are often difficult to predict. Finally, we draw a number of policy implications based on our observations.
Health Policy

Rogowski, W.H.; Grosse, S.D.; Khoury, M.J.
Challenges of translating genetic tests into clinical and public health practice.
Nat. Rev. Genet. 10, 489-495 (2009)
Research in genetics and genomics has led to an expanding list of molecular genetic tests, which are increasingly entering health care systems. However, the evidence surrounding the benefits and harms of these tests is frequently weak. Here we present the main challenges to the successful translation of new research findings about genotype-phenotype associations into clinical practice. We discuss the means to achieve an accelerated translation research agenda that is conducted in a reasonable, fair and efficient manner.
Nature Reviews - Genetics

Mielck, A.
Soziale Ungleichheit und Gesundheit.
In: Gostomzyk, J.G.* [Eds.]: Angewandte Sozialmedizin. Handbuch für Weiterbildung und Praxis; 15.Erg.Lfg. 12/09. Landsberg a.L.: ecomed-Verl.-Ges., 2009. 1-28
no Abstract
Riepe, M.W.; Mittendorf, T.; Förstl, H.; Frölich, L.; Haupt, M.; Leidl, R.; Vauth, C.; von der Schulenburg, M.G.
Quality of life as an outcome in Alzheimer's disease and other dementias - obstacles and goals.
BMC Neurology 9, 47:47 (2009)
The number of individuals at risk for dementia will probably increase in ageing societies as will the array of preventive and therapeutic options, both however within limited economic resources. For economic and medical purposes valid instruments are required to assess disease processes and the efficacy of therapeutic interventions for different forms and stages of illness. In principal, the impact of illness and success of an intervention can be assessed with biomedical variables, e.g. severity of symptoms or frequency of complications of a disease. However, this does not allow clear judgement on clinical relevance or comparison across different diseases. DISCUSSION: Outcome model variables such as quality of life (QoL) or health care resource utilization require the patient to appraise their own well-being or third parties to set preferences. In Alzheimer's disease and other dementias the evaluation process performed by the patient is subject to the disease process itself because over progress of the disease neuroanatomical structures are affected that mediate evaluation processes. SUMMARY: Published research and methodological considerations thus lead to the conclusion that current QoL-instruments, which have been useful in other contexts, are ill-suited and insufficiently validated to play a major role in dementia research, decision making and resource allocation. New models integrating biomedical and outcome variables need to be developed in order to meet the upcoming medical and economic challenges.
BMC Neurology

Brunner, H.; Stollenwerk, B.
Standardmethoden der gesundheitsökonomischen Bewertung. Allgemeine Konzepte: Ökonomisches Prinzip, Wirtschaftlichkeitsprinzip, Rationalprinzip.
In: Lauterbach, K.W.*; Stock, S.*; Brunner, H.* [Eds.]: Gesundheitsökonomie: Lehrbuch für Mediziner und andere Gesundheitsberufe. Bern: Huber, 2009. 279-349
Wiczinski, E.; Döring, A.; John, J.; von Lengerke, T.
Obesity and health-related quality of life: Does social support moderate existing associations?
Br. J. Health Psychol. 14, 717-34 (2009)
OBJECTIVES: Obesity has been shown to be negatively related to physical health-related quality of life (HQOL) much more strongly than mental HQOL. This is remarkable given findings on obesity-related social stigmata and associations with depression. Considering obesity as a stressor, this study tests for a moderating role of social support for obesity/HQOL associations among women and men. DESIGN: Data come from N=2,732 participants aged 35-74 years in a 2004-2005 general population survey in the Augsburg region, Germany. METHODS: Body weight and height were assessed by anthropometric measurements (classified by body mass index using WHO standards), social support by the Social Support Questionnaire 14-item Short-Form (F-SozU-K14) and HQOL by the 12-item Short-Form Health Survey (SF-12). In multiple regression and general linear models, age, education, family status, health insurance, and place of residence were adjusted for. RESULTS: Among both genders, obesity was associated with reduced physical but not mental HQOL. Among men reporting strong social support, physical HQOL was impaired neither in the moderately nor the severely obese group (compared with normal weight), while it was given less social support. Among women, poor physical HQOL was associated with obesity regardless of

social support. CONCLUSIONS: In this adult population sample, no association was found for obesity with mental HQOL. In contrast, a negative association with physical HQOL exists for all subgroups except men with strong social support, indicating that social support buffers obesity-related impairments in physical HQOL in men but not in women. This suggests that obese women and men with strong social support represent distinct populations, with possible implications for obesity care.
British Journal of Health Psychology

Icks, A.; Dickhaus, T.; Hörmann, A.; Heier, M.; Giani, G.; Kuch, B.; Meisinger, C.
Differences in trends in estimated incidence of myocardial infarction in non-diabetic and diabetic people: Monitoring Trends and Determinants on Cardiovascular Diseases (MONICA)/Cooperative Health Research in the Region of Augsburg (KORA) registry.
Diabetologia 52, 1836-1841 (2009)
One major objective of the St Vincent Declaration was to reduce the excess risk of myocardial infarction in patients with diabetes mellitus. We estimated the trend of the incidence and relative risk of myocardial infarction in the diabetic and non-diabetic populations in southern Germany from 1985 to 2006. Using data from the Monitoring Trends and Determinants on Cardiovascular Diseases (MONICA)/Cooperative Health Research in the Region of Augsburg (KORA) Project in southern Germany, we ascertained all fatal and non-fatal first myocardial infarctions between 1985 and 2006 (n = 14,891, age 25-74 years). We estimated the diabetic and the non-diabetic populations using data on diabetes prevalence from surveys, and evaluated incidence of myocardial infarction in the two estimated populations. To test for time trends, we fitted Poisson regression models. Of individuals with first myocardial infarction, 71% were male and 28% known to have diabetes. In the non-diabetic population, myocardial infarction incidence decreased by about 1.5% to 2.0% per year. A comparable decrease was seen in the population of diabetic women. However, in the population of diabetic men, incidence of myocardial infarction increased by about 1% per year. Over the whole study period, myocardial infarction incidence decreased by 34% and 27% in non-diabetic men and women respectively (RR 0.66, 95% CI 0.59-0.74 and 0.73, 0.62-0.87 respectively). In diabetic women, it decreased by 27% (RR 0.73, 0.61-0.88), whereas in diabetic men, it increased by 25% (RR 1.25, 1.07-1.45). Our results suggest that the St Vincent goal of reducing excess cardiovascular morbidity in diabetic individuals has not been achieved and that the situation in men has actually got worse.
Diabetologia

Haucke, F.; Holle, R.; Wichmann, H.-E.
Epidemiologische Erforschung und ökonomische Bewertung gesundheitlicher Umweltrisiken.
Bundesgesundheitsbl.-Gesund. 52, 1166-1178 (2009)
Die Methoden der quantitativen Nutzung von Humandaten im Bereich der umweltepidemiologischen Forschung gewinnen zunehmend an Bedeutung und bieten einen wichtigen Anknüpfungspunkt für die ökonomische Betrachtung umweltbedingter Gesundheitseffekte mit dem Ziel, begrenzte Ressourcen möglichst effizient einzusetzen. Dieser Übersichtsbeitrag stellt wesentliche epidemiologische und ökonomische Konzepte und Methoden sowie deren Schnittstellen dar und zeigt auf, wie diese als Basis für umweltpolitische Entscheidungen genutzt werden können. Es werden zunächst die grundsätzliche Vorgehensweise der umweltepidemiologischen Forschung sowie die Prinzipien der Abschätzung, Bewertung und des Managements von Umweltrisiken erläutert. Anschließend werden Ziele und Konzepte ökonomischer Untersuchungen im Rahmen der Bewertung umweltbedingter Gesundheitseffekte beschrieben und grundlegende Monetarisierungskonzepte sowie deren Anwendungsbereiche abgegrenzt. Mit dem Environmental Attributable Fraction Model sowie dem Wirkungspfadansatz werden zwei konzeptionell unterschiedliche Ansätze aufgezeigt, anhand derer die Ergebnisse epidemiologischer und ökonomischer Forschung verknüpft werden können. Die theoretischen Konzepte werden auf zwei konkrete Beispiele bedeutender Umweltrisiken, Feinstaubbelastung und Radonexposition, angewendet.
Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz

Kainzinger, F.; Raible, C.; Petrek, K.; Müller-Nordhorn, J.; Willich, S.N.
Optimization of hospital stay through length-of-stay-oriented case management: An empirical study.
J. Public Health 17, 395-400 (2009)
Background and objectives An important component of efficient and high-quality treatment of patients under DRG conditions is the control of patients’ length of stay in hospitals. Medical processes need to be structured in such a way that unnecessary extensions of the length of stay are avoided, thus achieving an economically and qualitatively optimal result. The study presented here examines the question of whether the introduction of length-of-stay-oriented case management can optimize the duration of patients' hospital stays. Methods In total, 168 inpatient cases and their matched control cases from the cardiology and urology stations of a maximum care hospital are examined in this study. Results The result of the t-test for the difference of means indicates that the average length of stay of the intervention cases (5.79 days) was significantly shorter than the average length of stay of the control cases (7.34 days). With respect to the re-admission rate, a statistically significant dependence could not be determined. Discussion and conclusion The operationalization of case management in daily clinical routines was tested by a comprehensive survey. Length-of-stay-oriented case management provides transparency of the entire treatment process and integrates procedures to an optimal extent. However, the doctor's sovereignty over therapy is not affected by the introduction of length-of-stay-oriented case management. Hence, the form of case management presented here serves as a new and innovative control and monitoring system for hospitals, as it makes institutions that implement such a system more competitive through the improvement of economical aspects as well as through the introduction of higher process efficiency.
Journal of Public Mental Health

Porzsolt, F.; Schreyögg, J.
Scientific evidence and the cost of innovations in the health-care system. Die wissenschaftliche Evidenz und der Preis für Innovationen im Gesundheitssystem.
Med. Klin. Intensivmed. Notfmed. 104, 622-630 (2009)
When depicting the relationship between evidence and the cost of an innovation in the health-care system, the overall risks of

assessment, the redistribution of risks in a regulated market, and the ethical consequences must first be taken into account. There are also evidence-based criteria and economic considerations which are relevant when calculating the cost of an innovation. These topics can indicate, but not exhaustively deal with the complicated relationship between scientific evidence and calculating the cost of an innovation in the health-care system. The following three statements summarize the current considerations in the continuing discussion of this topic: aEuro cent Scientific evidence undoubtedly exists which should be taken into consideration when calculating the cost of an innovation in the health-care system. aEuro cent The existing scientific evidence is, however, not sufficient to reach such a decision. Additional information about the benefit perceived by the patient is required. aEuro cent No standardized method exists to measure this additional information. Therefore, a definition problem also exists in the health-care system when setting a price according to scientific evidence.
Medizinische Klinik - Intensivmedizin und Notfallmedizin

Beck, J.A.; Meisinger, C.; Heier, M.; Kuch, B.; Hörmann, A.; Greschik, C.; Koenig, W.
Effect of blood glucose concentrations on admission in non-diabetic versus diabetic patients with first acute myocardial infarction on short- and long-term mortality (from the MONICA/KORA Augsburg Myocardial Infarction Registry).
Am. J. Cardiol. 104, 1607-1612 (2009)
The aim of this study was to investigate the association between increased admission glucose in nondiabetic (ND) patients and in patients with type 2 diabetes mellitus (T2DM) with first acute myocardial infarctions (AMIs) and 28-day as well as 1- and 3-year case fatality. The Monitoring Trends and Determinants in Cardiovascular Disease (MONICA)/Cooperative Health Research in the Region of Augsburg (KORA) myocardial infarction registry database in Augsburg, Germany, was used, and 1,631 patients without and 659 patients with T2DM (aged 25 to 74 years) who were admitted from 1998 to 2003 with first AMIs were included. Mortality follow-up was carried out in 2005. ND patients with AMIs with admission glucose >152 mg/dl (top quartile) compared with those in the bottom quartile had an odds ratio of 2.82 (95% confidence interval [CI] 1.30 to 6.12) for death within 28 days after multivariate adjustment; correspondingly, patients with T2DM with admission glucose >278 mg/dl (top quartile) compared with those in the bottom quartile (<152 mg/dl) showed a nonsignificantly increased odds ratio of 1.45 (95% CI 0.64 to 3.31). After the exclusion of patients who died within 28 days, a nonsignificantly increased relative risk (RR) was seen between admission blood glucose and 1-year mortality in ND subjects (RR 2.71, 95% CI 0.90 to 8.15), whereas no increased RR was found in subjects with diabetes (RR 0.99, 95% CI 0.34 to 2.82). After 3 years, there was no increased risk for death in patients with high admission blood glucose levels, neither for ND patients nor for those with T2DM. In conclusion, elevated admission blood glucose is associated with increased short-term mortality risk in patients with AMIs, particularly in ND subjects. These patients constitute a high-risk group needing aggressive, comprehensive polypharmacotherapy.
American Journal of Cardiology, The

Rathmann, W.; Strassburger, K.; Heier, M.; Holle, R.; Thorand, B.; Giani, G.; Meisinger, C.
Incidence of type 2 diabetes in the elderly German population and the effect of clinical and lifestyle risk factors: KORA S4/F4 cohort study.
Diabetic Med. 26, 1212-1219 (2009)
Aims: To determine the incidence of Type 2 diabetes in an elderly population in Germany and its association with clinical and lifestyle factors. - Methods: Oral glucose tolerance tests (OGTT, World Health Organization criteria) were carried out in a random sample of 1353 subjects (age group 55-74 years; 62% response) in Augsburg (Southern Germany) (1999-2001). The cohort was re-investigated in 2006-2008. Of those individuals without diabetes (baseline), 887 (74%) participated in the follow-up. - Results: Ninety-three (10.5%) developed diabetes during the 7-year follow-up period {standardized incidence rates [95% confidence interval (CI)] per 1000 person-years: total 15.5; 12.6, 19.1; men 20.2; 15.6, 26.1; women 11.3; 7.9, 16.1}. In both sexes, those who developed diabetes were slightly older, were more obese, had a more adverse metabolic profile (higher glucose values, HbA1c, fasting insulin, uric acid, and triglycerides) and were more likely to have hypertension at baseline than were participants remaining free of diabetes ($P < 0.05$). On stepwise logistic regression, age, parental diabetes, body mass index, uric acid, current smoking, HbA1c and fasting and 2-h glucose (OGTT) were strong predictors of diabetes incidence. The risk of diabetes was higher in subjects with isolated impaired glucose tolerance (odds ratio 8.8; 95% CI 5.0, 15.6) than in isolated impaired fasting glucose (4.7; 2.2, 10.0), although the difference did not reach statistical significance. - Conclusions: For the first time, we have estimated the incidence of Type 2 diabetes in an elderly German cohort and demonstrated that it is among the highest in Europe. The OGTT appears to be useful in identifying individuals with high Type 2 diabetes risk. Our results support a role of smoking in the progression to diabetes.
Diabetic Medicine

Menn, P.; Holle, R.
Comparing three software tools for implementing markov models for health economic evaluations.
Pharmacoeconomics 27, 745-753 (2009)
BACKGROUND: Various software packages are commonly used for the implementation and calculation of decision-analytic models for health economic evaluations. However, comparison of these programs with regard to ease of implementing a model is lacking. OBJECTIVES: (i) to compare the assets and drawbacks of three commonly used software packages for Markov models with regard to ease of implementation; and (ii) to investigate how a technical model validation can be conducted by comparing the results of the three implementations. METHODS: A Markov model on chronic obstructive pulmonary disease was implemented in TreeAge, Microsoft Excel and Arena with the same assumptions on model structure, transition probabilities and costs. A hypothetical smoking cessation programme for patients in stage 1 was evaluated against usual care. The packages were compared with respect to time and effort for implementation, run-time, features for the presentation of results, and flexibility. Agreement between the packages on average costs and life-years gained and on the incremental cost-effectiveness ratio was considered for technical validation in the form of expected values (between TreeAge and Excel only) and Monte Carlo simulations. RESULTS: Ease of implementation was best in TreeAge, whereas Arena offered the highest

flexibility. Deterministic results were in agreement between TreeAge and Excel, as were simulated values between all three packages. CONCLUSIONS: Excel offers an intuitive spreadsheet interface, but the acquisition of and the training in TreeAge or Arena is worthwhile for more complex models. Double implementation is a practicable validation technique that should be conducted to ensure correct model implementation.
PharmacoEconomics

Mielck, A.; Altgeld, T.; Reisig, V.; Kümpers, S.
Quantitative Zielvorgaben zur Verringerung der gesundheitlichen Ungleichheit. Lernen von England und anderen westeuropäischen Staaten.
In: Richter, M.*; Hurrelmann, K.* [Eds.]: Gesundheitliche Ungleichheit - Grundlagen, Probleme, Perspektiven. Wiesbaden: VS Verl. f. Sozialwissenschaften, 2009. 459-477
In einigen westeuropäischen Staaten wird schon seit geraumer Zeit versucht, das Ziel „Verringerung der gesundheitlichen Ungleichheit“ so genau wie möglich zu definieren. Dabei wird auch vor einer Quantifizierung dieser Zielsetzung nicht zurückgeschreckt. Mit 'Quantifizierung' sind hier zahlenmäßig fixierte Vorgaben gemeint wie: Die zurzeit vorhandenen Unterschiede in der Mortalität zwischen Statusgruppe A und Statusgruppe B sollen in 10 Jahren um 15% kleiner sein. Derartige Vorgaben bergen erhebliche Risiken, aber auch Möglichkeiten. Die Risiken sind primär politischer Natur: Nach Ablauf der gesetzten Frist ist gut zu überprüfen, wie gut dieses Ziel erreicht worden ist, und auch schon in den Jahren bis zum Ablauf der Frist ist gut zu sehen, ob die Entwicklung in die vorgesehene Richtung geht. Diese Überprüfung bietet wenig Spielraum für Verschleierungen oder Verharmlosungen. Den Risiken steht jedoch ein wichtiger Vorteil gegenüber: Die Planung von Maßnahmen kann sehr zielgerichtet erfolgen. Misserfolge können zu einer neuen und besseren Ausrichtung der Maßnahmen führen. Quasi von selbst stellen sich sehr praxisnahe konkrete Fragen wie z.B.: Welche Maßnahme hat welchen Effekt auf die gesundheitliche Ungleichheit? Wer ist für welche Maßnahme verantwortlich? Wie können diese Maßnahmen fachlich und zeitlich koordiniert werden? Wer ist für die Koordination verantwortlich? Wie kann der Erfolg der Maßnahmen dadurch abgesichert werden, dass die Personengruppe, deren Gesundheitszustand verbessert werden soll, in die Planung und Durchführung der Maßnahmen eingebunden wird? Wie wirken sich die sozialen und politischen Entwicklungen, die außerhalb des geplanten Maßnahme-Katalogs liegen (Arbeitsmarkt, Reform der Krankenversicherung etc.) auf die gesundheitliche Ungleichheit aus?
Langer, A.; Rogowski, W.H.
Systematic review of economic evaluations of human cell-derived wound care products for the treatment of venous leg and diabetic foot ulcers.
BMC Health Serv. Res. 9:115 (2009)
Tissue engineering is an emerging field. Novel bioengineered skin substitutes and genetically derived growth factors offer innovative approaches to reduce the burden of diabetic foot and venous leg ulcers for both patients and health care systems. However, they frequently are very costly. Based on a systematic review of the literature, this study assesses the cost-effectiveness of these growth factors and tissue-engineered artificial skin for treating chronic wounds. Methods: On the basis of an extensive explorative search, an appropriate algorithm for a systematic database search was developed. The following databases were searched: BIOSIS Previews, CRD databases, Cochrane Library, EconLit, Embase, Medline, and Web of Science. Only completed and published trial-or model-based studies which contained a full economic evaluation of growth factors and bioengineered skin substitutes for the treatment of chronic wounds were included. Two reviewers independently undertook the assessment of study quality. The relevant studies were assessed by a modified version of the Consensus on Health Economic Criteria (CHEC) list and a published checklist for evaluating model-based economic evaluations. Results: Eleven health economic evaluations were included. Three biotechnology products were identified for which topical growth factors or bioengineered skin substitutes for the treatment of chronic leg ulceration were economically assessed: (1) Apligraf (R), a bilayered living human skin equivalent indicated for the treatment of diabetic foot and venous leg ulcers (five studies); (2) Dermagraft (R), a human fibroblast-derived dermal substitute, which is indicated only for use in the treatment of full-thickness diabetic foot ulcers (one study); (3) REGRANEX (R) Gel, a human platelet-derived growth factor for the treatment of deep neuropathic diabetic foot ulcers (five studies). The studies considered in this review were of varying and partly low methodological quality. They calculated that due to shorter treatment periods, fewer complications and fewer inpatient episodes the initial cost of the novel biotechnology products may be offset, making the treatment cost-effective or even cost-saving. The results of most studies were sensitive to initial costs of the products and the evidence of effectiveness. Conclusion: The study results suggest that some growth factors and tissue-engineered artificial skin products feature favourable cost-effectiveness ratios in selected patient groups with chronic wounds. Despite the limitations of the studies considered, it is evident that health care providers and coverage decision makers should take not only the high cost of the biotechnology product but the total cost of care into account when deciding about the appropriate allocation of their financial resources. However, not only the cost-effectiveness but first of all the effectiveness of these novel biotechnology products deserve further research.
BMC Health Services Research

Mielck, A.
Arbeitslosigkeit und Armut: Soziale Bedingungen der notfallmedizinischen Versorgung.
Akutmedizin - Die ersten 24 Stunden entscheiden. München: Urban & Fischer, 2009. 1067-1076
Als Standardwerk der Akutmedizin geht dieses Buch weit über die reine Notfallversorgung traumatologischer, internistischer und pädiatrischer Patienten hinaus. Es beinhaltet außerdem: Spezielle Notfallsituationen, z.B. Katastropheneinsätze, Tauchunfälle, Seenotrettung. Psychiatrische und psychosoziale Problemsituationen - entsprechend der zunehmenden Bedeutung erweitert und vertieft. Ökonomische, demographische, organisatorische sowie perspektivische Aspekte.
Langer, A.; Rogowski, W.H.
Deskriptive Entscheidungstheorie.
In: Schwaiger, M.*; Meyer, A.H.* [Eds.]: Theorien und Methoden der Betriebswirtschaft. Handbuch für Wissenschaftler und Studierende. München: Vahlen, 2009. 177-191
Gegenstand dieses Beitrags ist die deskriptive Entscheidungstheorie. Zunächst wird in der Einführung eine Abgrenzung zwischen dem deskriptiven Ansatz und der

normativen Theorie der Entscheidungsforschung unternommen. Des Weiteren wird die Bedeutung der Entscheidungstheorie für die Betriebswirtschaftslehre herausgestellt. Im Hauptteil wird auf deskriptive Entscheidungsmodelle sowie Präferenztheorien, wie Regret- und Disappointment-Theorie, näher Bezug genommen. Als Ausgangspunkt der Darstellung deskriptiver Modelle dienen verhaltenswissenschaftliche Hypothesen der Diskussion solcher Modelle, wobei insbesonddere auf den Problemkreis "kognitiver Stress und Suchverhalten" und der damit verbundenen Strategien der Informationsverarbeitung (Heuristiken) und der Vereinfachung des Entscheidungsproblems (Inkrementalanalyse) abgehoben wird. Daneben wird das aufbau- bzw. ablauforientierte Grundmodell der deskriptiven Entscheidungstheorie vorgestellt.

Luxenhofer, B.; Keller, M.; Mielck, A.
Haben die Ärzte, die in ärmeren Gemeinden arbeiten, die kränkeren Diabetes-mellitus-Typ-2-Patienten? Regionale Unterschiede bei DMP-Patienten in Bayern.
Diabetol. Stoffwechs. 4, 374-383 (2009)
Zielsetzung: Untersucht wurde der Zusammenhang zwischen den beiden folgenden Merkmalen: (a) soziale Lage der Gemeinde, in der die Arztpraxis liegt, und (b) Gesundheitszustand der von diesem Arzt behandelten Patienten mit Diabetes mellitus Typ 2. Methode: Grundlage für die Daten über den Gesundheitszustand der Patienten sind die Dokumentationsbögen, die im Rahmen des Disease Management Programms (DMP) in Bayern zwischen dem 1.10.2003 und dem 31.12.2006 ausgefüllt wurden. Als Indikatoren für den Gesundheitszustand dienen diabetestypische Angaben. Berücksichtigt wird auch, ob die Patienten schon einmal an einer Diabetesschulung teilgenommen hatten. Die Daten zur sozialen Lage der Gemeinde stammen aus den Routinedaten des Bayerischen Landesamtes für Statistik und Datenverarbeitung (Sozialhilfe- und Arbeitslosenquote, Lohn- und Einkommenssteueraufkommen). Für die dichotomen Outcome-Variablen wurden bivariate Analysen durchgeführt, für die metrischen Outcome-Variablen auch Multilevel-Analysen. Ergebnisse: Der Zusammenhang zwischen der sozialen Lage der Gemeinde und dem Gesundheitszustand bzw. der Schulung der dort behandelten DMP-Patienten ist zumeist nur schwach ausgeprägt. Die deutlichsten Zusammenhänge zeigen die Multilevel-Analysen beim BMI. Demnach haben die Patienten in Gemeinden mit geringem Lohn- und Einkommenssteueraufkommen einen um 0,7 kg / m2 höheren BMI als die Patienten in Gemeinden mit hohem Lohn- und einkommenssteueraufkommen. Schlussfolgerung: In den Gemeinden mit niedrigem Sozialstatus weisen die Patienten zwar tendenziell einen schlechteren Gesundheitszustand auf, und sie haben auch seltener an Schulungen teilgenommen, die Unterschiede sind aber zumeist gering. Objective: We looked at the association between (a) the social status of the communities where physicians work, and (b) the health status of patients with type 2 diabetes who are treated by these physicians. Method: The data on health status are based on the documentation of the "Disease Management Program (DMP)" of diabetes mellitus type 2 in Bavaria, filled out between October 2003 and December 2006. Indicators are, for example, coronary heart disease, hypertension and BMI. Information on previous participation in diabetes training courses is included as well. The data on the community are taken from routine data of the Statistical Office. Indicators are the percentage of people who are unemployed, who receive public welfare, and the tax revenues per taxpayer. Bivariate analyses were conducted for binary outcome variables, and multilevel analyses for continuous variables. Results: The association between (a) the social status of the community and (b) the health status of the patients and their participation in a training course is rather weak. The clearest picture can be seen in the multilevel analysis for Body Mass Index: For patients in low income communities it is about 0.7 kg / m2 higher than for - patients in high income communities. Conclusion: The hypothesis that physicians working in poor communities have patients who are more sick can hardly be supported for this group of patients with type 2 diabetes. Patients treated in low status communities tend to have worse health, and they less often participated in diabetes training courses, but these differences are rather small.
Diabetologie und Stoffwechsel

Schweikert, B.; Hahmann, H.; Steinacker, J.M.; Imhof, A.; Muche, R.; Koenig, W.; Liu, Y.F.; Leidl, R.
Intervention study shows outpatient cardiac rehabilitation to be economically at least as attractive as inpatient rehabilitation.
Clin. Res. Cardiol. 98, 787-795 (2009)
BACKGROUND: Since the late 1990 s, cost pressure has led to a growing interest in outpatient rehabilitation in Germany where predominantly inpatient rehabilitation has been provided. Taking into account the feasibility of a randomized design, the aim of this study was to compare outpatient and inpatient cardiac rehabilitation from a societal perspective. METHOD: A comprehensive cohort design was applied. Costs during rehabilitation were measured using individual documentation of the rehabilitation centers. Economic end points were quality of life (EQ-5D), and total direct and indirect costs. A propensity score approach, integrated into a simultaneous regression framework for cost and effects, was used to control for selection bias. Bootstrap analysis was applied for assessing uncertainty in cost-effectiveness. RESULTS: A total of 163 patients were included in the study (112 inpatients, 51 outpatients). As randomization was chosen by only 2.5% of participants, the study had to be analyzed as an observational study. Direct costs during inpatient rehabilitation were significantly higher by 600 euro (+/-318; p < 0.001) compared to outpatient rehabilitation (2,016 euro +/- 354 euro vs. 1,416 euro +/- 315), while there was no significant difference in health-related quality of life. Over the 12-month follow-up period, adjusted costs difference in total cost was estimated at -2,895 euro (p = 0.102) and adjusted difference in effects at 0.018 quality-adjusted life years (QALYs) (n.s.) in favor of outpatient treatment. CONCLUSION: The ratio of mean cost over mean effect difference (incremental cost-effectiveness ratio) indicates dominance of outpatient rehabilitation, but at a considerable statistical uncertainty. However, outpatient rehabilitation cannot be rejected from an economic perspective.
Clinical Research in Cardiology

Tiemann, O.; Schreyögg, J.
Effects of ownership on hospital efficiency in Germany.
BuR 2, 115-145 (2009)
The objective of our study was to evaluate the efficiency of public, private for-profit, and private non-profit hospitals in Germany. First, bootstrapped data envelopment analysis (DEA) was used to evaluate the efficiency of a panel (n = 1,046) of public, private for-profit, and private non-profit hospitals between 2002 and 2006. This was followed by a second-step truncated linear regression model with bootstrapped DEA efficiency scores

as dependent variable. The results show that public hospitals performed significantly better than their private for-profit and non-profit counterparts. In addition, we found a significant positive association between hospital size and efficiency, and that competitive pressure had a significant negative impact on hospital efficiency.
Business Research - BuR

Menn, P.
Einsatz entscheidungsanalytischer Modelle für die ökonomische Evaluation medizinischer Verfahren am Beispiel chronisch obstruktiver Lungenerkrankungen.
München, Ludwig-Maximilian-Universität, Medizinische Fakultät, Diss., 2009, 190 S.
Die chronisch obstruktive Lungenerkrankung (COPD), derzeit weltweit die vierthäufigste Todesursache, hat schwerwiegende Auswirkungen auf die betroffenen Patienten und verursacht jedes Jahr hohe Kosten für die Gesellschaft. Ziel dieser Arbeit war es, ein entscheidungsanalytisches Modell zu COPD mit aktuellen Parametern für Deutschland zu erstellen, das zur gesundheitsökonomischen Evaluation von Interventionen eingesetzt werden kann. Dazu wurde ein Markov-Modell mit sieben Zuständen entwickelt, mit dem eine Kosten-Nutzwert-Analyse aus gesellschaftlicher Perspektive mit einer Laufzeit von 60 Jahren durchgeführt wurde. Die Patienten starteten im Alter von 45 und mit leichter COPD in das Modell. Neben Wahrscheinlichkeiten für die Übergänge zwischen den Zuständen wurden auch stadienspezifische Nutzwerte und Kosten bestimmt und jeweils mit 3% diskontiert. Die Schätzung der Übergangswahrscheinlichkeiten basiert auf umfangreichen Literaturrecherchen, um für jeden Bereich die beste derzeit verfügbare Evidenz zu identifizieren. Da kaum deutsche Studien zum Krankheitsverlauf von COPD existieren, mussten größtenteils die Ergebnisse internationaler Studien verwendet werden. Im Bereich von Nutzwerten bei akuten Exazerbationen lagen dagegen auch international kaum Informationen vor. Daher wurde eine eigene Studie zur Gewinnung solcher Nutzwerte geplant und in Zusammenarbeit mit den Asklepios-Fachkliniken München-Gauting durchgeführt. Dazu füllten Patienten standardisierte Instrumente zur Messung ihrer gesundheitsbezogenen Lebensqualität aus. So war es möglich, deutsche Daten in das Modell aufzunehmen, die auf einer Selbsteinschätzung der Patienten basieren. Der Ressourcenverbrauch zur Bestimmung der stadienspezifischen Kosten und die Bewertung beruhen auf einer deutschen Kostenstudie und aktuellen Preisen. Dabei wurden Krankenhausaufenthalte, ambulante ärztliche Leistungen, Medikamente, Rehabilitationen und Hilfsmittel sowie Produktionsausfälle durch Arbeits- und Erwerbsunfähigkeit berücksichtigt. Als Beispiel zur Anwendbarkeit des Modells diente ein Raucherentwöhnungsprogramm für Patienten mit leichter COPD. Dabei beeinflusste der Raucherstatus die Mortalität und die Wahrscheinlichkeit eines Krankheitsfortschritts. Die Implementierung dieses Modells erfolgte in den drei Softwarepaketen TreeAge, Excel und ARENA. Zur technischen Validierung wurden die Ergebnisse der drei Programme anschließend auf ihre Übereinstimmung hin überprüft. Außerdem wurden uni- und multivariate sowie probabilistische Sensitivitätsanalysen durchgeführt, um die Robustheit des Modellergebnisses zu untersuchen. Es zeigte sich, dass die gewählte Intervention im Vergleich zur Standardbehandlung dominant ist, also zu höheren Gesundheitseffekten bei gleichzeitig geringeren Kosten führt. Sensitivitätsanalysen wiesen darauf hin, dass die mit diesem Ergebnis verbundene Unsicherheit besonders auf fehlende Evidenz im Bereich der Kosten in leichten Krankheitsstadien basiert. Obwohl ein Großteil der COPD-Patienten in Deutschland ein leichtes oder moderates Stadium aufweist, fehlen gerade für diese frühen Schweregrade Studien zum Ressourcenverbrauch und den Krankheitskosten. Solche Daten sind jedoch dringend erforderlich, um die Wirtschaftlichkeit von Interventionen und die Belastung der Gesellschaft durch diese Erkrankung abschätzen zu können.

Heyder, J.; Beck-Speier, I.; Ferron, G.A.; Josten, M.; Karg, E.W.; Kreyling, W.G.; Lenz, A.-G.; Maier, K.L.; Reitmeir, P.; Ruprecht, L.; Takenaka, S.; Wohland, T.; Ziesenis, A.; Schulz, S.
Long-term responses of canine lungs to acidic particles.
Inhal. Toxicol. 21, 920-932 (2009)
Sixteen beagle dogs were housed in four large chambers under minimum restraint. They were exposed for 16 months to clean air and individual baseline data of markers were obtained. For 13 months, eight dogs were further exposed to clean air and eight dogs for 6 h/d to 1-µm MMAD (mass median aerodynamic diameter) acidic sulfate particles carrying 25 µmol H^+ m^{-3} into their lungs. To establish functional responses (lung function, cell and tissue integrity, redox balance, and non-specific respiratory defense capacity), each exposed animal served as its own control. To establish structural responses, the eight non-exposed animals served as controls. Acidic particles were produced by nebulization of aqueous sodium hydrogen sulfate at pH 1.5. Only subtle exposure-related changes of lung function and structure were detected. A significant increase in respiratory burst function of alveolar macrophages points to a marginal inflammatory response. This can be explained by the significant production of prostaglandin E2, activating cyclooxygenase-dependent mechanisms in epithelia and thus inhibiting lung inflammation. The non-specific defense capacity was slightly affected, giving increased tracheal mucus velocity and reduced in vivo dissolution of moderately soluble test particles. Hypertrophy and hyperplasia of bronchial epithelia were not observed, but there was an increase in volume density of bronchial glands and a shift from neutral to acidic staining of epithelial secretory cells in distal airways. The acidic exposure had thus no pathophysiological consequences. It is therefore unlikely that long-term inhalation of acidic particles is associated with a health risk.
Inhalation Toxicology

Lindert, J.; von Ehrenstein, O.S.; Priebe, S.; Mielck, A.; Brähler, E.
Depression and anxiety in labor migrants and refugees - a systematic review and meta-analysis.
Soc. Sci. Med. 69, 246-257 (2009)
Prevalence rates of depression and anxiety among migrants (i.e. refugees, labor migrants) vary among studies and it's been found that prevalence rates of depression and anxiety may be linked to financial strain in the country of immigration. Our aim is to review studies on prevalence rates of depression and/or anxiety (acknowledging that Post-traumatic Stress Disorder (PTSD) is within that class of disorders), and to evaluate associations between the Gross National Product (GNP) of the immigration country as a moderating factor for depression, anxiety and PTSD among migrants. We carried out a systematic literature review in the databases MEDLINE and EMBASE for population based studies published from 1990 to 2007 reporting prevalence rates

of depression and/or anxiety and or PTSD according to DSM- or ICD- criteria in adults, and a calculation of combined estimates for proportions using the DerSimonian-Laird estimation. A total of 348 records were retrieved with 37 publications on 35 populations meeting our inclusion criteria. 35 studies were included in the final evaluation. Our meta-analysis shows that the combined prevalence rates for depression were 20 percent among labor migrants vs. 44 percent among refugees; for anxiety the combined estimates were 21 percent among labor migrants vs. 40 percent among (n=24,051) refugees. Higher GNP in the country of immigration was related to lower symptom prevalence of depression and/or anxiety in labor migrants but not in refugees. We conclude that depression and/or anxiety in labor migrants and refugees require separate consideration, and that better economic conditions in the host country reflected by a higher GNP appear to be related to better mental health in labor migrants but not in refugees.
Social Science & Medicine

Broedl, U.C.; Lebherz, C.; Lehrke, M.; Stark, R.G.; Greif, M.; Becker, F.; von Ziegler, A.; Tittus, J.; Reiser, M.; Becker, C.; Göke, B.; Parhofer, K.G.; Leber, A.W.
Low adiponectin levels are an independent predictor of mixed and non-calcified coronary atherosclerotic plaques.
PLoS ONE 4:e4733 (2009)
Background : Atherosclerosis is the primary cause of coronary artery disease (CAD). There is increasing recognition that lesion composition rather than size determines the acute complications of atherosclerotic disease. Low serum adiponectin levels were reported to be associated with coronary artery disease and future incidence of acute coronary syndrome (ACS). The impact of adiponectin on lesion composition still remains to be determined. Methodology/Principal Findings: We measured serum adiponectin levels in 303 patients with stable typical or atypical chest pain, who underwent dual-source multi-slice CT-angiography to exclude coronary artery stenosis. Atherosclerotic plaques were classified as calcified, mixed or non-calcified. In bivariate analysis adiponectin levels were inversely correlated with total coronary plaque burden ($r = -0.21$, $p = 0.0004$), mixed ($r = -0.20$, $p = 0.0007$) and non-calcified plaques ($r = -0.18$, $p = 0.003$). No correlation was seen with calcified plaques ($r = -0.05$, $p = 0.39$). In a fully adjusted multivariate model adiponectin levels remained predictive of total plaque burden (estimate: −0.036, 95%CI: −0.052 to −0.020, $p<0.0001$), mixed (estimate: −0.087, 95%CI: −0.132 to −0.042, $p = 0.0001$) and non-calcified plaques (estimate: −0.076, 95%CI: −0.115 to −0.038, $p = 0.0001$). Adiponectin levels were not associated with calcified plaques (estimate: −0.021, 95% CI: −0.043 to −0.001, $p = 0.06$). Since the majority of coronary plaques was calcified, adiponectin levels account for only 3% of the variability in total plaque number. In contrast, adiponectin accounts for approximately 20% of the variability in mixed and non-calcified plaque burden. Conclusions/Significance : Adiponectin levels predict mixed and non-calcified coronary atherosclerotic plaque burden. Low adiponectin levels may contribute to coronary plaque vulnerability and may thus play a role in the pathophysiology of ACS.
PLoS ONE

Stark, R.G.; Schunk, M.; Leidl, R.; Meisinger, C.; Holle, R.
Prozessevaluation von Disease Management Programmen bei Typ 2 Diabetes auf Basis einer bevölkerungsrepräsentativen Studie in der Region Augsburg (KORA).
Betr.-wirtschaftl. Forsch. u. Prax. 61, 283-302 (2009)
n der gesetzlichen Krankenversicherung sollen Disease Management Programme (DMP) den Ablauf und die QualitÃ¤t der medizinischen Behandlung von Typ 2 Diabetiker verbessern. Auf Basis einer reprÃ¤sentativen Befragung vergleicht der Beitrag nach den Vorgaben der Risikostruktur-Ausgleichsverordnung Angaben zur Versorgung von DMP-Teilnehmern mit denen von Nicht-Teilnehmern. Die DMP-Teilnehmer berichteten hÃ¤ufiger DMP-relevante medizinische Untersuchungen, Ã¤rztliche Beratungen, Verordnungen von Antidiabetika und Blutdrucksenkern sowie hÃ¤ufigere Teilnahme an Schulungen. Die Selbstkontrolle der Patienten unterschied sich weniger deutlich. Unter den DMP-Patienten gab es erhebliche Unterschiede in der Wahrnehmung des DMP. Zur Prozeßverbesserung sollten Ärzte motiviert werden, mehr Patienten aktiv einzubeziehen und zu prüfrn, wie Nicht-Teilnehmer adäquater versorgt werden können.
Betriebswirtschaftliche Forschung und Praxis

Haucke, F.; Raible, C.
Risikomanagement im Krankenhaus. Empirische Ergebnisse der Evaluation eines umfassenden Risikomanagementansatzes.
Krankenhaus 5, 432-438 (2009)
Krankenhaus, Das

John, J.
Neue Wege der Kosten-Nutzen-Bewertung in der Medizin? Anmerkungen zum Methodenvorschlag des Instituts für Qualität und Wirtschaftlichkeit im Gesundheitswesen.
G + G 9, 7-14 (2009)
Gesundheit und Gesellschaft - Blickpunkt

Mielck, A.; Koller, D.; Bayerl, B.; Spies, G.
Luftverschmutzung und Lärmbelastung: Soziale Ungleichheiten in einer wohlhabenden Stadt wie München.
Soz. Fortschr. 58, 43-48 (2009)
Im Mittelpunkt des Beitrags stehen die Fragen: Sind die Belastungen durch Luftverschmutzung und Lärm in den statusniedrigen Bevölkerungsgruppen besonders groß? Sind diese Belastungen in den Stadtgebieten am größten, in denen der Anteil einkommens-armer Personen besonders hoch ist? Grundlage der Analyse sind die Daten des ‚Münchner Gesundheitsmonitorings' aus dem Jahr 2004. Angaben zur Sozialhilfedichte der einzelnen Stadtbezirke dienen als Grundlage für die Einteilung in die drei Gruppen ‚ärmere, mittlere und reichere Stadtbezirke'. Ergebnisse: Die Belastungen durch Luftverschmutzung und Lärm sind bei den unteren Statusgruppen und in den ärmeren Stadtbezirken besonders groß. Das Ausmaß der sozialen Teilhabe wird auch erkennbar an der sozialen Verteilung von Luftverschmutzung und Lärm. Notwendig sind spezifische Interventionen zur Verringerung dieser gesundheitlichen Belastungen; diese Maßnahmen sollten sich vor allem auf die sozial benachteiligten Personengruppen und die ärmeren Stadtbezirke konzentrieren.
Sozialer Fortschritt

Favor, J.; Bradley, A.; Conte, N.; Janik, D.; Pretsch, W.; Reitmeir, P.; Rosemann, M.; Schmahl, W.; Wienberg, J.; Zaus, I.

Analysis of Pax6 contiguous gene deletions in the mouse, Mus musculus, identifies regions distinct from Pax6 responsible for extreme small-eye and belly-spotting phenotypes.
Genetics 182, 1077-1088 (2009)
In the mouse pax6 function is critical in a dose-dependent manner for proper eye development. pax6 Configuous gene deletions were shown to be homozygous lethal at an early embryonic stage. Heterozygotes express belly spotting and extreme microphthalmia. The eye phenotype is more Severe than in heterozygous pax6, intragenic null mutants, raising the possibility that deletions are functionally different. from intragenic null mutations or that a region distinct from Pax6 included in the deletions affects eye phenotype. we recovered and identified the exact regions deleted in three new Pax6 deletions. All are homozygous lethal at an early embryonic stage. None express belly spotting. One expresses extreme microphthalmia and two express the milder eye phenotype similar to Pax6 intragenic null mutants. Analysis of Pax6 expression levels and the major isoforms excluded the hypothesis that the deletions expressing extreme microphthalmia are directly due to the action of pax6 and functionally different from intragenic null mutations. A region distinct from Pax6 containing eight genes was identified for bell), spotting. A second region containing one gene (Rcn I) was identified for the extreme microphthalmia phenotype. Rcn1 is a Ca+2 -binding protein, resident in the endoplasmic reticulum, participates in the secretory pathway and expressed in the eye. Our results suggest that deletion of Rcn1 directly or indirectly contributes to the eye phenotype in Pax6 contiguous gene deletions.
Genetics

Wenig, C.M.; Schmidt, C.O.; Kohlmann, T.; Schweikert, B.
Costs of back pain in Germany.
Eur. J. Pain 13, 280-286 (2009)
With 12-month prevalence rates of more than 70%, back pain is currently one of the major health problems for German adults and entails major economic consequences. The aim of this study was to estimate back pain-related costs from a societal perspective and to determine the impact of sociodemographic variables on costs. Based on back pain-related survey data of a large German adult sample (9267 respondents, response rate 60%), costs were assessed using a prevalence-based bottom-up approach. Direct costs caused by utilisation of healthcare services, as well as indirect costs due to back pain-related production losses were considered. All prices are expressed in 2005 Euros. Average total back pain costs per patient were estimated to be €1322 (95% CI [1173–1487]) per year. These costs are split between direct (46%) and indirect (54%) costs. Bivariate analysis showed considerable differences in total costs between the Von Korff back pain grades (GCPS Group I: Mean 414.4, 95% CI [333.2–506.3]; II: 783.6 [574.5–1044.4]; III: 3017.2 [2392.9–3708.6]; IV: 7115.7 [5418.5–9006.5]). Male gender, increasing age, single status, low education, unemployment, and increasing back pain grade had a significant positive impact on the cost magnitude in multivariate analysis. Despite several limitations, this study provides important information concerning the relevance of back pain as a health problem and its socioeconomic consequences. The information may be of value for decision-making and allocation of research fund resources.
European Journal of Pain

von dem Knesebeck, O.; Bauer, U.; Geyer, S.; Mielck, A.
Social inequality in health care - a plea for systematic research.
Gesundheitswesen 71, 59-62 (2009)
Inequalities in health care are often discussed in an undifferentiated way in Germany. Against this background, this article presents an analysis scheme for a classification of relevant studies and an identification of research needs. To this aim, areas of health care are differentiated (ambulant and inpatient care, prevention and health promotion) and a difference is made between access, utilization and quality of care. According to this scheme, research regarding inequalities in health care can be conducted in nine fields. For each field, exemplary results of a recent study from Germany are summarized. It becomes apparent that there is a substantial lack of systematic research in inequalities in health care in Germany.
Gesundheitswesen, Das

Gapp, O.
Betriebswirtschaftliche Forschungsbeiträge zum Management in gesetzlichen Krankenkassen - ein Überblick.
Z. Ges. Versicher.-Wirtsch. 98, 165-186 (2009)
This paper reviews all published business research into the management of German statutory health insurance. A comprehensive systematic search of literature was done from 1996 to September 2008. Notably, almost all identified studies were published in health or insurance specific journals or as practical book contributions. In general management journals, research into the health insurance sector is seldom. All investigated management fields of the health insurance are substantially lacking research. Findings from general economic research or research into health insurance in other countries cannot be transferred easily. Therefore research has to adapt concepts from general economic literature or develop new concepts for future studies of the health insurance sector in Germany.
Zeitschrift für die Gesamte Versicherungswissenschaft

Koller, D.; Lack, N.; Mielck, A.
Social differences in the utilisation of prenatal screening, smoking during pregnancy and birth weight - empirical analysis of data from the Perinatal Study in Bavaria (Germany).
Gesundheitswesen 71, 10-18 (2009)
Perinatal studies provide an excellent database for public health research, to date this potential has rarely been used, however. Taking the example of the Perinatal Study in Bavaria, the objective is to demonstrate the pros and cons of this database. As it includes only very few variables on socio-economic status, an additional variable is calculated assessing the socio-economic status of the community where the mother lives. This is rarely done in Germany, and as far as we know the procedure proposed here has not been applied before. METHODS: The analyses are based on the data from 2004. They focus on three dependent variables: number of prenatal screenings, maternal smoking during pregnancy, birth weight of the baby. The following independent variables are included as well: age of the mother, nationality of the mother (e.g., German, Mediterranean countries), single mother (yes/no), occupational status of the mother, community where the mother lives (4- or 5-digit postal code). The socio-economic status of the community is assessed by the poverty rate, linking two other datasets, one for transferring the postal codes to community names, the other providing information per community. The multivariate analyses

are conducted by logistic regressions. RESULTS: Information was available from about 76 000 births. Concerning the variable 'few prenatal screenings', the analyses show an increased risk for mothers from Eastern Europe and from the Mediterranean countries, for single mothers and for mothers with low occupational status. The risk factor 'maternal smoking during pregnancy' is increased for mothers from the Mediterranean countries and for single mothers. It is especially high, however, for low status blue collar workers: compared with white collar workers their smoking prevalence is 4.67-times (large cities) or even 6.14-times (smaller communities) higher. The risk factor 'low birth weight of the baby' is again increased for single mothers and for mothers with low occupational status. An association with the poverty rate is mainly seen for the variable 'maternal smoking during pregnancy', with higher smoking prevalences in the poor communities. DISCUSSION: The results demonstrate that the data from the perinatal studies are important for public health research. Concerning the risk factors analysed here, large social differences can be observed. In order to show time trends, it would be important to repeat these analyses on a routine basis. From a methodological point of view, it can be stressed that regional differences in health and health care have rarely been looked at in Germany, and that the procedure proposed here provides a new starting point for closing this research gap.
Gesundheitswesen, Das

Ziegler, D.; Rathmann, W.; Meisinger, C.; Dickhaus, T.; Mielck, A.
Prevalence and risk factors of neuropathic pain in survivors of myocardial infarction with pre-diabetes and diabetes. The KORA Myocardial Infarction Registry.
Eur. J. Pain 13, 582-587 (2009)
The lowest glycemic threshold for and the risk factors associated with neuropathic pain have not been established. The aim of this study was to determine the prevalence and risk factors of neuropathic pain in survivors of myocardial infarction with diabetes, impaired glucose tolerance (IGT), impaired fasting glucose (IFG), normal glucose tolerance (NGT). Subjects aged 25-74 years with diabetes (n = 214) and controls matched for age and sex (n = 212) from the population-based KORA (Cooperative Health Research in the Region of Augsburg) Myocardial Infarction Registry were assessed for neuropathic pain by the Michigan Neuropathy Screening Instrument using its pain-relevant questions and an examination score cutpoint >2. An oral glucose tolerance test was performed in the controls. Among the controls, 61 (28.8%) had IGT (either isolated or combined with IFG), 70 (33.0%) had isolated IFG, and 81 had NCT. The prevalence of neuropathic pain was 21.0% in the diabetic Subjects, 14.8% in those with IGT, 5.7% in those with IFG, and 3.7% in those with NCT (overall $p < 0.001$). In the entire population studied (n = 426), age, waist circumference, peripheral arterial disease (PAD), and diabetes were independent factors significantly associated with neuropathic pain, while in the diabetic group it was waist circumference, physical activity, and PAD (all $p < 0.05$). In conclusion, the prevalence of neuropathic pain is relatively high among survivors of myocardial infarction with diabetes and IGT compared to those with isolated IFG and NGT. Associated cardiovascular risk factors including abdominal obesity and low physical activity may constitute targets to prevent neuropathic pain in this population.
European Journal of Pain

Hauner, H.; Kohlmann, T.; Landgraf, W.; Holle, R.; Pirk, O.; Scholten, T.
Costs of antihyperglycemic treatment and consumables and treatment satisfaction in patients with type 2 diabetes: Results of a cross-sectional cost evaluation study of long-acting Insulin glargine compared with NPH insulin in Germany (LIVE-DE).
Dtsch. Med. Wochenschr. 134, 1207-1213 (2009)
Background: Economic aspects and patient-reported outcomes play an increasing role in the choice of therapeutic options. The aim of the LIVE-DE study (Long-acting insulin glargine versus NPH insulin cost evaluation in Germany[DE]) was to assess expenditures incurred in the care of diabetic patients, as well treatment satisfaction of patients with type 2 diabetes treated with insulin glargine (GLAR) or NPH insulin (NPH). Patients and methods: A retrospective, non-interventional, cross-sectional study was undertaken in Germany of 1,602 insulin-treated patients (982 on GLAR, 620 on NPH), enrolled from 199 randomly selected general practitioner or internal medicine specialist practices. Total cost of diabetes care (insulins, oral antidiabetic drugs, glucagon use, consumables for insulin administration and blood glucose self-monitoring devices) were calculated from total recorded expenditures, for a period of six months, from the perspective of statutory health insurance. Cost data were obtained from publicly available sources, based on the prices in the year 2007. Patient treatment satisfaction was assessed using previously validated questionnaires (SF-12, PAID, DTSQ, ITEQ). Results: Physicians prescribed GLAR more often than NPH combined with oral antidiabetic drugs (43% vs 16%), whereas NPH was more often used in an intensified insulin regimen compared to GLAR (79% vs 49%). The mean total costs per patient over six months were lower in GLAR than NPH treated patients (658 +/- 258 vs 685 +/- 242 Euros [(sic)]; p
Deutsche Medizinische Wochenschrift - DMW

Holle, R.; Gräßel, E.; Ruckdäschel, S.; Wunder, S.; Mehlig, H.; Marx, P.; Pirk, O.; Butzlaff, M.; Kunz, S.; Lauterberg, J.
Dementia care initiative in primary practice - study protocol of a cluster randomized trial on dementia management in a general practice setting.
BMC Health Serv. Res. 9:91 (2009)
Background: Current guidelines for dementia care recommend the combination of drug therapy with non-pharmaceutical measures like counselling and social support. However, the scientific evidence concerning non-pharmaceutical interventions for dementia patients and their informal caregivers remains inconclusive. Targets of modern comprehensive dementia care are to enable patients to live at home as long and as independent as possible and to reduce the burden of caregivers. The objective of the study is to compare a complex intervention including caregiver support groups and counselling against usual care in terms of time to nursing home placement. In this paper the study protocol is described. Methods/Design: The IDA (Initiative Demenzversorgung in der Allgemeinmedizin) project is designed as a three armed cluster-randomized trial where dementia patients and their informal caregivers are recruited by general practitioners. Patients in the study region of Middle Franconia, Germany, are included if they have mild or moderate dementia, are at least 65 years old, and are members of the German AOK (Allgemeine Ortskrankenkasse) sickness fund. In the control group patients receive regular treatment, whereas in the two intervention groups general practitioners participate in a

training course in evidence based dementia treatment, recommend support groups and offer counseling to the family caregivers either beginning at baseline or after the 1-year follow-up. The study recruitment and follow-up took place from July 2005 to January 2009. 303 general practitioners were randomized of which 129 recruited a total of 390 patients. Time to nursing home admission within the two year intervention and follow-up period is the primary endpoint. Secondary endpoints are cognitive status, activities of daily living, burden of care giving as well as healthcare costs. For an economic analysis from the societal perspective, data are collected from caregivers as well as by the use of routine data from statutory health insurance and long-term care insurance. Discussion: From a public health perspective, the IDA trial is expected to lead to evidence based results on the community effectiveness of non-pharmaceutical support measures for dementia patients and their caregivers in the primary care sector. For health policy makers it is necessary to make their decisions about financing new services based on strong knowledge about the acceptance of measures in the population and their cost-effectiveness.
BMC Health Services Research

Rogowski, W.H.; Burch, J.; Palmer, S.; Craigs, C.; Golder, S.; Woolacott, N.
The effect of different treatment durations of clopidogrel in patients with non-ST-segment elevation acute coronary syndromes: A systematic review and value of information analysis.
Health Technol. Assess. 13, iii-iv (2009)
To update the previous systematic review of the use of clopidogrel in combination with aspirin for patients with non-ST-elevation acute coronary syndrome (NSTE-ACS), investigating the optimal duration of treatment and effects of withdrawal from treatment. Data sources: Ten electronic databases and internet resources were searched from 2003 to February 2007, including MEDLINE, MEDLINE In-Process, EMBASE, BIOSIS, CENTRAL and CINAHL. Review methods: Randomised controlled trials (RCTs) of clopidogrel plus aspirin compared with aspirin alone were used to evaluate clinical effectiveness and safety. Inclusion criteria included any comparator trial for duration of treatment studies, and any study design conducted in patients with NSTE-ACS, percutaneous coronary intervention (PCI), stroke, peripheral artery disease (PAD) or ST-elevation myocardial infarction (STEMI) for evidence of rebound on withdrawal of treatment. The existing model was updated to provide a more robust approach to evaluating the cost-effectiveness of alternative durations of clopidogrel and to assess the potential value of further research using value of information approaches. Results: Two RCTs were included for the review of clinical effectiveness and safety. The only RCTs identified that evaluated different durations of clopidogrel treatments were conducted in patients with stroke, PAD, STEMI or PCI. Two small RCTs and one uncontrolled retrospective cohort study were identified for the review of rebound after thienopyridine withdrawal in patients with medically-treated NSTE-ACS. On broadening the criteria, five RCTs, two observational cohorts, nine case series and 33 case reports were identified in patients post-PCI, and two case series and two case reports were identified in patients with stroke, PAD or STEMI. The CURE trial reported that the proportion of patients experiencing cardiovascular death, myocardial infarction or stroke was lower in the clopidogrel group at 30 days [relative risk (RR) 0.79; 95% confidence interval (CI) 0.67-0.92] and from 30 days to 12 months (RR 0.82; 95% CI 0.70-0.95). Clopidogrel seems to be effective in reducing adverse cardiovascular events in patients with NSTE-ACS at intermediate and high risk of ischaemic events, and appears to increase the risk of bleeding when compared with aspirin in patients with intermediate risk of ischaemic events. In terms of the cost-effectiveness of alternative durations of clopidogrel, the updated model reinforced the conclusions from the earlier analysis, i.e. a policy of 12 months of clopidogrel for patients with NSTE-ACS appears to be cost-effective in both 'average' patients and higher-risk patients. The incremental cost-effectiveness (ICER) of 12 months' duration ranged from 13,380 pound to 20,66 pound l per additional quality-adjusted life-year (QALY) across the different scenarios. For lower-risk patients, treatment beyond 3 months does not appear to be cost-effective. The ICER of 12 months' treatment with clopidogrel varied between 49,436 pound and 68,691 pound per QALY Estimates of expected value of perfect information (EVPI) were higher for the combined analysis and for analysis of high-risk patients alone (between 48.69 pound million and 108.4 pound million at a threshold of 30,000 pound per QALY). At a threshold of 20,000-pound 30,000 pound per QALY, total EVPI ranged between 3.27 pound million and 20.38 pound million in the lower-risk group. Conclusions: The review was limited by the lack of available data. There is considerable variation in the costs of uncertainty surrounding the different scenarios and populations considered. The validity of these may also be less reliable in the higher-risk groups owing to changes in clinical practice. An adequately powered, well-conducted RCT that directly compares different durations of clopidogrel treatment in patients with NSTE-ACS would ideally be required to provide more robust evidence in relation to the impact of clopidogrel withdrawal.
Health Technology Assessment

Lindgren, C.M.; Heid, I.M.; Randall, J.C.; Lamina, C.; Steinthorsdottir, V.; Qi, L.; Speliotes, E.K.; Thorleifsson, G.; Willer, C.J.; Herrera, B.M.; Jackson, A.U.; Lim, N.; Scheet, P.; Soranzo, N.; Amin, N.; Aulchenko, Y.S.; Chambers, J.C.; Drong, A.; Luan, J.A.; Lyon, H.N.; Rivadeneira, F.; Sanna, S.; Timpson, N.J.; Zillikens, M.C.; Zhao, J.H.; Almgren, P.; Bandinelli, S.; Bennett, A.J.; Bergman, R.N.; Bonnycastle, L.L.; Bumpstead, S.J.; Chanock, S.J.; Cherkas, L.; Chines, P.; Coin, L.; Cooper, C.; Crawford, G.; Döring, A.; Dominiczak, A.; Doney, A.S.; Ebrahim, S.; Elliott, P.; Erdos, M.R.; Estrada, K.; Ferrucci, L.; Fischer, G.; Forouhi, N.G.; Gieger, C.; Grallert, H.; Groves, C.J.; Grundy, S.; Guiducci, C.; Hadley, D.; Hamsten, A.; Havulinna, A.S.; Hofman, A.; Holle, R.; Holloway, J.W.; Illig, T.; Isomaa, B.; Jacobs, L.C.; Jameson, K.; Jousilahti, P.; Karpe, F.; Kuusisto, J.; Laitinen, J.; Lathrop, G.M.; Lawlor, D.A.; Mangino, M.; McArdle, W.L.; Meitinger, T.; Morken, M.A.; Morris, A.P.; Munroe, P.; Narisu, N.; Nordstrom, A.; Nordstrom, P.; Oostra, B.A.; Palmer, C.N.A.; Payne, F.; Peden, J.F.; Prokopenko, I.; Renström, F.; Ruokonen, A.; Salomaa, V.; Sandhu, M.S.; Scott, L.J.; Scuteri, A.; Silander, K.; Song, K.J.; Yuan, X.; Stringham, H.M.; Swift, A.J.; Tuomi, T.; Uda, M.; Vollenweider, P.; Waeber, G.; Wallace, C.; Walters, G.B.; Weedon, M.N.; Witteman, J.C.M.; Zhang, C.L.; Zhang, W.H.; Caulfield, M.J.; Collins, F.S.; Smith, G.D.; Day, I.N.M.; Franks, P.W.; Hattersley, A.T.; Hu, F.B.; Jarvelin, M.R.; Kong, A.; Kooner, J.S.; Laakso, M.; Lakatta, E.; Mooser, V.; Morris, A.D.; Peltonen, L.; Samani, N.J.; Spector, T.D.; Strachan, D.P.; Tanaka, T.; Tuomilehto, J.; Uitterlinden, A.G.; van Duijn, C.M.; Wareham, N.J.; Watkins, H.; Waterworth, D.M.; Boehnke,

M.; Deloukas, P.; Groop, L.; Hunter, D.J.; Thorsteinsdottir, U.; Schlessinger, D.; Wichmann, H.-E.; Frayling, T.M.; Abecasis, G.R.; Hirschhorn, J.N.; Loos, R.J.F.; Stefansson, K.; Mohlke, K.L.; Barroso, I.S.; McCarthy, M.I.
Genome-wide association scan meta-analysis identifies three loci influencing adiposity and fat distribution.
PLoS Genet. 5:e1000508 (2009)
To identify genetic loci influencing central obesity and fat distribution, we performed a meta-analysis of 16 genome-wide association studies (GWAS, N = 38,580) informative for adult waist circumference (WC) and waist-hip ratio (WHR). We selected 26 SNPs for follow-up, for which the evidence of association with measures of central adiposity (WC and/or WHR) was strong and disproportionate to that for overall adiposity or height. Follow-up studies in a maximum of 70,689 individuals identified two loci strongly associated with measures of central adiposity; these map near TFAP2B (WC, P = 1.9x10(-11)) and MSRA (WC, P = 8.9x10(-9)). A third locus, near LYPLAL1, was associated with WHR in women only (P = 2.6x10(-8)). The variants near TFAP2B appear to influence central adiposity through an effect on overall obesity/fat-mass, whereas LYPLAL1 displays a strong female-only association with fat distribution. By focusing on anthropometric measures of central obesity and fat distribution, we have identified three loci implicated in the regulation of human adiposity.
PLoS Genetics

Hartz, S.; John, J.
Public health policy decisions on medical innovations: What role can early economic evaluation play?
Health Policy 89, 184-192 (2009)
Our contribution aims to explore the different ways in which early economic data can inform public health policy decisions on new medical technologies. Methods: A literature research was conducted to detect methodological contributions covering the health policy perspective. Results: Early economic data on new technologies can support public health policy decisions in several ways. Embedded in horizon scanning and HTA activities, it adds to monitoring and assessment of innovations. It can play a role in the control of technology diffusion by informing coverage and reimbursement decisions as well as the direct public promotion of healthcare technologies, leading to increased efficiency. Major problems include the uncertainty related to economic data at early stages as well as the timing of the evaluation of an innovation. Conclusions: Decision-makers can benefit from the information supplied by early economic data, but the actual use in practice is difficult to determine. Further empirical evidence should be gathered, while the use could be promoted by further standardization.
Health Policy

Mielck, A.; Kiess, R.; von dem Knesebeck, O.; Stirbu, I.; Kunst, A.E.
Association between forgone care and household income among the elderly in five Western European countries - analyses based on survey data from the SHARE-study.
BMC Health Serv. Res. 9:52 (2009)
Background: Studies on the association between access to health care and household income have rarely included an assessment of 'forgone care', but this indicator could add to our understanding of the inverse care law. We hypothesize that reporting forgone care is more prevalent in low income groups. Methods: The study is based on the 'Survey of Health, Ageing and Retirement in Europe (SHARE)', focusing on the non-institutionalized population aged 50 years or older. Data are included from France, Germany, Greece, Italy and Sweden. The dependent variable is assessed by the following question: During the last twelve months, did you forgo any types of care because of the costs you would have to pay, or because this care was not available or not easily accessible? The main independent variable is household income, adjusted for household size and split into quintiles, calculating the quintile limits for each country separately. Information on age, sex, self assessed health and chronic disease is included as well. Logistic regression models were used for the multivariate analyses. Results: The overall level of forgone care differs considerably between the five countries (e. g. about 10 percent in Greece and 6 percent in Sweden). Low income groups report forgone care more often than high income groups. This association can also be found in analyses restricted to the subsample of persons with chronic disease. Associations between forgone care and income are particularly strong in Germany and Greece. Taking the example of Germany, forgone care in the lowest income quintile is 1.98 times (95% CI: 1.08-3.63) as high as in the highest income quintile. Conclusion: Forgone care should be reduced even if it is not justified by an 'objective' need for health care, as it could be an independent stressor in its own right, and as patient satisfaction is a strong predictor of compliance. These efforts should focus on population groups with particularly high prevalence of forgone care, for example on patients with poor self assessed health, on women, and on low income groups. The inter-country differences point to the need to specify different policy recommendations for different countries.
BMC Health Services Research

Leidl, R.
Preferences, quality of life and public health.
Eur. J. Public Health 19, 228-229 (2009)
European Journal of Public Health
Editorial
Editorial
Koller, D.; Mielck, A.
Regional and social differences concerning overweight, participation in health check-ups and vaccination. Analysis of data from a whole birth cohort of 6-year old children in a prosperous German city.
BMC Public Health 9:43 (2009)
Studies on health inequalities still focus mostly on adults. Research about social disparities and health in children is slowly increasing, also in Germany, but these studies are mostly restricted to individual social variables derived from the parents to determine social class. This paper analyses the data of the medical check-up prior to school enrolment to determine differences concerning overweight, participation in health check-ups and immunization; it includes individual social variables but also regional variables describing the social environment of the children. Methods: The dataset includes 9,353 children who started school in 2004 in Munich, Germany. Three dependent variables are included (i.e. overweight, health check-ups, vaccinations). The individual level social variables are: children's sex, mother tongue of the parents, Kindergarten visit. On the small scale school district level, two regional social variables could be included as well, i.e. percentage of single-parent households, percentage of households with low educational

level. Associations are assessed by cross tables and regression analyses. The regional level variables are included by multilevel analyses. Results: The analyses indicate that there is a large variation between the school districts concerning the three dependent variables, and that there is no district with very 'problematic values' for all three of them (i.e. high percentage of overweight, low levels of health check-ups and vaccinations). Throughout the bivariate and multivariate analyses, the mother tongue of the children's parents shows the most pronounced association with these dependent variables; i.e. children growing up in non-German-speaking families tend to be more overweight and don't visit preventive check-ups as often as children of German-speaking parents. An opposite association can be seen concerning vaccinations. Regional level influences are present as well, but they are rather small when the individual level social variables are controlled for. Conclusion: The dataset of the medical check-up prior to school enrolment offers a great opportunity for public health research, as it comprises a whole age cohort. The number and scope of variables is quite limited, though. On one hand, it includes only few variables on health or health related risks. On the other, it would be important to have more information from the region where the children live, e. g. the availability of community and health care services for parents and children, social networks of families with children, areas where children can play outside, traffic noise and air pollution. Despite these shortcomings, the need for specific interventions can already be derived from the data analyzed here, e.g. programs to reduce overweight in children should focus on parents with a mother tongue other than German.
BMC Public Health

Hahn, V.; Halle, M.; Schmidt-Trucksäss, A.; Rathmann, W.; Meisinger, C.; Mielck, A.
Physical activity and the metabolic syndrome in elderly German men and women: Results from the population-based KORA survey.
Diabetes Care 32, 511-513 (2009)
The purpose of this study is to determine the optimal duration and intensity of exercise for elderly people for the prevention of the metabolic syndrome. RESEARCH DESIGN AND METHODS - The population-based Cooperative Research in the Region of Augsburg (KORA) S4 Survey with 1,653 participants aged 55-74 years was used to investigate the relationship between the metabolic syndrome and physical activity. RESULTS - Fifty-seven percent of men and 48% of women showed clinical symptoms of the metabolic syndrome. Leisure activities were common (>80% walked >30 min/day). Sports activities performed regularly for : <= 1 h per week reduced file odds of having the metabolic (odds ratio 0.70 [95% CI 0.49-1.02] for men and 0.74 [0.53-1.04] for women), and sports activities >2 h per week were even more effective (0.62 [0.42-0.92] for men and 0.59 [039-0.89] for women). In contrast, activities such as walking and cycling did not have an additional influence. CONCLUSIONS - Intense physical activity by the elderly should be promoted in addition to leisure physical activity for the prevention of the metabolic syndrome.
Diabetes Care

Rogowski, W.H.
The cost-effectiveness of screening for hereditary hemochromatosis in Germany: A remodeling study.
Med. Decis. Making 29, 224-238 (2009)
Genetic tests for hereditary hemochromatosis (HH) are currently included in the German ambulatory care reimbursement scheme but only for symptomatic individuals and the offspring of HH patients. This study synthesizes the most current evidence to examine whether screening in the broader population is cost-effective and to identify the best choice of initial and follow-up screening tests. Methods. A probabilistic decision-analytic model was constructed to calculate cost per life year gained (LYG) for HH screening among male Caucasians aged 30. Three strategies were considered in both the general population and male offspring of HH patients: phenotypic (transferrin saturation, TS), genotypic (C282Y mutation), and sequential (genotype if TS is elevated) screening. Results. The incremental cost-effectiveness of sequential screening among male offspring, sequential population-wide screening, and genotypic screening is 41 000, 124 000, and 161 000 (sic)/LYG, respectively. All other strategies were subject to simple or extended dominance. The results are subject to high uncertainty. The most influential parameters in the deterministic one-way sensitivity analysis are discounting of life years gained and the adherence of patients to preventive phlebotomy. Discussion. The current German policy of only screening at-risk individuals is consistent with health economic decision making based on typically accepted thresholds. However, conducting the DNA test after the first elevated TS result is more cost-effective than waiting for a second TS result as recommended by the German guidelines. Further empirical work regarding adherence to long-term prevention recommendations and explicit and well-justified guidance for the choice of discount rates in German economic evaluation are needed.
Medical Decision Making

Weckbach, S.; Findeisen, H.M.; Schoenberg, S.O.; Kramer, H.; Stark, R.G.; Clevert, D.A.; Reiser, M.F.; Parhofer, K.G.
Systemic cardiovascular complications in patients with long-standing diabetes mellitus: Comprehensive assessment with whole-body magnetic resonance imaging/magnetic resonance angiography.
Invest. Radiol. 44, 242-250 (2009)
The primary objective was to evaluate the prevalence of atherosclerotic disease, myocardial infarctions, and cerebrovascular disease in patients with long-standing diabetes using whole-body magnetic resonance imaging (WB-MRI) combined with whole-body magnetic resonance angiography (WB-MRA) and to estimate the cumulative disease burden in a new MRA-based score. Materials and Methods: The study was approved by the ethics committee and all patients gave informed written consent. Sixty-five patients with long-standing (>10 years) diabetes mellitus without acute symptoms were prospectively evaluated. The patients were clinically assessed and received WB-MRI/WB-MRA containing an examination of the brain, the heart, the arterial vessels (abdominal aorta, the supraaortic, renal, pelvic, and peripheral arteries), and the feet. Prevalence rates were calculated and compared with a healthy control group of 200 individuals after adjustment for age and sex by a logistic regression analysis using exact parameter estimates (Cochran-Mantel-Haenszel-statistics). Finally, an MRA based vessel score (sum of grades of all evaluated vessels divided by the number of vessels; grades range from 1, normal, to 6, complete occlusion) indicative of atherosclerotic disease burden was created for this study. This vessel score's association with clinical and biochemical parameters (age, sex, type of diabetes,

diabetes duration, body mass index, blood pressure, smoking, coronary artery disease-status, retinopathy, serum creatinine, hemoglobin A1c test, low density lipoprotein- concentration, medication) was assessed with an age and sex adjusted analysis (generalized linear model). Results: In the diabetic patients, we found prevalence rates of 49% for peripheral artery disease, 25% for myocardial infarction, 28% for cerebrovascular disease, and 22% for neuropathic foot disease. In all vascular beds, at least 50% of the pathologies were previously unknown. Myocardial infarction (P = 0.0002), chronic ischemic cerebral lesions (P = 0.0008), and atherosclerotic disease were significantly more common in diabetic than in control subjects (internal carotid artery: P = 0.006, vertebral artery: P = 0.009, intracerebral vessels: P = 0.02, superficial femoral artery: P = 0.006, anterior tibial artery: P = 0.01, posterior tibial artery: P = 0.02, fibular artery: 0.003). The WB-MRI/WB-MRA-based score showed a significant association with age (P = 0.0008), male sex (P = 0.03), nephropathy (P = 0.006), diabetic retinopathy (P = 0.007), and coronary artery disease status (P = 0.006). Body mass index, blood pressure, hemoglobin A1c test, low density lipoprotein-cholesterol, and medications showed no significant association with the score. Conclusions: Using WB-MRI combined with WB-MRA we found a high prevalence of occult atherosclerotic disease in long-standing diabetic patients. This study shows that the true atherosclerotic burden in these patients is largely underestimated.
Investigative Radiology

von dem Knesebeck, O.; Mielck, A.
Soziale Ungleichheit und gesundheitliche Versorgung im höheren Lebensalter.
Z. Gerontol. Geriatr. 42, 39-46 (2009)
In this article the association between social inequality and selected aspects of health care among the aged is analysed. Analyses are based on German data (release 1) of the 'Survey of Health, Ageing and Retirement in Europe' (SHARE) in 2004. Data from 1921 respondents aged 50 years or more are analysed. Three indicators of social inequality are used (education, income, and financial assets). In terms of health care, indicators of geriatric assessment by the general practitioner of the respondent (questions about balance, physical exercise, and drugs as well as examination of balance and weight control) and secondary prevention (mammogram, endoscopic examination of colon, eye examination) are included. Results of cross-tabs and logistic regression analyses show that geriatric assessment is less comprehensive among people in a comparatively high socioeconomic position. On the other hand, people in a higher socioeconomic position use screening examinations more often than those in a lower position. Inconsistency of results indicates the necessity to distinguish different areas of health care when analysing social inequalities. Moreover, results indicate that no simple answer can be given to the question whether and to what extent social inequalities in health among older people can be explained by inequalities in medical care.
Zeitschrift für Gerontologie und Geriatrie

Happich, M.; Moock, J.; von Lengerke, T.
Health state valuation methods and reference points: The case of tinnitus.
Value Health 12, 88-95 (2009)
Many studies support the finding that patients, compared to the general public, valuate a given health condition differently. Based on Prospect Theory, this difference can be explained by adaptation processes resulting in differences in individual reference points. Using tinnitus as a case in point, our objective is to analyze empirically to what extent differences in risk attitudes (as a proxy to reference points) mediate differences in health valuations. Two hundred ten tinnitus patients and a similar number of unaffected persons indicated their willingness to undergo, hypothetically, an intervention (surgery or treatment) that would either improve or worsen the condition, thus revealing their risk attitudes. Utilities were elicited using three different methods: visual analogue scale (VAS), time trade-off (TTO), and standard gamble (SG). Repeated measure analysis of variance was used to test for mediation of utility differences by reference points. Health status (affected-unaffected) has a significant effect on tinnitus utilities and risk attitude; at the same time, the latter is significantly associated with utilities. Adjusting for risk attitude, differences by health status disappear for SG and TTO, and are alleviated for VAS. Reference points in terms of risk attitudes are a potential confounder in the valuation of health states. Taking into account theoretical predictions and issues in measuring SG, TTO, and risk attitudes, these results cast doubt on the construct validity of SG and TTO, and point to the need to recognize and further clarify the role of reference points in health valuation research.
Value in Health

Reincke, M.; Rump, L.C.; Quinkler, M.; Hahner, S.; Diederich, S.; Lorenz, R.; Seufert, J.; Schirpenbach, C.; Beuschlein, F.; Bidlingmaier, M.; Meisinger, C.; Holle, R.; Endres, S.
Risk factors associated with a low glomerular filtration rate in primary aldosteronism.
J. Clin. Endocrinol. Metab. 94, 869-875 (2009)
Context: Primary aldosteronism (PA) is associated with vascular end organ damage. Objective: We evaluated the newly established German Conn's Registry for evidence of renal impairment and compared the data with those from hypertensive subjects of a population-based survey. Design: We conducted a case-control study. Patients and Controls: A total of 408 patients with PA from the Conn's registry treated in five German centers were matched for age, sex, and body mass index in a 1:1 ratio with 408 hypertensive control subjects from the population-based F3 survey of the Kooperative Gesundheitsforschung in the region of Augsburg (KORA). Main Outcome Measures: We measured serum creatinine and calculated glomerular filtration rate (GFR). Results: The percentage of patients with a serum creatinine concentration above the normal range of 1.25 mg/dl was higher in patients with PA than in hypertensive controls (29 vs. 10%; P < 0.001). Regression analysis showed that age, male sex, low potassium, and high aldosterone concentrations were independent predictors of a lower GFR. Adrenalectomy reduced systolic blood pressure from a mean of 160 to 144 mm Hg. In parallel, we observed an increase in serum creatinine and a decrease of GFR from 71 to 64 ml/min (P < 0.001). A similar trend was seen after spironolactone treatment. Conclusions: In a large cohort of patients with PA, markers of disease activity such as plasma aldosterone and serum potassium are independent predictors of a lower GFR. Specific interventions, such as adrenalectomy or spironolactone treatment, are associated with a further decline in GFR.
Journal of Clinical Endocrinology & Metabolism, The

Herder, C.; Lankisch, M.; Ziegler, D.; Rathmann, W.; Koenig, W.; Illig, T.; Döring, A.; Thorand, B.; Holle, R.; Giani, G.; Martin, S.; Meisinger, C.
Subclinical inflammation and diabetic polyneuropathy.
Diabetes Care 32, 680-682 (2009)
Subclinical inflammation represents a risk factor of type 2 diabetes and several diabetes complications, but data on diabetic neuropathies are scarce. Therefore, we investigated whether circulating concentrations of acute-phase proteins, cytokines, and chemokines differ among diabetic patients with or without diabetic polyneuropathy. RESEARCH DESIGN AND METHODS - We measured 10 markers of subclinical inflammation in 227 type 2 diabetic patients with diabetic polyneuropathy who participated in the population-based MONICA/KORA Survey F3 (2004-2005; Augsburg, Germany). Diabetic polyneuropathy was diagnosed using the Michigan Neuropathy Screening Instrument (MNSI). RESULTS - After adjustment for multiple confounders, high levels of C-reactive protein and interleukin (IL)-6 were most consistently associated with diabetic polyneuropathy, high MNSI score, and specific neuropathic deficits, whereas some inverse associations were seen for IL-18. CONCLUSIONS - This study shows that subclinical inflammation is associated with diabetic polyneuropathy and neuropathic impairments. This association appears rather specific because only certain immune mediators and impairments are involved.
Diabetes Care

Schunk, M.; Schweikert, B.; Gapp, O.; Reitmeir, P.; Meisinger, C.; Mielck, A.; Holle, R.
Time trends in type 2 diabetes patients' disease management and outcomes: Evidence from two KORA surveys in Germany.
Exp. Clin. Endocrinol. Diabet. 117, 88-94 (2009)
To explore time trends in diabetes management and intermediate health outcomes of people with type 2 diabetes, data from two population-based survey studies were compared. The surveys were conducted in the Augsburg region of Southern Germany in 1997/98 and in 2004/05, and included physical examinations, interviews, self-administered questionnaires and laboratory tests. Data from 334 participants aged 40-84 were analysed, including a longitudinal sub-sample of 50 persons. Results show significant time trends towards improvements over the seven year period. Controlling for age, sex, education and duration of diabetes, people felt better informed about diabetes (Odds Ratio (OR) 1.87; 95% CI: 1.12, 3.14) and stated greater adherence to the treatment plan (OR 4.42; CI: 2.62, 7.45) as well as higher participation in diabetes education programmes (OR 2.20; CI: 1.44,3.38). Mean haemoglobin A1c levels decreased by -0.97% from 7.3% to 6.3% (CI:-0.66%, -1.28%). Physical activity (>= 1 h/week) was more frequent (OR 2.75; CI: 1.65, 4.59), although Body Mass Index increased by 1.43 kg/m(2) (CI: 0.86, 2.00). The positive changes in disease management and metabolic outcomes for type 2 diabetic patients between 1997/98 and 2004/05 indicate a shift towards greater patient involvement in diabetes care and possibly more efficient medical management practices.
Experimental and Clinical Endocrinology & Diabetes

Ziegler, D.; Rathmann, W.; Dickhaus, T.; Meisinger, C.; Mielck, A.
Neuropathic pain in diabetes, prediabetes and normal glucose tolerance: The MONICA/KORA Augsburg Surveys S2 and S3.
Pain Med. 10, 393-400 (2009)
The prevalence of neuropathic pain in prediabetes and the associated risk factors in the general population are not known. The aim of this study was to determine the prevalence and risk factors of neuropathic pain in subjects with diabetes, impaired fasting glucose (IFG), impaired glucose tolerance (IGT), or normal glucose tolerance (NGT). Survey of neuropathic painful polyneuropathy assessed by the Michigan Neuropathy Screening Instrument using its pain-relevant questions and an examination score cutpoint > 2 in a diabetic and control population. An oral glucose tolerance test was performed in the control subjects. Population of the city of Augsburg and two surrounding counties. Subjects with diabetes (N = 195) and controls matched for age and sex (N = 198) from the population-based MONItoring trends and determinants in CArdiovascular/Cooperative Research in the Region of Augsburg (MONICA/KORA) Augsburg Surveys S2 and S3 aged 25-74 years. Among the controls, 46 (23.2%) had IGT (either isolated or combined with IFG), 71 (35.9%) had isolated IFG, and 81 had NGT. The prevalence (95% confidence interval) of neuropathic pain was 13.3 (8.9-18.9)% in the diabetic subjects, 8.7 (2.4-20.0)% in those with IGT, 4.2 (0.9-11.9)% in those with IFG, and 1.2 (0.03-6.7)% in those with NGT (overall P = 0.003). In the entire population (N = 393), age, weight, peripheral arterial disease (PAD), and diabetes were risk factors significantly associated with neuropathic pain, while in the diabetic group, these factors were age, weight, and PAD (all P < 0.05). The prevalence of neuropathic pain is two- to threefold increased in subjects with IGT and diabetes compared with those with isolated IFG. Apart from diabetes, the predominant risk factors are age, obesity, and PAD.
Pain Medicine

Schweikert, B.; Hunger, M.; Meisinger, C.; König, H.H.; Gapp, O.; Holle, R.
Quality of life several years after myocardial infarction: Comparing the MONICA/KORA registry to the general population.
Eur. Heart J. 30, 436-443 (2009)
The aim of this study was to assess the impact of myocardial infarction (MI) on health-related quality of life (HRQL) in MI survivors measured by EuroQol (EQ-5D) and to compare it with the general population. A follow-up study of all MI survivors included in the MONICA/KORA registry was performed. About 2950 (67.1%) patients responded. Moderate or severe problems were most frequent in EQ-5D dimension pain/discomfort (55.0%), anxiety/depression (29.2%), and mobility (27.9%). Mean EQ VAS score was 65.8 (SD 18.5). Main predictors of lower HRQL included older age, diabetes, increasing body mass index, current smoking, and experience of re-infarction. Type of revascularizational treatment showed no impact on HRQL. Compared with the general population, adjusted EQ VAS was 6.2 (95% confidence interval 3.4-8.9) points lower in 45-year-old MI patients converging with growing age up to the age of 80. With regard to HRQL dimensions, MI survivors had a significantly higher risk of incurring problems in the dimension pain/discomfort, usual activities, and especially in anxiety/depression which was more pronounced in younger age. Mobility was the single dimension, in which MI showed an inverse effect. MI is combined with significant reduction in HRQL compared with the general population. The main impairments occur in the dimension pain/discomfort, usual activities, and

particularly anxiety/depression. The relative impairment decreases with higher ages.
European Heart Journal

2008

Postma, M.J.; de Vries, R.; Welte, R.; Edmunds, W.J.
Health economic methodology illustrated with recent work on Chlamydia screening: The concept of extended dominance.
Sex. Transm. Infect. 84, 152-154 (2008)
The health economic concepts of dominance were reviewed on the basis of two recently published cost-effectiveness analyses on screening for asymptomatic Chlamydia trachomatis, one in this journal. On the basis of dominance, some strategies may be deleted from the set options from which to choose. The two investigated studies were from the United Kingdom and The Netherlands. Both studies nicely illustrate situations of so-called extended dominance in practical decision making. Extended dominance is a theoretical topic in many health-economic text books but is only scarcely encountered in daily practice. Although the concept of extended dominance is theoretical in nature, a formal analysis and explanation may help show which options under consideration are not optimal from a strictly health-economic perspective; however, these options might still be attractive policy options for other reasons.
Sexually Transmitted Infections

Leidl, R.
A model to decompose the performance of supplementary private health insurance markets.
Int. J. Health Care Finance Econ. 8, 193-208 (2008)
For an individual insurance firm offering supplementary private health insurance, a model is developed to decompose market performance in terms of insurer profits. For the individual contract, the model specifies the conditions under which adverse selection, cream skimming, and moral hazard occur, shows the impact of information on contracting, and the profit contribution. Contracts are determined by comparing willingness to pay for insurance with the individual's risk position, and information on both sides of the market. Finally, performance is aggregated up to the total market. The model provides a framework to explain the attractiveness of supplementary markets to insurers.
International Journal of Health Care Finance and Economics

Kuch, B.; von Scheidt, W.; Kling, B.; Heier, M.; Hoermann, A.; Meisinger, C.
Differential Impact of Admission C-Reactive Protein Levels on 28-Day Mortality Risk in Patients With ST-Elevation Versus Non-ST-Elevation Myocardial Infarction (from the Monitoring Trends and Determinants on Cardiovascular Diseases [MONICA]/Cooperative Health research in the Region of Augsburg [KORA] Augsburg Myocardial Infarction Registry).
Am. J. Cardiol. 102, 1125-1130 (2008)
The present study investigated the association between C-reactive protein (CRP) on admission independently and in combination with troponin and short-term prognosis in an unselected sample of patients with acute myocardial infarction (AMI) from the community. The study population consisted of 1,646 patients aged 25 to 74 years who were consecutively hospitalized with AMI within 12 hours after symptom onset. They were divided into the 2 groups of CRP positive (n = 919) or CRP negative (n = 727) with respect to admission CRP (cutoff <= 0.3 mg/dl). CRP-positive patients had significantly more in-hospital complications and a higher 28-day case-fatality rate (9.6% vs 3.4%; p <0.0001). Troponin at admission (n = 1,419) also correlated with 28-day case-fatality rate (troponin-negative 3.4% vs troponin-positive patients 8.0%; p <0.002). Multivariable analysis showed that both troponin positivity and CRP positivity were associated with a 2-fold (adjusted odds ratio 1.99, 95% confidence interval 1.15 to 3.44; adjusted odds ratio 2.05, 95% confidence interval 1.09 to 3.84, respectively) increased risk of dying within 28 days after the acute event for all patients with AMI. Stratifying by AMI type showed that in patients with ST-elevation myocardial infarction (STEMI), troponin positivity, but not CRP positivity, independently predicted 28-day case fatality. In patients with non-STEMI, CRP positivity, but not troponin positivity, predicted outcome. In conclusion, admission CRP was a powerful parameter for risk stratification of patients with AMI. Stratification by AMI type and troponin showed that CRP was a better short-term risk predictor for patients with non-STEMI, and troponin was, for patients with STEMI.
American Journal of Cardiology, The

Upadhyay, S.; Stöger, T.; Harder, V.; Thomas, R.F.; Schladweiler, M.C.; Semmler-Behnke, M.; Takenaka, S.; Karg, E.W.; Reitmeir, P.; Bader, M.; Stampfl, A.; Kodavanti, U.P.; Schulz, S.
Exposure to ultrafine carbon particles at levels below detectable pulmonary inflammation affects cardiovascular performance in spontaneously hypertensive rats.
Part. Fibre Toxicol. 5:19 (2008)
Background: Exposure to particulate matter is a risk factor for cardiopulmonary disease but the underlying molecular mechanisms remain poorly understood. In the present study we sought to investigate the cardiopulmonary responses on spontaneously hypertensive rats (SHRs) following inhalation of UfCPs (24 h, 172 mug.m-3), to assess whether compromised animals (SHR) exhibit a different response pattern compared to the previously studied healthy rats (WKY). Methods: Cardiophysiological response in SHRs was analyzed using radiotelemetry. Blood pressure (BP) and its biomarkers plasma renin-angiotensin system were also assessed. Lung and cardiac mRNA expressions for markers of oxidative stress (hemeoxygenase-1), blood coagulation (tissue factor, plasminogen activator inhibitor-1), and endothelial function (endothelin-1, and endothelin receptors A and B) were analyzed following UfCPs exposure in SHRs. UfCPs-mediated inflammatory responses were assessed from broncho-alveolar-lavage fluid (BALF). Results: Increased BP and heart rate (HR) by about 5% with a lag of 1-3 days were detected in UfCPs exposed SHRs. Inflammatory markers of BALF, lung (pulmonary) and blood (systemic) were not affected. However, mRNA expression of hemeoxygenase-1, endothelin-1, endothelin receptors A and B, tissue factor, and plasminogen activator inhibitor showed a significant induction (~2.5-fold; $p < 0.05$) with endothelin-1 being the maximally induced factor (6-fold; $p < 0.05$) on the third recovery day in the lungs of UfCPs exposed SHRs; while all of these factors - except hemeoxygenase-1 - were not affected in cardiac tissues. Strikingly, the UfCPs-mediated altered BP is paralleled by the induction of renin-angiotensin system in plasma. Conclusion: Our finding shows that UfCPs exposure at levels which does not induce detectable pulmonary neutrophilic inflammation, triggers distinct effects in the lung and also at the systemic level in compromised SHRs. These effects are characterized by

increased activity of plasma renin-angiotensin system and circulating white blood cells together with moderate increases in the BP, HR and decreases in heart rate variability. This systemic effect is associated with pulmonary, but not cardiac, mRNA induction of biomarkers reflective of oxidative stress; activation of vasoconstriction, stimulation of blood coagulation factors, and inhibition of fibrinolysis. Thus, UfCPs may cause cardiovascular and pulmonary impairment, in the absence of detectable pulmonary inflammation, in individuals suffering from preexisting cardiovascular diseases.
Particle and Fibre Toxicology

Kuch, B.; Heier, M.; von Scheidt, W.; Kling, B.; Hoermann, A.; Meisinger, C.
20-year trends in clinical characteristics, therapy and short-term prognosis in acute myocardial infarction according to presenting electrocardiogram: The MONICA/KORA AMI Registry (1985-2004).
J. Intern. Med. 264, 254-264 (2008)
OBJECTIVES: To examine the extent to which evidence-based beneficial therapy is applied in practice, whether this is changing over time and is associated with improved outcomes. BACKGROUND: Randomized trials have proved efficacy of several treatments for acute myocardial infarction (AMI) with ST-elevation (STEMI), non-ST-elevation (NSTEMI) and bundle branch block (BBB). DESIGN AND SETTING: We prospectively examined all 6748 consecutive patients with AMI aged 25-74 years hospitalized in the study region's major clinic stratified into four time-periods: 1985-1989 (n = 1622), 1990-1994 (n = 1588), 1995-1999 (n = 1450) and 2000-2004 (n = 2088). RESULTS: The increase in numbers of AMI in the last period was mainly, but not exclusively driven by NSTEMI cases. Evidence-based pharmacological therapy increased steeply over time. Invasive procedures increased mainly in the last period with percutaneous coronary intervention and coronary artery bypass graft performed in 30% and 15% in 1998 and 66.0% and 22%, respectively, in 2004. In-hospital complications and 28-day-case fatality decreased significantly from period 1 to period 4 in all patients with AMI. Marked reductions in 28-day-case fatality were mostly seen in BBB patients during the last period (25.3% vs. 10.3%, $P < 0.001$). Of interest, the odds in 28-day-case fatality reduction was diminished after correction for recanalization therapy (from 0.35, 95% CI: 0.16-0.74 to 0.52, 95% CI: 0.19-1.45). CONCLUSIONS: Over the past 20 years, there were substantial changes in pharmacological and interventional therapies in AMI accompanied by reductions in in-hospital complications and 28-day-case fatality in all infarction types with marked reductions in 28-day-case fatality in BBB patients. The latter observation may mainly be because of the increased use of interventional therapy.
Journal of Internal Medicine

Neubauer, S.; Holle, R.; Menn, P.; Grossfeld-Schmitz, M.; Graesel, E.
Measurement of informal care time in a study of patients with dementia.
Int. Psychogeriatr. 20, 1160-1176 (2008)
BACKGROUND: Previous assessments of informal care time have tended to consider only the amount of time spent with the patient by the primary informal caregiver; however, in many cases, more than one person is providing care for the patient. We assess total informal care time of people caring for patients with dementia, and estimate the bias that can arise if consideration is not made of the time spent by all participating informal caregivers. METHOD: We used an extended version of the questions on informal care time from the Resource Utilization in Dementia (RUD) instrument. Caregivers were asked to state the number of days and the number of hours on a typical day they had assisted the patient in activities of daily living (ADL), instrumental ADL (IADL), and supervision during the last four weeks. Multivariate regression analyses were conducted to identify factors that could account for the amount of informal care time. RESULTS: 357 informal caregivers took part. Values were missing from only 4.5% of all interviews. On average, the primary informal caregiver cared for the patient 1.5, 2.1 and 1.9 hours per day in ADL, IADL and supervision respectively. Fifty-seven percent of all patients had more than one informal caregiver. Total informal care time was underestimated by about 14% if the time of caregivers other than the primary caregiver was not taken into account. The informal care time was significantly higher if the caregiver was the patient's partner and the patient's health status was lower. CONCLUSION: Our results show that most previous studies probably underestimated costs of informal care because the time of informal caregivers other than the primary caregiver was not considered.
International Psychogeriatrics

Gapp, O.; Schweikert, B.; Meisinger, C.; Holle, R.
Disease management programmes for patients with coronary heart disease--an empirical study of German programmes.
Health Policy 88, 176-185 (2008)
OBJECTIVE: To evaluate healthcare and outcomes of disease management programmes (DMPs) for patients with coronary heart disease (CHD) in primary care, and to assess selection of enrollment for these programmes. METHODS: A cross-sectional survey of 2330 statutorily insured patients with a history of acute myocardial infarction (AMI) was performed in 2006 by the population-based KORA Myocardial Infarction Register from the region of Augsburg, Germany. Patients enrolled in DMP-CHDs receive evidence-based care, with patients not enrolled receiving standard care. To control for selection bias, a propensity score approach was used. RESULTS: Main factors influencing DMP participation were age (OR 0.98, 95% CI 0.96-0.99), diabetes (OR 1.56, CI 1.25-1.95) and time since last heart attack (OR 0.98, CI 0.95-0.99). Significantly more patients enrolled in DMP-CHDs stated that they received medical counselling for smoking (OR 3.77, CI 1.07-13.34), nutrition (OR 2.15, 1.69-2.74) and for physical activity (OR 2.58, 1.99-3.35). Furthermore, prescription of statins (OR 1.58, CI 1.24-2.00), antiplatelets (OR 1.96, CI 1.43-2.69) and beta-blockers (not significant) were higher in the DMP group. With respect to outcomes, we did not see relevant differences in quality of life and body mass index, and only a minor reduction in smoking. CONCLUSIONS: Enrollment into DMPs for CHD exhibits systematic selection effects. Participants tend to experience--at least on a short to medium term and for AMI patients--better quality of healthcare services. However, since DMP-CHDs were initiated only 2 years ago, we were unable to identify significant improvements in health outcomes. Only the reduction in smoking provides a first indication of better quality outcomes following DMP-CHD. Thus, policy-makers must provide appropriate incentives to sickness funds and physicians in order to ensure initiation and continuation of high quality DMPs.
Health Policy

Graf von der Schulenburg, J.M.; Greiner, W.; Jost, F.; Klusen, N.; Kubin, M.; Leidl, R.; Mittendorf, T.; Rebscher, H.; Schoeffski, O.; Vauth, C.; Volmer, T.; Wahler, S.; Wasem, J.; Weber, C.; Hanover Consensus Group ()
German recommendations on health economic evaluation: Third and updated version of the Hanover Consensus.
Value Health 11, 539-544 (2008)
no Abstract
Value in Health

Reisig, V.; Mielck, A.; Kümpers, S.; Altgeld, T.
Gerechtigkeit schafft mehr Gesundheit für alle!
In: Proceedings (14. Kongress - Armut und Gesundheit - am 5./ 6.12.2008 in Berlin). Berlin: 2008.
Pretzl, B.; Kim, T.S.; Holle, H.; Eickholz, P.
Long-term results of guided tissue regeneration therapy with non-resorbable and bioabsorbable barriers. IV. A case series of infrabony defects after 10 years.
J. Periodontol. 79, 1491-1499 (2008)
BACKGROUND: A 10-year follow-up study was conducted to clinically evaluate the long-term results after guided tissue regeneration (GTR) therapy of infrabony defects using non-resorbable and bioabsorbable barriers. METHODS: Twelve pairs of contralateral infrabony defects were treated in 12 subjects with advanced periodontitis. Within each subject, one defect received a non-resorbable barrier and the other received a bioabsorbable barrier by random assignment. Clinical parameters were obtained at baseline and at 12 and 120+/-6 months after surgery. RESULTS: Eight of 12 subjects were available for the examination at 120+/-6 months. Twelve and 120+/-6 months after GTR therapy statistically significant (P<0.05) vertical clinical attachment level (CAL-V) gain was observed in both groups (3.4+/-1.0 mm and 1.5+/-1.2 mm for the control group at 12 and 120 months, respectively, and 3.3+/-1.6 mm and 3.5+/-2.5 mm for the test group at 12 and 120 months, respectively). However, 120+/-6 months after GTR therapy, three infrabony defects (two controls and one test) had lost >2 mm of the attachment that had been gained 12 months after GTR therapy, and a statistically significant mean CAL-V loss of 1.7+/-1.3 mm was observed from 12 to 120+/-6 months in the control group. One tooth in the control group was lost between 60 and 120+/-6 months. The case series failed to show statistically significant differences between test and control regarding CAL-V gain 120+/-6 months after surgery. CONCLUSION: CAL-V gain achieved 12 months after GTR therapy in infrabony defects using non-resorbable and bioabsorbable barriers was stable after 10 years in 12 of 16 defects.
Journal of Periodontology

Rückert, I.-M.; Böcken, J.; Mielck, A.
Are German patients burdened by the practice charge for physician visits ('Praxisgebuehr')? A cross sectional analysis of socio-economic and health related factors.
BMC Health Serv. Res. 8:232 (2008)
BACKGROUND: In 2004, a practice charge for physician visits ('Praxisgebuehr') was implemented in the German health care system, mainly in order to reduce expenditures of sickness funds by reducing outpatient physician visits. In the statutory sickness funds, all adults now have to pay euro 10 at their first physician visit in each 3 month period, except for vaccinations and preventive services. This study looks at the effect of this new patient fee on delaying or avoiding physician visits, with a special emphasis on different income groups. METHODS: Six representative surveys (conducted between 2004 and 2006) of the Bertelsmann Healthcare Monitor were analysed, comprising 7,769 women and men aged 18 to 79 years. The analyses are based on stratified analyses and logistic regression models, including a focus on the subgroup having a chronic disease. RESULTS: Two results can be highlighted. First, avoiding or delaying a physician visit due to this fee is seen most often among younger and healthier adults. Second, those in the lowest income group are much more affected in this way than the better of. The multivariate analysis in the subgroup of respondents having a chronic disease shows, for example, that this reaction is reported 2.45 times more often in the lowest income group than in the highest income group (95% CI: 1.90-3.15). CONCLUSION: The analyses indicate that the effects of the practice charge differ by socio-economic group. It would be important to assess these effects in more detail, especially the effects on health care quality and health outcomes. It can be assumed, however, that avoiding or delaying physician visits jeopardizes both, and that health inequalities are increasing due to the practice charge.
BMC Health Services Research

Donath, C.; Graeßel, E.; Großfeld-Schmitz, M.; Haag, C.; Kornhuber, J.; Neubauer, S.
Diagnostik und Therapie von Demenzerkrankungen in der hausärztlichen Praxis: Ein Stadt-Land-Vergleich.
Psychiatr. Prax. 35, 142-145 (2008)
ANLIEGEN: Hausärztliche Diagnostik und Therapie bei Demenzpatienten im Stadt-Land-Vergleich. METHODE: Querschnittsanalyse (n = 390) von Daten der Studie "IDA - Initiative Demenzversorgung in der Allgemeinmedizin". ERGEBNISSE: Die Versorgung hinsichtlich klinischer Diagnostik, Überweisung zum Facharzt und Therapie unterscheidet sich nicht zwischen städtischen und ländlichen Praxen. Es zeigten sich signifikante Unterschiede im Einsatz von Bildgebung zwischen Stadt (57,9%) und Land (42,7%). SCHLUSSFOLGERUNGEN: Die Ergebnisse sprechen für eine ähnliche Patientenversorgung in urbanen und ländlichen Regionen.
Psychiatrische Praxis

Mielck, A.
Zum Zusammenhang zwischen sozialer Ungleichheit und gesundheitlicher Versorgung.
In: Tiesmeyer, K.*; Brause, M.*; Lierse, M.*; Lukas-Nülle, M.*; Hehlmann, T.* [Eds.]: Der blinde Fleck. Ungleichheit in der Gesundheitsversorgung. Bern: Hans Huber, 2008. 21-38
Perz, S.; Küfner, R.; Holle, R.
Monitoring der Qualität von EKG-Registerungen in bevölkerungsbasierten Untersuchungen.
In: Malberg, H.*; Sander-Thömmes, T.*; Wessel, N.*; Wolf, W.* [Eds.]: Biosignalverarbeitung : Innovation bei der Erfassung und Analyse bioelektrischer und biomagnetischer Signale (Workshop Biosignalverarbeitung, 16-18 Juli 2008, Potsdam). Braunschweig; Berlin: Physikalisch-Technische Bundesanstalt, 2008. 168-171
Für die Validität und die Präzision diagnostisch relevanter elektrokardiographischer (EKG-) Ivferkmale spielt die Qualität der EKG-Registrierung eine bedeutende Rolle. Dies gilt trolz der Verfügbarkeit leistung.)jähiger Verfahren der Computer-EKG-Analyse mit vielen Möglichkeiten der Signal bereinigung. Im

Rahmen des Qualitätssicherungsprogramms des 4. KORA Gesundheits-Surveys (KORA-S4) wurde ein kontinuierliches Monitoring der EKG-Signalqualität durchgeführt. Ziel war die Verfügbarkeit störllngsarmer EKG-Sequenzen für die exakte und unverzerrte Schätzung bevölkerungsbezogener EKG-Parameter. Im KORA-S4 wurden 4261 Personen aus der Allgemeinbevölkerllng der Region Augsburg im Rahmen eines umfangreichen standardisierten Prögramms untersucht.
Mielck, A.
Armut macht krank - Krankheit macht arm. Vermeidung von Scham und Stigmatisierung bei Maßnahmen zur Verringerung der gesundheitlichen Ungleichheit.
In: Proceedings (Schande Armut. Stigmatisierung und Beschämung. 7.Armutskonferenz, Salzburg, Österreich, 04.03.-05.03.2008). Wien: Die Armutskonferenz. Österreichisches Netzwerk gegen Armut und soziale Ausgrenzung, 2008. 41-44
Hartz, S.C.; Rogowski, W.H.
Entscheidungsprozesse über die Kostenerstattung für neue medizinische Verfahren in den USA.
Gesundheitsökon. Qualitätsmanag. 13, 345-357 (2008)
Erstattung in den USA - MedicareZiel: Erstattung ist für den wirtschaftlichen Erfolg eines Herstellers neuer medizinischer Technologien entscheidend. Dieser Beitrag liefert einen Überblick über die Entscheidungsprozesse über die Kostenerstattung und Anforderungen für neue medizinische Verfahren wie z. B. Produkte der regenerativen Medizin beim staatlichen Programm Medicare sowie über bestehende Erstattungsentscheidungen zu verschiedenen Produkten. Methode: Vorhandene Prozessbeschreibungen wurden im Internet recherchiert, aus der Medicare Coverage Database wurden über 60 Erstattungsentscheidungen zu Produkten der regenerativen Medizin untersucht. Ergebnis: Bei Medicare lassen sich zwei Entscheidungsprozesse unterscheiden. "National Coverage Decisions" gelten landesweit für alle Medicare-Anbieter, während die weniger formalen "Local Coverage Decisions" auf Ebene der Medicare-Vertragspartner getroffen werden. Entscheidend für die Erstattung eines neuen Verfahrens ist die Erfüllung des gesetzlich vorgegebenen Kriteriums "reasonable and necessary", dessen Operationalisierung in der Praxis jedoch nicht eindeutig ist. Eine LCD weist die Erstattung von autologer Chondrozytenimplantation mangels Evidenz zur Wirksamkeit zurück, Apligraf® und Dermagraft® werden mit unterschiedlichen Indikationseinschränkungen erstattet. Becaplermin ist als "self-administered drug" in Medicare Part A und B von der Erstattung ausgeschlossen. Schlussfolgerung: Prozesse und Anforderungen bei Medicare sind zugänglich und transparent. Die Verwendung von Kosteneffektivität ist umstritten und spielt derzeit bei Medicare - anders als beim englischen National Health Service - explizit keine Rolle. Hersteller sollten sich jedoch mittelfristig auch auf den Nachweis der Kosteneffektivität einstellen.Teil 2: Erstattung in den USA - private VersicherungsträgerZielsetzung: Eine Erstattung im Zielmarkt ist für den wirtschaftlichen Erfolg eines Herstellers einer neuen medizinischen Technologie von entscheidender Bedeutung. Dieser Beitrag liefert einen Überblick über die Entscheidungsprozesse über die Kostenerstattung für neue medizinische Verfahren wie z. B. Produkte der regenerativen Medizin bei ausgewählten privaten Versicherungsträgern in den USA sowie über bestehende Erstattungsentscheidungen zu verschiedenen Produkten. Methode: Die Internetseiten von über 60 privaten Versicherungsträgern wurden auf vorhandene Prozessbeschreibungen sowie auf Erstattungsentscheidungen von Produkten der regenerativen Medizin hin recherchiert. Ergebnisse: Erstattungsentscheidungen bei privaten Versicherungsträgern werden meist vom Medical Director getroffen. Entscheidend ist dabei, dass ein Verfahren "medically necessary" und nicht "investigational/experimental" ist. Erstattungsentscheidungen verschiedener Versicherungsträger sind heterogen und fallen selbst bei gleicher Evidenzlage teilweise unterschiedlich aus. Schlussfolgerung: Bei privaten Versicherungsträgern sind Prozessbeschreibungen und Anforderungen uneinheitlich sowie häufig intransparent. Bewertungen der Wirtschaftlichkeit spielen auch im privaten Sektor derzeit eine eher untergeordnete Rolle.
Gesundheitsökonomie & Qualitätsmanagement

Krauth, C.; John, J.; Aidelsburger, P.; Brüggenjürgen, B.; Hansmeier, T.; Hessel, F.; Kohlmann, T.; Moock, J.; Rothgang, H.; Schweikert, B.; Seitz, R.; Wasem, J.
Stellungnahme der AG Methoden der gesundheitsökonomischen Evaluation (AG MEG) zu dem Methodenpapier 'Methodik für die Bewertung von Verhältnissen zwischen Nutzen und Kosten im System der deutschen gesetzlichen Krankenversicherung' des Instituts für Qualität.
Gesundheitswesen 70, e1-e16 (2008)
Mit dem Wettbewerbsstärkungsgesetz von April 2007 kann das Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG) vom Gemeinsamen Bundesausschuss (G-BA) mit der Kosten-Nutzen-Bewertung von Arzneimitteln beauftragt werden. Im Januar 2008 hat das IQWiG in einem ersten Methodenvorschlag dargelegt, wie es die Kosten-Nutzen-Bewertung zukünftig durchzuführen gedenkt. In der vorliegenden Stellungnahme der AG Methoden der gesundheitsökonomischen Evaluation (AG MEG) wird der Methodenvorschlag des IQWiG kritisch bewertet und Empfehlungen für eine Weiterentwicklung der Methoden gegeben. Zentrale Aussagen der Stellungnahme sind: (1) Das Methodenpapier ist unbalanciert. Es widmet sich zu einem überwiegenden Teil nicht dem Assessment, der eigentlichen Aufgabe des IQWiG, sondern dem Appraisal, das von den nachfolgenden Entscheidungsträgern (Gemeinsamer Bundesausschuss und Spitzenverband Bund) zu leisten ist. (2) Das IQWiG beabsichtigt, lediglich indikationsspezifische Vergleiche durchführen. Es übersieht dabei, dass die Entscheidungsträger über Erstattungsbeträge von Arzneimitteln in unterschiedlichen Indikationsgebieten entscheiden und dabei faktisch jeweils auch über die Gesundheitsausgaben insgesamt entscheiden. (3) Das IQWiG beabsichtigt ein zweistufiges Bewertungsverfahren, bei dem eine Kosten-Nutzen-Bewertung nur durchgeführt wird, wenn die vorgeschaltete Nutzenbewertung einen Zusatznutzen ausweist. Insofern ist sicherzustellen, dass alle relevanten Nutzenkomponenten der Kosten-Nutzen-Bewertung bereits in der Nutzenbewertung berücksichtigt werden. Dementsprechend sind spezifische gesundheitsökonomische Nutzenparameter (wie zum Beispiel QALYs) zu berücksichtigen, zudem sollte die Community Effectiveness abgebildet werden und die langfristigen Outcomes sollten bereits in der Nutzenbewertung modelliert werden. In der Stellungnahme werden weitere Probleme diskutiert, die sich um die zentralen Kritikpunkte gruppieren. Zudem erweist sich, dass der Methodenvorschlag des IQWiG noch nicht vollständig ist. Dementsprechend wird empfohlen, auch für die nächste Fassung des Methodenvorschlags ein Stellungnahmeverfahren vorzusehen.

Gesundheitswesen, Das

Mielck, A.; Janßen, C.
Ein Modell zur Erklärung der gesundheitlichen Ungleichheit.
Public Health Forum 16, 4-5 (2008)
Public Health Forum

Gräßel, E.; Donath, C.; Lauterberg, J.; Haag, C.; Neubauer, S.
Demenzkranke und Pflegestufen: Wirken sich Krankheitssymptome auf die Einstufung aus?
Gesundheitswesen 70, 129-136 (2008)
As the levels of care within long-term nursing care regulations are defined according to limitations in performing fundamental activities of daily living, the extent to which medically diagnosed cognitive, emotional and behavioral dementia symptoms are taken into account in the grading, should be investigated. METHOD: 390 patients with mild to moderate dementia from the Mid-Franconia region, were included into the IDA ("Initiative Demenzversorgung in Allgemeinmedizin") study by specially trained general practitioners. The GPs had diagnosed dementia and noted the accompanying signs at baseline. In an interview with the caregiver, the Barthel Index was used to measure the level of help required with fundamental daily tasks. Predictors for grading were set down using logistic regression analysis. RESULTS: Where one accompanying sign is present, about half the patients had not been assigned a grade. Besides the Barthel Index, the presence of agitation and agnosia and the absence of depression are the only independent predictors for grading. All other symptoms, impairment of the executive function, loss of orientation, aphasia, anxiety, sleeplessness, aggressiveness and tendency to wander, have no significant predictive value. CONCLUSION: In the future development of nursing care insurance, the need for nursing care should be redefined using symptoms associated with dementia, particularly sleeplessness, aggressiveness and the tendency to wander as inclusion criteria. This is a prerequisite of improving the care available to dementia patients in the long term and also of expanding relief measures for family caregiver.
Gesundheitswesen, Das

Kreck, S.; Klaus, J.; Leidl, R.; von Tirpitz, C.; Konnopka, A.; Matschinger, H.; König, H.H.
Cost effectiveness of ibandronate for the prevention of fractures in inflammatory bowel disease-related osteoporosis: Cost-utility analysis using a Markov model.
Pharmacoeconomics 26, 311-328 (2008)
Osteoporosis is a frequent complication in patients with inflammatory bowel disease. Recent studies have shown bisphosphonates to considerably reduce fracture risk in patients with osteoporosis, and preventing fractures with bisphosphonates has been reported to be cost effective in older populations. However, no studies of the cost effectiveness of these agents in preventing fractures in patients with inflammatory bowel disease are available. OBJECTIVE: To investigate the cost effectiveness of the bisphosphonate ibandronate combined with calcium/colecalciferol ('ibandronate') in patients with osteopenia or osteoporosis due to inflammatory bowel disease in Germany. Treatment strategies used for comparison were sodium fluoride combined with calcium/colecalciferol ('fluoride') and calcium/colecalciferol ('calcium') alone. STUDY DESIGN AND METHODS: A cost-utility analysis was conducted using data from a randomized controlled trial (RCT). Changes in bone mineral density (BMD) were adjusted and predicted for a standardized population receiving each respective treatment. A Markov model was developed, with probabilities of transition to fracture states consisting of BMD-dependent and -independent components. The BMD-dependent component was assessed using predicted change in BMD from the RCT. The independent component captured differences in bone quality and micro-architecture resulting from prevalent fractures or treatment with anti-resorptive drugs.The analysis was conducted for a population with a mean age of the RCT patients (women aged 36 years, men aged 38 years) with osteopenia (T-score about -2.0 at baseline), a population of the same age with osteoporosis (T-score of -3.0 at baseline) and for an older population (both sexes aged 65 years) with osteoporosis (T-score of -3.0). Outcomes were measured as costs per QALY gained from a societal perspective. The treatment duration in the RCT was 42 months. A 5-year period was assumed to follow, during which the treatment effects linearly declined to 0. The simulation time was 10 years.Prices for medication and treatment were presented as year 2004 values; costs and effects were discounted at 5%. To test the robustness of the results, univariate and probabilistic sensitivity analyses (Monte Carlo simulation) were conducted. RESULTS: The calcium strategy dominated the fluoride strategy. When the ibandronate strategy was compared with the calcium strategy, the base-case cost-effectiveness ratios (costs per QALY gained) were between euro 407 375 for an older female population with osteoporosis and euro 6 516 345 for a younger female population with osteopenia. Univariate sensitivity analyses resulted in variations between 4% of base-case results and dominance of calcium. In Monte Carlo simulations, conducted for the various populations, the probability of an ICER of ibandronate below euro 50 000 per QALY was never greater than 20.2%. CONCLUSION: The ibandronate strategy is unlikely to be considered cost effective by decision makers in men or women with characteristics of those in the target population of the RCT, or in older populations with osteoporosis.
PharmacoEconomics

Mielck, A.
Zum Zusammenhang zwischen sozialer Ungleichheit und gesundheitlicher Versorgung.
In: Tiesmeyer, K.* [Eds.]: Der blinde Fleck : Ungleichheiten in der Gesundheitsversorgung. Bern [u.a.]: Huber, 2008. 21-38
Rogowski, W.H.; Hartz, S.C.; John, J.H.
Clearing up the hazy road from bench to bedside: A framework for integrating the fourth hurdle into translational medicine.
BMC Health Serv. Res. 8:194 (2008)
New products evolving from research and development can only be translated to medical practice on a large scale if they are reimbursed by third-party payers. Yet the decision processes regarding reimbursement are highly complex and internationally heterogeneous. This study develops a process-oriented framework for monitoring these so-called fourth hurdle procedures in the context of product development from bench to bedside. The framework is suitable both for new drugs and other medical technologies. METHODS: The study is based on expert interviews and literature searches, as well as an analysis of 47 websites of coverage decision-makers in England, Germany and the USA. RESULTS: Eight key steps for monitoring fourth hurdle procedures from a company perspective were determined: entering the scope of a healthcare payer; trigger of decision

process; assessment; appraisal; setting level of reimbursement; establishing rules for service provision; formal and informal participation; and publication of the decision and supplementary information. Details are given for the English National Institute for Health and Clinical Excellence, the German Federal Joint Committee, Medicare's National and Local Coverage Determinations, and for Blue Cross Blue Shield companies. CONCLUSION: Coverage determination decisions for new procedures tend to be less formalized than for novel drugs. The analysis of coverage procedures and requirements shows that the proof of patient benefit is essential. Cost-effectiveness is likely to gain importance in future.
BMC Health Services Research

Raible, C.; Amann, S.°; Querbach, C.°
Unit-dose-versorgung: Auswirkungen auf patienten- und mitarbeiterzufriedenheit innerhalb eines universitätskünikums
Krankenhauspharmazie 29, 207-217 (2008)
Background: A high quality drug supply is guaranteed, if the so called "5-R-rule" applies. This means that the right drug at the right time in the right dose is correctly applied to the right patient. It is questionable how a new form of drug supply, the unit-dose-system, will effect satisfaction of patients and employees in comparison to the normal ward stock system. Aim: The major aim was to measure the satisfaction of patients and employees, resulting from different drug provision systems. Method: Performing a prospective, consecutive observational study with a control and treatment phase (from 06/2005-12/2006). For each group 80 patients were included. The study was placed in selected surgical and internal wards of the Klinikum rechts der Isar (MRI) at the Technical University of Munich. Patient satisfaction, which was measured by a standardised questionnaire as well as the experiences, findings and estimations of the employees, which were surveyed using interviews with professionals, acted as parameters. Data retrieved by the patient questionnaires were analysed using statistical and multivariate methods. For the interpretation of the interviews with the professionals the qualitative content analysis according to Mayring was applied. Results: Between the study groups, both the demographical and medical characteristics are comparable. The satisfaction of patients with the hospital pharmacy supply increases from 79.3 % by 7.3 percentage points to 86.6 % ($p = 0.008$). The results of the staff survey show a heterogeneous image. In most instances the consulting and information services of the hospital pharmacists were appraised as good. Positive aspects of the new supply organisation are e. g. improved transparency in prescription and automatic picking of the drugs in the hospital pharmacy. Negative aspects include the risk of new error source in the electronic prescription and the dependence on electronic systems. The lack of spontaneity and flexibility as well as the high efforts of coordination of the new system are the main critical points. On the surgical wards, the outcomes of the qualitative parameters are better than on the internal wards. Discussion and conclusion: The implementation of the study in an academic hospital restricts the generalisability of the results to other suppliers. In this study the unit-dose-supply lead to a higher patient satisfaction with drug supply. Due to better results regarding all qualitative parameters on the surgical wards, the unit-dose-system should be implemented in these areas first. Decision-makers should integrate the staff from the first step of implementation onwards so that they can handle the new system in an efficient way.
Krankenhauspharmazie KPH

Kuhn, K.A.; Knoll, A.; Mewes, H.-W.; Schwaiger, M.; Bode, A.; Broy, M.; Daniel, H.; Feussner, H.; Gradinger, R.; Hauner, H.; Höfler, H.; Holzmann, B.; Horsch, A.; Kemper, A.; Krcmar, H.; Kochs, E.F.; Lange, R.; Leidl, R.; Mansmann, U.; Mayr, E.W.; Meitinger, T.; Molls, M.; Navab, N.; Nüsslin, F.; Peschel, C.; Reiser, M.; Ring, J.; Rummeny, E.J.; Schlichter, J.; Schmid, R.; Wichmann, H.-E.; Ziegler, S.
Informatics and medicine--from molecules to populations.
Methods Inf. Med. 47, 283-295 (2008)
To clarify challenges and research topics for informatics in health and to describe new approaches for interdisciplinary collaboration and education. METHODS: Research challenges and possible solutions were elaborated by scientists of two universities using an interdisciplinary approach, in a series of meetings over several months. RESULTS AND CONCLUSION: In order to translate scientific results from bench to bedside and further into an evidence-based and efficient health system, intensive collaboration is needed between experts from medicine, biology, informatics, engineering, public health, as well as social and economic sciences. Research challenges can be attributed to four areas: bioinformatics and systems biology, biomedical engineering and informatics, health informatics and individual healthcare, and public health informatics. In order to bridge existing gaps between different disciplines and cultures, we suggest focusing on interdisciplinary education, taking an integrative approach and starting interdisciplinary practice at early stages of education.
Methods of Information in Medicine

Happich, M.; John, J.; Stamenitis, S.; Clouth, J.; Polnau, D.
The quality of life and economic burden of neuropathy in diabetic patients in Germany in 2002--Results from the Diabetic Microvascular Complications (DIMICO) study.
Diabetes Res. Clin. Pract. 81, 223-230 (2008)
To describe the health-related quality of life (HRQOL), the resource utilization and annual costs associated with diabetic neuropathy (DN) in Germany. METHODS: In this retrospective, observational study German internists, diabetologists and general practitioners provided information on 185 adult type 1 and type 2 diabetic patients with DN. Health-related quality of life (HRQOL) was assessed using generic and disease specific questionnaires. Socio-demographic and resource use data were assessed from medical charts and through patient interviews. Based on these results, national-level cost estimates were calculated using German unit costs. RESULTS: The majority of DN patients were severely impaired with regard to general physical HRQOL. Disease specific HRQOL decreased continuously with increasing DN severity. In accordance, costs associated with DN increased as DN progressed, with costs from the societal perspective increasing about 50-fold from the lowest severity stage (patients with sensory-motor neuropathy without symptoms) (euro431) to patients with lower extremity amputation in the year 2002 (euro21,476). The German statutory health insurance covered more than two thirds of the total costs of DN. CONCLUSIONS: The results described in this report show that diabetic neuropathy in adults with type 1 or type 2 diabetes generates significant reductions in the patient's quality of life and a substantial economic burden both for society and health insurance.
Diabetes Research and Clinical Practice

Hartz, S.; John, J.
Contribution of economic evaluation to decision making in early phases of product development: A methodological and empirical review.
Int. J. Technol. Assess. Health Care 24, 465-472 (2008)
Economic evaluation as an integral part of health technology assessment is today mostly applied to established technologies. Evaluating healthcare innovations in their early states of development has recently attracted attention. Although it offers several benefits, it also holds methodological challenges.Objectives: The aim of our study was to investigate the possible contributions of economic evaluation to industry's decision making early in product development and to confront the results with the actual use of early data in economic assessments.Methods: We conducted a literature research to detect methodological contributions as well as economic evaluations that used data from early phases of product development.Results: Economic analysis can be beneficially used in early phases of product development for various purposes including early market assessment, R&D portfolio management, and first estimations of pricing and reimbursement scenarios. Analytical tools available for these purposes have been identified. Numerous empirical works were detected, but most do not disclose any concrete decision context and could not be directly matched with the suggested applications.Conclusions: Industry can benefit from starting economic evaluation early in product development in several ways. Empirical evidence suggests that there is still potential left unused.
International Journal of Technology Assessment in Health Care

Schweikert, B.; Hahmann, H.; Leidl, R.
Development and first assessment of a questionnaire for health care utilization and costs for cardiac patients.
BMC Health Serv. Res. 8:187 (2008)
The valid and reliable measurement of health service utilization, productivity losses and consequently total disease-related costs is a prerequisite for health services research and for health economic analysis. Although administrative data sources are usually considered to be the most accurate, their use is limited as some components of utilization are not systematically captured and, especially in decentralized health care systems, no single source exists for comprehensive utilization and cost data. The aim of this study was to develop and test a questionnaire for the measurement of disease-related costs for patients after an acute cardiac event (ACE). METHODS: To design the questionnaire, the literature was searched for contributions to the assessment of utilization of health care resources by patient-administered questionnaires. Based on these findings, we developed a retrospective questionnaire appropriate for the measurement of disease-related costs over a period of 3 months in ACE patients. Items were generated by reviewing existing guidelines and by interviewing medical specialists and patients. In this study, the questionnaire was tested on 106 patients, aging 35-65 who were admitted for rehabilitation after ACE. It was compared with prospectively measured data; selected items were compared with administrative data from sickness funds. RESULTS: The questionnaire was accepted well (response rate = 88%), and respondents completed the questionnaire in an average time of 27 minutes. Concordance between retrospective and prospective data showed an intraclass correlation (ICC) ranging between 0.57 (cost of medical intake) and 0.9 (hospital days) with the other main items (physician visits, days off work, medication) clustering around 0.7. Comparison between self-reported and administrative data for days off work and hospitalized days were possible for n = 48. Respective ICCs ranged between 0.92 and 0.94, although differences in mean levels were observed. CONCLUSION: The questionnaire was accepted favorably and correlated well with alternative measurement approaches. This first assessment showed promising characteristics of this questionnaire in different aspects of validity for patients with ACE. However, additional research and more extensive tests in other patient groups would be worthwhile.
BMC Health Services Research

Rückinger, S.; von Kries, R.; Pauli, S.; Munte, A.; Mielck, A.
Die Krebsfrüherkennungsuntersuchung für Frauen wird in Regionen mit niedrigerem Haushaltseinkommen seltener in Anspruch genommen - Analyse von Daten der Kassenärztlichen Vereinigung Bayerns.
Gesundheitswesen 70, 393-397 (2008)
Ziel der Studie: Soziale Ungleichheiten in der gesundheitlichen Versorgung sind in Deutschland bisher kaum untersucht worden. Die vorhandenen Forschungsergebnisse lassen aber vermuten, dass Personen mit niedrigem sozialem Status weniger an den Krebsfrüherkennungsuntersuchungen teilnehmen.
Gesundheitswesen, Das

Eller, M.; Holle, R.; Landgraf, R.; Mielck, A.
Social network effect on self-rated health in type 2 diabetic patients - results from a longitudinal population-based study.
Int. J. Public Health 53, 188-194 (2008)
The aim is to analyse the association between social network and self-rated health in a longitudinal design for persons with type 2 diabetes, comparing them with persons without diabetes. METHODS: The analyses are based on data from the population-based 'KORA-A study' conducted in the region of Augsburg (Germany), with data from 1990/1995 (t (0)) and 1998 (t (1)), including 164 persons with type 2 diabetes and 207 persons without diabetes. The social network was assessed by the Berkman/Syme index. RESULTS: For the type 2 diabetes group, the multivariate analyses show that a high score of social network at t (0) is associated with good self-rated health at t (1), even if self-rated health at t (0) is included in the model (OR 2.69; 95 % CI: 1.21-5.98). For the non-diabetes group, no such association was found. CONCLUSIONS: The results point towards a 'buffer effect' of the social network, indicating that the positive effect on health can be seen mostly among those who are exposed to a high level of burden, in this case exposed to a chronic disease such as type 2 diabetes.
International Journal of Public Health

Mielck, A.
'Die Ärzte sind die natürlichen Anwälte der Armen': Der Beitrag von Ärzten zur Verringerung der gesundheitlichen Ungleichheit.
Dtsch. Med. Wochenschr. 133, 1457-1460 (2008)
Deutsche Medizinische Wochenschrift - DMW

Mielck, A.
Regionale Unterschiede bei Gesundheit und gesundheitlicher Versorgung : Weiterentwicklung der theoretischen und methodischen Ansätze.

In: Bauer, U.*; Bittlingmayer, U.H.*; Richter, M.* [Eds.]: Health Inequalities : Determinanten und Mechanismen gesundheitlicher Ungleichheit. Wiesbaden: VS Verl. für Sozialwissenschaften, 2008. 167-187

von Klot, S.; Mittleman, M.A.; Dockery, D.W.; Heier, M.; Meisinger, C.; Hörmann, A.; Wichmann, H.-E.; Peters, A.
Intensity of physical exertion and triggering of myocardial infarction : A case-crossover study.
Eur. Heart J. 29, 1881-1888 (2008)
AIMS: Acute myocardial infarction (AMI) can be precipitated or triggered by discrete transient exposures including physical exertion. We evaluated whether the risk of having an AMI triggered by physical exertion exhibits an exposure-response relationship, and whether it varies by ambient temperature or by taking place indoors or outdoors. METHODS AND RESULTS: We conducted a case-crossover study within the Myocardial Infarction Registry in Augsburg, Germany in 1999-2003. One thousand three hundred and one patients reported levels of activity and time spent outdoors on the day of AMI and three preceding days in an interview. The case-crossover analyses showed an association of physical exertion with AMI symptom onset within 2 h, which was strong for strenuous exertion (METs >or= 6) [relative risk (RR) 5.7, 95% confidence interval (CI) 3.6-9.0), and still significant for moderate exertion (METs = 5) (RR 1.6, 95% CI 1.2-2.1) compared to very light or no exertion. Strenuous exertion outside was associated with a four-fold larger RR of AMI symptom onset than exertion performed indoors, which was not explained by temperature. CONCLUSION: This study confirms previous results and shows a graded exposure-response relationship between physical exertion intensity and triggering of AMI onset. These findings may have implications for behavioural guidance of people at risk of AMI.
European Heart Journal

Lampert, T.; Mielck, A.
Gesundheit und soziale Ungleichheit: eine Herausforderung für Forschung und Politik.
G + G 8, 7-16 (2008)
Gesundheit und Gesellschaft - Blickpunkt

Lindert, J.; Brähler, E.; Wittig, U.; Mielck, A.; Priebe, S.
Depressivität, Angst und posttraumatische Belastungsstörung bei Arbeitsmigranten, Asylbewerbern und Flüchtlingen: Systematische Übersichtsarbeit zu Originalstudien.
Psychother. Psychosom. Med. Psychol. 58, 109-122 (2008)
Hintergrund: Weltweit gab es im Jahr 2006 etwa 200 Millionen transnationale Migranten. Migranten werden unterschieden in „freiwillige", insbesondere Arbeitsmigranten oder sogenannte „Gastarbeiter" und „unfreiwillige" Migranten, insbesondere Flüchtlinge und Asylbewerber. Depressivität, Angst und posttraumatische Belastungsstörung sind häufige Syndrome in der Allgemeinbevölkerung, die Studienergebnisse in Bezug auf Migranten sind heterogen. Ziele Ziel dieses Reviews ist es, die Prävalenzraten von Depressivität, Angst (Syndrome und Störungen) und posttraumatischer Belastungsstörung (PTBS) bei Arbeitsmigranten und Flüchtlingen zu beschreiben und zu vergleichen sowie zu untersuchen, ob ein Zusammenhang zwischen den Prävalenzraten und der Studienqualität vorliegt.Methode Wir suchten zunächst systematisch Studien in den elektronischen Datenbanken EMBASE und MEDLINE von im Zeitraum von 1994 - 2007 veröffentlichten Originalstudien. Die Studien, die die Ein- und Ausschlusskriterien erfüllten, wurden systematisch beschrieben und nach 15 Qualitätskriterien bewertet. Ergebnisse Die systematische Literatursucher ergab 348 Ergebnisse, von diesen erfüllten 37 Studien mit 35 untersuchten Populationen die Einschlusskriterien, die Studien beziehen sich auf n = 24 681 Migranten (Arbeitsmigranten: n = 16 971; Flüchtlinge: n = 7710). Die Studiengröße variiert zwischen einem Minimum von n = 55 Teilnehmer und einem Maximum von n = 4558 Teilnehmer (mediane Teilnehmerzahl: n = 338). Die Prävalenzraten der untersuchten Studien liegen für Depressivität zwischen 3 % und 47 % (Arbeitsmigranten) bzw. zwischen 3 % und 81 % (Flüchtlinge); für Angst zwischen 6 % und 44 % (Arbeitsmigranten) bzw. zwischen 5 % und 90 % (Flüchtlinge) und für PTBS zwischen 4 % und 86 %. Keine Studie erfüllt die 15 von uns aufgestellten Qualitätskriterien. Zusammenfassung und Ausblick Migranten sind eine heterogene Gruppe mit unterschiedlichen Prävalenzraten von Depressivität, Angst und posttraumatische Belastungsstörung. Dringend benötigt zur realistischen Abschätzung des Versorgungsbedarfes werden bevölkerungsrepräsentative Studien.
Psychotherapie, Psychosomatik, Medizinische Psychologie

Mielck, A.; Altgeld, T.; Reisig, V.; Kümpers, S.
Quantitative Zielvorgaben zur Verringerung der gesundheitlichen Ungleichheit. Erfahrungen aus England und Umsetzungsmöglichkeiten in Deutschland.
In: Gesundheit Berlin* [Ed.]: Proceedings (Dokumentation 13. bundesweiter Kongress 'Armut und Gesundheit', Berlin, Germany, 30.11.-01.12.2007). Berlin: Gesundheit Berlin-Brandenburg e.V., 2008. CD-ROM

Gapp, O.
Die Balanced Scorecard in gesetzlichen Krankenkassen: Eine empirische Studie zum Stand der Anwendung und deren Ausgestaltung.
Z. oeffentl. gemeinwirtsch. Unternehmen 31, 107-132 (2008)
Oliver Gapp; The Balanced Sc orecard in the statutory health insurance: an empirical study of the implementation and design Balanced Scorecard; co mpetition; controlling; empirical study; healthcare system; man- agement; sickness fund; stat utory health insurance The usefulness of the Balanced Scorecard (B SC) as a management tool for German sick- ness funds has been discussed for a few years. However empirical studies are still miss- Das Managementkonzept der Balanced Scorecard (BSC) wird seit wenigen Jahren in Bezug auf dessen Einsatz in gesetzlichen Krankenkassen diskutiert. Bislang fehlen hierzu empirische Untersuchungen. Ziel des vorliegenden Beitrags ist es, in einer empirischen Studie den Bekanntheitsgrad, den Stand der Anwendung sowie den Aufbau und die Ausgestaltung der BSC in gesetzlichen Krankenkassen zu untersuchen. Darüber hinaus werden die Charakteristika der BSC-Krankenkassen und der Einsatz BSC-naher Steuerungsinstrumente dargestellt. Hierzu wurden bei einer schriftlichen Vollerhebung 247 gesetzliche Krankenkassen im Sommer 2006 angeschrieben. Ferner wurden leitfadengestützte Experteninterviews durchgeführt. Die Ergebnisse zeigen, dass sich die BSC als Steuerungsinstrument für gesetzliche Krankenkassen bei entsprechenden Anpassungen gut eignet, insbesonder wegen des Integrationspotenzials qualitativer Erfolgsgrößen. Allerdings wird die BSC in Krankenkassen bislang noch seltener angewandt als in anderen Branchen. The usefulness of the Balanced Scorecard (BSC) as a management tool for German sickness funds has been discussed for a few years. However

empirical studies are still missing. The aim of this study is to investigate empirically the level of awareness and implementation as well as the design of the BSC in sickness funds. Furthermore characteristics of BSC-funds and the application of (BSC-related) management instruments will be examined. In a comprehensive survey 247 sickness funds were contacted with a questionnaire and structured interviews were preformed. The results show amongst others, that with appropriate adjustments the BSC seems to be a suitable management tool for sickness funds, in particular because of its integration of qualitative measures. However, the diffusion of the BSC in sickness funds is behind other branches.
Zeitschrift für Öffentliche und Gemeinwirtschaftliche Unternehmen

Krauth, C.; John, J.; Aidelsburger, P.; Brüggenjürgen, B.; Hansmeier, T.; Hessel, F.; Kohlmann, T.; Moock, J.; Rothgang, H.; Schweikert, B.; Seitz, R.; Wasem, J.
Stellungnahme der AG Methoden der gesundheitsökonomischen Evaluation (AG MEG) in der Deutschen Gesellschaft für Sozialmedizin und Prävention. (DGSMP) zum 1. Entwurf des IQWiG Methodenpapiers zur Kosten-Nutzen-Bewertung von Arzneimitteln.
Gesundheitsökon. Qualitätsmanag. 13, 171-173 (2008)
Since the coming into force of the GKV-Wettbewerbsstärkungsgesetz ("Act to strengthen competition in the statutory health insurance system") in April 2007, the Gemeinsame Bundesausschuss (G-BA "Federal Joint Committee") can commission the Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG--Institute for Quality and Efficiency in Health Care") with the assessment of costs and benefits of drugs. In January 2008, IQWiG published a working document for consultation describing the proposed methods for carrying out those evaluations. This commentary by the AG Methoden der Gesundheitsökonomischen Evaluation (AG MEG--"Working Group for methods of economic evaluation in health care") provides a critical appraisal and recommendations for the further development of IQWIG's draft guidelines. The core statements of the commentary are as follows: (1) The draft guidelines are unbalanced. Instead of providing comprehensive methodological guidance for health technology assessment, which is the actual task of IQWiG, they deal predominantly with the methods of technology appraisal which is in the responsibility of the decision-making bodies, i.e. of the G-BA and the Spitzenverband Bund der Krankenkassen ("Central Federal Association of Health Insurance Funds"). (2) IQWiG intends to compare the cost-effectiveness of alternative treatment options only within a given therapeutic area. The rationale for this restriction is not clear, as the decision-makers have to determine ceiling prices across therapeutic areas and diseases and effectively the overall volume of health care expenditure, as well. (3) IQWiG aims at carrying out an economic evaluation only if in a preceding benefit assessment a drug has been judged to be superior. Therefore, it has to be assured that the benefit assessment is performed in such a way that its results may be used for the economic assessment. This requires the application of summary scores for the joint measurement of multidimensional endpoints (as, e.g., QALYs), to evaluate community effectiveness instead of efficacy, and to choose a time horizon that is sufficiently long to reflect any differences in the health benefits between the technologies being compared. Furthermore, the comment hints at some additional problems embodied in the draft guidelines and a number of key methodological issues which are not discussed at all in the working document. In summary, the methods currently proposed by IQWiG are not up to the task of conducting economic evaluations. It is strongly recommended to perform a public consultation process for the revised draft guidelines anew.
Gesundheitsökonomie & Qualitätsmanagement
Leidl, R.
Orientierungspunkte für die Beurteilung der Wirtschaftlichkeit von Gesundheitsleistungen in Deutschland.
Z. Evid. Fortbild. Qual. Gesundhwes. 102, 110-111 (2008)
Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen

Rückert, I.-M.; Mielck, A.
Soziale Ungleichheit beim Stillen in Deutschland: Stand der empirischen Forschung und Handlungsempfehlungen.
Präv. Gesundheitsf. 3, 56-66 (2008)
Hintergrund: Der Zusammenhang zwischen dem sozioökonomischen Status (SES) der Mutter einerseits und dem Stillen andererseits wurde bereits in mehreren empirischen Studien beschrieben, meist jedoch nur am Rande. Eine deutschsprachige Veröffentlichung speziell zum Thema 'Stillen und SES' liegt unseres Wissens bisher noch nicht vor. Es fehlt auch ein Überblick über die bereits verfügbaren empirischen Informationen zu diesem Thema. Dies hat dazu geführt, dass bis heute kaum über das Thema „soziale Ungleichheit beim Stillen“ diskutiert wird. Die hier vorgestellte Arbeit soll eine Antwort auf die Frage geben, in welchen sozialen Statusgruppen ein besonders großer Bedarf an Maßnahmen zur Förderung des Stillens vorhanden ist, und welche Handlungsempfehlungen sich daraus ableiten lassen. Methoden Der Überblick basiert auf einem systematischen Review epidemiologischer Studien, in denen (meist im Rahmen anderer Fragestellungen) Daten zum Stillen und/oder zur Stilldauer sowie zum SES erhoben wurden. Hauptquelle war dabei die elektronische Datenbank 'Medline'. Ergebnisse Insgesamt wurden 15 Publikationen aus Deutschland gefunden, die eine Aussage über den Zusammenhang zwischen Stillen und SES beinhalten. In einer Studie wurde kein klarer Zusammenhang gefunden, sie weist allerdings eine sehr kleine Fallzahl auf. Die anderen 14 Studien ergeben dagegen ein deutliches Bild: Mütter mit einem höheren sozialen Status (zumeist definiert über den Bildungsabschluss) stillen häufiger und länger als Mütter mit einem niedrigen sozialen Status. In 8 weiteren Untersuchungen wurden zwar Daten zu Stillen und SES erhoben, jedoch nicht miteinander in Beziehung gesetzt. Schlussfolgerung In der Diskussion über das Stillen wird immer wieder betont, dass Muttermilch die beste Form der Ernährung für Säuglinge bis zu einem Alter von mindestens 6 Monaten sei. In Deutschland ist beim Stillen (nach einem deutlichen Tiefstand in den 1970er Jahren) in letzter Zeit wieder eine 'Renaissance' zu beobachten, aber offenbar ist eine intensivere Stillförderung besonders bei den unteren Statusgruppen erforderlich. Als Ansatz zur Erklärung dieser statusspezifischen Unterschiede beim Verbreitungsgrad gesundheitsrelevanten Verhaltens bietet sich das Modell 'diffusion of innovations' an.
Prävention und Gesundheitsförderung

Leidl, R.
Promoting economic value in public health.
Eur. J. Public Health 18, 216 (2008)

European Journal of Public Health

Pretzl, B.; Kaltschmitt, J.; Kim, T.S.; Reitmeir, P.; Eickholz, P.
Tooth loss after active periodontal therapy. 2: Tooth-related factors.
J. Clin. Periodontol. 35, 175-182 (2008)
To assess tooth-related factors contributing to tooth loss over a period of 10 years after completion of active periodontal therapy (APT). MATERIAL AND METHODS: All patients who had received APT by the same experienced periodontist, 10 years before beginning the research, were recruited until 100 patients were re-examined. Examinations included, at the patient level: test for interleukin-1 polymorphism, compliance to supportive periodontal therapy (SPT), mean plaque scores during SPT; at the tooth level: assessment of baseline bone loss (type, amount), tooth type, furcation status and abutment status. Logistic multilevel regression was performed for statistical analysis. RESULTS: Hundred patients with 2301 teeth at the baseline (completion of APT) were retrospectively examined. One hundred fifty-five teeth were lost over 10 years after APT. Logistic multilevel regression identified high plaque scores, irregular attendance of SPT and age as patient-related factors significantly accounting for tooth loss. Tooth-related factors significantly contributing to tooth loss were baseline bone loss, furcation involvement and use as an abutment tooth. However, in patients with regular SPT, 93% of teeth with 60-80% bone loss at the baseline, survived 10 years. CONCLUSION: The following tooth-related risk factors for tooth loss were identified: baseline bone loss, furcation involvement, and use as an abutment tooth.
Journal of Clinical Periodontology

Eickholz, P.; Kaltschmitt, J.; Berbig, J.; Reitmeir, P.; Pretzl, B.
Tooth loss after active periodontal therapy. 1: Patient-related factors for risk, prognosis, and quality of outcome.
J. Clin. Periodontol. 35, 165-174 (2008)
Assessment of patient-related factors contributing (1) to tooth loss and (2) to the quality of treatment outcome 10 years after initiation of anti-infective therapy. MATERIAL AND METHODS: All patients who had received active periodontal treatment 10 years ago by the same examiner were recruited consecutively until a total of 100 patients were re-examined. Re-examination was performed by a second examiner and included clinical examination, test for interleukin-1 (IL-1) polymorphism, smoking history, review of patients' files (e.g. regularity of supportive periodontal therapy: SPT). Statistical analysis included Poisson and logistic regressions. RESULTS: Fifty-three patients attended SPT regularly, 59 were females, 38 were IL-1 positive. Poisson regressions identified mean plaque index during SPT ($p<0.0001$), irregular attendance of SPT ($p<0.0001$), age ($p<0.0001$), initial diagnosis ($p=0.0005$), IL-1 polymorphism ($p=0.0007$), smoking ($p=0.0053$), and sex ($p=0.0487$) as factors significantly contributing to tooth loss. Additionally, mean plaque index during SPT ($p=0.011$) and irregular SPT ($p=0.002$) were associated with a worse periodontal status 10 years after initiation of therapy. CONCLUSION: The following risk factors for tooth loss were identified: ineffective oral hygiene, irregular SPT, IL-1 polymorphism, initial diagnosis, smoking, age and sex.
Journal of Clinical Periodontology

Ziegler, D.; Rathmann, W.; Dickhaus, T.; Mielck, A.; KORA Study Group (Meisinger, C.; Wichmann, H.-E.; Holle, R.; John, J.; Illig, T.; Peters, A.)
Prevalence of polyneuropathy in pre-diabetes and diabetes is associated with abdominal obesity and macroangiopathy: The MONICA/KORA Augsburg Surveys S2 and S3.
Diabetes Care 31, 464-469 (2008)
It is controversial whether there is a glycemic threshold above which polyneuropathy develops and which are the most important factors associated with polyneuropathy in the general population. The aim of this study was to determine the prevalence and risk factors of polyneuropathy in subjects with diabetes, impaired fasting glucose (IFG), impaired glucose tolerance (IGT), or normal glucose tolerance (NGT). RESEARCH DESIGN AND METHODS: Subjects with diabetes (n = 195) and control subjects matched for age and sex (n = 198) from the population-based MONICA (Monitoring Trends and Determinants on Cardiovascular Diseases)/KORA (Cooperative Research in the Region of Augsburg) Augsburg Surveys 1989/1990 (S2) and 1994/1995 (S3) aged 25-74 years were contacted again and assessed in 1997/1998 by the Michigan Neuropathy Screening Instrument using a score cut point >2. An oral glucose tolerance test was performed in the control subjects. RESULTS: Among the control subjects, 46 (23.2%) had IGT, 71 (35.9%) had IFG, and 81 had NGT. The prevalence of polyneuropathy was 28.0% in the diabetic subjects, 13.0% in those with IGT, 11.3% in those with IFG, and 7.4% in those with NGT (P
Diabetes Care

Lehrke, M.; Konrad, A.; Schachinger, V.; Tillack, C.; Seibold, F.; Stark, R.G.; Parhofer, K.G.; Broedl, U.C.
CXCL16 is a surrogate marker of inflammatory bowel disease.
Scand. J. Gastroenterol. 43, 283-288 (2008)
Impaired barrier function of the gut and inadequate immunological response to intestinal pathogens are the cornerstones in the pathogenesis of inflammatory bowel disease (IBD). CXCL16 is a protein which shares pattern recognition receptor functions, relevant for adhesion and phagocytosis of bacterial products, with the properties of an adhesion molecule and inflammatory chemokine. The relevance of CXCL16 in IBD has so far been elusive. This objective of this study was to determine the association between CXCL16 and IBD. Material and methods. Soluble CXCL16 (sol-CXCL16) serum levels in a cohort of 239 patients with Crohn's disease were measured, 114 patients with ulcerative colitis and 144 controls. Results. In a univariate analysis, sol-CXCL16 was found to be markedly increased in patients with Crohn's disease or ulcerative colitis compared with that in controls ($p<0.001$). This was significantly associated with an increase of the inflammatory marker C-reactive protein (CRP) ($p<0.01$). In the multivariate analysis (adjusted for age, gender, body mass index (BMI), white blood cell (WBC) count, resistin and CRP) sol-CXCL16 was associated with Crohn's disease above versus below the median (OR 10.53 (3.97-27.78) $p<0.001$) and ulcerative colitis (OR 3.46 (1.40-8.55) $p<0.01$). Conclusion. Our findings suggest that CXCL16 may play a pro-inflammatory role in IBD, particularly Crohn's disease.
Scandinavian Journal of Gastroenterology

Mielck, A.
Soziale Ungleichheit und Gesundheit in Deutschland: Die internationale Perspektive.
Bundesgesundheitsbl.-Gesund. 51, 345-352 (2008)
In den letzten Jahren hat sich in Deutschland eine lebhafte Diskussion zum Thema gesundheitliche Ungleichheit entwickelt. Die internationale Perspektive wird dabei jedoch weitgehend

vernachlässigt. Wichtig sind hier vor allem 2 Fragen: Ist die gesundheitliche Ungleichheit in Deutschland so groß wie in den anderen westeuropäischen Staaten? Welche Themen und Initiativen stehen im Vordergrund bei einer über die westeuropäischen Staaten hinausgehenden, weltweiten Betrachtung von Problemen der gesundheitlichen Ungleichheit? Es liegen bereits empirische Studien vor, die eine Beantwortung der ersten Frage ermöglichen. Diese Information ist jedoch relativ weit verstreut und bisher noch nicht systematisch zusammengefasst worden. Der hier vorliegende Überblick macht deutlich, dass die gesundheitliche Ungleichheit in Deutschland ungefähr das gleiche Ausmaß aufweist wie in den anderen westeuropäischen Staaten. Die globale Betrachtung zeigt auf, wie aus wissenschaftlicher Sicht versucht wird, die großen Unterschiede zwischen den reichen und armen Staaten stärker als bisher zu thematisieren.
Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz

von Lengerke, T.; Wolfenstetter, S.B.; John, J.
Adipositasassoziierte Versorgungsinanspruchnahme und Krankheitskosten in Deutschland.
In: Hilbert, A.*; Rief, W.*; Dabrock, P.* [Eds.]: Gewichtige Gene: Adipositas zwischen Prädisposition und Eigenverantwortung. Bern [u.a.]: Huber, 2008. 83-101 (Psychologie Forschung)
Arnold-Wörner, N.; Holle, R.; Rathmann, W.; Mielck, A.
The importance of specialist treatment, treatment satisfaction and diabetes education for the compliance of subjects with type 2 diabetes - results from a population-based survey.
Exp. Clin. Endocrinol. Diabet. 116, 123-128 (2008)
AIMS: This study aims to investigate the degree to which subjects with type 2 diabetes comply with treatment recommendations concerning diet, physical exercise and self-care, the consistency of compliance across different treatment areas, and the association of compliance with individual characteristics of patients and their medical treatment. METHODS: The sample consists of 345 type 2 diabetes patients who had been drawn from two population-based surveys (MONICA) and from a myocardial infarction registry in Southern Germany, and who have participated in a survey in 1997/98. Data were collected by interviews, questionnaires and medical exams. Pearson correlation and logistic regression analysis were applied to test the relationships. A compliance score was established by adding up the components of the treatment regimen. RESULTS: Only one fifth of the subjects with type 2 diabetes showed good compliance in terms of the applied score. Compliance was highest in weight measuring and foot care, and poorest in following exercise recommendations, glucose testing, and recording the results. Overall, weak correlations were found between the components of the treatment regimen. Participation in diabetes education, regular consultation of physicians specialized in diabetes care, age (<70 years), and satisfaction with treatment were all associated with better compliance. CONCLUSIONS: Correlation between the different components of compliance behaviour was low, indicating that compliance should not be measured by one component only. As compliance with the treatment recommendations was poor, education programs for type 2 diabetic subjects should be propagated and the cooperation with diabetes specialists should be promoted.
Experimental and Clinical Endocrinology & Diabetes

Kemptner, D.; Wildner, M.; Abu-Omar, K.; Caselmann, W.H.; Kerscher, G.; Reitmeir, P.; Mielck, A.; Rütten, A.
Regionale Unterschiede des Gesundheitsverhaltens in Bayern - Mehrebenenanalyse einer bevölkerungsrepräsentativen Befragung in Verbindung mit sozioökonomischen Strukturdaten.
Gesundheitswesen 70, 28-37 (2008)
Es bestehen regionale Unterschiede der Sterblichkeit in Bayern. Eine vorangegangene Studie legte Verhaltensfaktoren und sozioökonomische Faktoren als Ursachen nahe. Ziel der vorliegenden Arbeit ist es, den Einfluss von verhaltensbedingten Risikofaktoren, sozioökonomischen Faktoren und regionalen Strukturen auf den individuellen Gesundheitszustand als Prädiktor der Sterblichkeit zu quantifizieren.
Gesundheitswesen, Das

2007
Rogowski, W.H.; Langer, A.
Gentests und deren Einsatz für Reihenuntersuchungen aus gesundheitsökonomischer Perspektive.
In: Schmidtke, J.* [Eds.]: (Gendiagnostik in Deutschland. Status quo und Problemerkundung. Supplement zum Gentechnologiebericht). Berlin: Berlin-Brandenburgische Akademie der Wissenschaften, 2007. 87-106 (Forschungsberichte der Interdisziplinären Arbeitsgruppen der Berlin-Brandenburgischen Akademie der Wissenschaften; 18)
no Abstract
Rogowski, W.H.
Key Issues in the Economic Evaluation of Gene Technology in Healthcare.
München, Ludwig-Maximilians-Universität München, Volkswirtschaftliche Fakultät, Diss., 2007, 159 S.
Icks, A.; Moebus, S.; Feuersenger, A.; Haastert, B.; Jöckel, K.-H.; Mielck, A.; Giani, G.
Widening of a social gradient in obesity risk? German national health surveys 1990 and 1998.
Eur. J. Epidemiol. 22, 685-690 (2007)
Whether differences in obesity prevalences across social status levels have widened remains controversial. METHODS: We used German national health surveys (1990-1992 and 1998, n = 7,466 and 5,583, age 25-69 years) to estimate obesity prevalences and its associations with calendar year, age (25-39, 40-60, and 61-69), and educational level (low, middle, and high), as well as an interaction term (year x educational level) in men and women. We used multiple regression models, considering the sample design. RESULTS: Obesity prevalence in 1990 and 1998 was 18.1 (95% CI 16.5-19.7) and 19.9 (18.2-21.6) in men and 20.9 (19.2-22.6) and 21.6 (19.3-23.7) in women, with statistically significantly higher prevalences in higher age and lower education. A statistically significant increase of obesity prevalence was present only in men after adjustment for age and education. The increase seems to be highest in high-educated subjects. However, interaction was not statistically significant, except in middle compared to high-educated men (OR 0.67; 0.47-0.96). CONCLUSIONS: Obesity prevalence increased only moderately in Germany between 1990-1992 and 1998. There was a tendency of reduction of the social gradient in obesity instead of a widening.
European Journal of Epidemiology

Mielck, A.; Helmert, U.
Das Arzt-Patienten-Verhältnis in der ambulanten Versorgung : Unterschiede zwischen GKV- und PKV-Versicherten.

In: Böcken, J.*; Braun, B.*; Amhof, R.* [Eds.]: Gesundheitsmonitor 2007: Gesundheitsversorgung und Gestaltungsoptionen aus der Perspektive von Bevölkerung und Ärzten. Gütersloh: Bertelsmann, 2007. 114-132

von Lengerke, T.
Individuum und Bevölkerung zwischen Verhältnissen und Verhalten.
In: von Lengerke, T.* [Eds.]: Public Health-Psychologie: Individuum und Bevölkerung zwischen Verhältnissen und Verhalten. Weinheim: Juventa, 2007. 11-18

Breckenkamp, J.; Mielck, A.; Razum, O.
Health inequalities in Germany: Do regional-level variables explain differentials in cardiovascular risk?
BMC Public Health 7:132 (2007)
Socioeconomic status is a predictor not only of mortality, but also of cardiovascular risk and morbidity. An ongoing debate in the field of social inequalities and health focuses on two questions: 1) Is individual health status associated with individual income as well as with income inequality at the aggregate (e. g. regional) level? 2) If there is such an association, does it operate via a psychosocial pathway (e.g. stress) or via a "neo-materialistic" pathway (e.g. systematic under-investment in societal infrastructures)? For the first time in Germany, we here investigate the association between cardiovascular health status and income inequality at the area level, controlling for individual socio-economic status. METHODS: Individual-level explanatory variables (age, socio-economic status) and outcome data (body mass index, blood pressure, cholesterol level) as well as the regional-level variable (proportion of relative poverty) were taken from the baseline survey of the German Cardiovascular Prevention Study, a cross-sectional, community-based, multi-center intervention study, comprising six socio-economically diverse intervention regions, each with about 1800 participants aged 25-69 years. Multilevel modeling was used to examine the effects of individual and regional level variables. RESULTS: Regional effects are small compared to individual effects for all risk factors analyzed. Most of the total variance is explained at the individual level. Only for diastolic blood pressure in men and for cholesterol in both men and women is a statistically significant effect visible at the regional level. CONCLUSION: Our analysis does not support the assumption that in Germany cardiovascular risk factors were to a large extent associated with income inequality at regional level.
BMC Public Health

von Lengerke, T.; Manz, R.
Krankheitsprävention und Gesundheitsförderung. Klassifikationen und eine dimensionale Systematik.
In: von Lengerke, T.* [Eds.]: Public Health-Psychologie: Individuum und Bevölkerung zwischen Verhältnissen und Verhalten. Weinheim: Juventa, 2007. 19-31

von Lengerke, T.; Abu-Omar, K.
Verhaltensepidemiologie. Einblicke in ein neues Wissengebiet.
In: von Lengerke, T.* [Eds.]: Public Health-Psychologie: Individuum und Bevölkerung zwischen Verhältnissen und Verhalten. Weinheim: Juventa, 2007. 32-44

von Lengerke, T.
Die "holy four". Rauchen, Alkoholkonsum, Bewegung und Ernährung (RABE).
In: von Lengerke, T.* [Eds.]: Public Health-Psychologie: Individuum und Bevölkerung zwischen Verhältnissen und Verhalten. Weinheim: Juventa, 2007. 74-76

Mielck, A.
Sozialer Status und Gesundheitszustand - Ansätze zur Verbesserung der gesundheitlichen Chancengleichheit.
Forum TTN 18, 42-57 (2007)
Forum TTN

John, J.
Effizienz als Richtschnur für die Gestaltung des Leistungskatalogs der Gesetzlichen Krankenversicherung? Anmerkungen zum normativen Geltungsanspruch gesundheitsökonomischer Evaluationen.
Forum TTN 18, 23-41 (2007)
Forum TTN

Huber, C.; Baumeister, S.E.; Ladwig, K.-H.; Mielck, A.
Living with a partner and health care use – results from the MONICA survey Augsburg in Southern Germany.
GMS Psycho-Social-Medicine 4:Doc13 (2007)
Several studies have shown that social relationships are associated with health care use. This study aims to test if and to which extent a proximal element of social relationships, particularly living together with a partner, influences the health care utilisation in the same way as a distal element such as group membership.Methods: On the basis of a representative random sample of a southern German population (4856 participants), the associations were assessed between the following groups of variables: number of consultations with the general practitioner or internists, type of social relationships (living with a partner, friends, relatives, group memberships), need (evaluated and perceived health status), socio-demographic variables.Results: All analyses showed associations between living with a partner and health care utilisation. Individuals living with a partner had lower levels of utilisation than individuals not living with a partner (mean: 4.3 vs. 5.2). These associations persisted after controlling for socio-demographic and need variables. For the other indicators of social relationships, though, there were no significant associations with outpatient visits.Conclusions: Distinguishing between different types of social relationships is important for disentangling the overall effects of social relationships on health care utilisation. Also, the empirical findings confirm that health care research should not be restricted to medical variables, but should also include psycho-social factors.
GMS Psycho-Social Medicine

Broedl, U.C.; Schachinger, V.; Lingenhel, A.; Lehrke, M.; Stark, R.G.; Seibold, F.; Göke, B.; Kronenberg, F.; Parhofer, K.G.; Konrad-Zerna, A.
Apolipoprotein A-IV is an independent predictor of disease activity in patients with inflammatory bowel disease.
Inflamm. Bowel Dis. 13, 391-397 (2007)
ApoA-IV, an apolipoprotein (apo) with antioxidant, antiatherogenic, and antiinflammatory properties, was recently demonstrated to inhibit dextran sulfate sodium (DSS)-induced experimental colitis in mice. We therefore hypothesized that apoA-IV may be associated with disease activity in patients with inflammatory bowel disease (IBD). METHODS: We addressed this question by testing for associations between apoA-IV genotypes, apoA-IV plasma levels, inflammatory parameters, and clinical disease activity in 206 patients with Crohn's disease (CD), 95 subjects with ulcerative colitis (UC), and 157 healthy controls. RESULTS: In CD patients, apoA-IV plasma levels were

inversely associated with C-reactive protein (CRP) (P = 0.005) and disease activity (P = 0.01) in univariate analysis. In multiple logistic regression analysis, apoA-IV levels were identified as an independent predictor of elevated CRP (odds ratio [OR] 0.956, 95% confidence interval [CI]: 0.916-0.998, P = 0.04) and active disease (OR 0.957, 95% CI: 0.918-0.998, P = 0.04). In UC patients the apoA-IV gene variant 360 His (P = 0.03) but not apoA-IV levels (P = 0.15) were associated with increased disease activity in univariate analysis. This association, however, was lost in multiple logistic regression analysis (OR 3.435, 95% CI 0.995-11.853, P = 0.05). CONCLUSIONS: To our knowledge, this is the first study to demonstrate an association of apoA-IV with disease activity in patients with CD. Further studies are needed to define the relationship of apoA-IV to IBD.
Inflammatory Bowel Diseases

Rogowski, W.H.
Current impact of gene technology on healthcare: A map of economic assessment.
Health Policy 80, 340-357 (2007)
Abstract: Objectives : It has been claimed that gene technology will induce revolutionary changes in healthcare. This paper investigates how and to what extent these changes have been economically assessed. Methods A generic framework was developed to distinguish between methodologically similar evaluations of healthcare technology. Methodological issues and the current state of economic evidence concerning human DNA technology were extracted from publications within these groups of evaluations. Results Economic evaluations of “healthcare consisting of gene technology” were identified primarily for in vitro diagnostics for hereditary disease and others for pharmacogenetics and molecular pathology. “Healthcare enabled by gene technology” is far more encompassing and includes, e.g., biotechnology drugs for which various health economic evaluations can be found. Yet here, the impact of gene technology intertwines with the impact of other technologies and is therefore hardly susceptible to evaluation. The fields of evaluation may be classified best according to the two dimensions “purpose” and “stage of development”. Current evaluations cover screening, diagnostic and treatment technologies in investigational, new and established stages. Apart from prenatal screening, healthcare consisting of gene technology was cost saving only for genotype tests replacing continuous phenotype tests and for one pharmacogenetic test. Conclusive evidence of favourable cost-effectiveness ratios is available only for few conditions. Conclusion:Hypotheses about the impact of gene technology on healthcare must be explicit about the definition of “genetic” medicine. A general statement regarding healthcare enabled by gene technology is not possible. Based on current evidence, an era of healthcare consisting of gene technology built on widespread predictive testing is not desirable from a health economic viewpoint.
Health Policy

Mielck, A.; Rogowski, W.H.
Bedeutung der Genetik beim Thema "soziale Ungleichheit und Gesundheit".
Bundesgesundheitsbl.-Gesund. 50, 181-191 (2007)
Zusammenfassung In Deutschland ist bisher kaum in systematischer Weise überlegt worden, ob und wie das Thema genetische Veranlagung und medizinische Gentests mit dem Thema soziale und gesundheitliche Ungleichheit verbunden ist. Der vorliegende Beitrag soll zur Schließung dieser Lücke beitragen. Er konzentriert sich dabei auf die vertikale soziale Ungleichheit, d. h. auf die Unterschiede nach dem sozialen Status. Im ersten Schritt wird darauf hingewiesen, dass sich die Diskussion über den möglichen Einfluss genetisch determinierter Faktoren auf die soziale Ungleichheit bisher vor allem auf die Merkmale Körpergröße und Intelligenz konzentriert hat. Es wird betont, dass der Sozialstatus vor allem sozial und nicht genetisch geprägt wird. Im zweiten Schritt wird die medizinische Nutzung genetischer Tests angesprochen. Es ist zu vermuten, dass die unteren Statusgruppen genetische Tests besonders selten in Anspruch nehmen und dass sie deren Ergebnisse besonders schlecht interpretieren können. In Bezug auf genetische Tests, die eine positive Wirkung auf den Gesundheitszustand haben können, ist daher mit einer Vergrößerung der gesundheitlichen Ungleichheit zu rechnen. Empirische Untersuchungen zur Überprüfung dieser Hypothesen liegen bisher jedoch kaum vor. Im dritten Schritt wird der Frage nachgegangen, ob das Vorliegen genetischer Informationen über ein Individuum zu sozialer Diskriminierung führen kann (z. B. bei Kranken-/Lebensversicherungen, Arbeitgebern). Es wird gefolgert, dass diese Gefahr bisher (noch) relativ gering ist. Zum Abschluss wird auf den Forschungsbedarf hingewiesen und auch darauf, dass bereits heute Interventionsbedarf besteht (z. B. gleicher Zugang zu genetischen Tests für alle Bevölkerungsgruppen, bessere Wissensvermittlung in den unteren Statusgruppen).
Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz

Gapp, O.
Umsetzungsverfahren gesetzlicher Krankenkassen mit der Balanced Scorecard: Ein Ergebnisbericht der Gründe, Vorgehensweise und Probleme.
Z. Ges. Versicher.-Wirtsch. 3, 281-304 (2007)
Zeitschrift für die Gesamte Versicherungswissenschaft

Konrad, A.; Lehrke, M.; Schachinger, V.; Seibold, F.; Stark, R.G.; Ochsenkühn, T.; Parhofer, K.G.; Göke, B.; Broedl, U.C.
Resistin is an inflammatory marker of inflammatory bowel disease in humans.
Eur. J. Gastroenterol. Hepatol. 19, 1070-1074 (2007)
Resistin, a recently discovered adipokine, has been shown to be associated with inflammatory conditions such as insulin resistance, obesity, atherosclerosis and rheumatoid arthritis. We therefore hypothesized that (i) resistin levels may be elevated in patients with inflammatory bowel disease (IBD) and (ii) resistin levels may be associated with disease activity in IBD. METHODS: We addressed these questions by testing for associations between resistin plasma levels, inflammatory parameters and clinical disease activity in a case-control study with 235 patients with Crohn's disease (CD), 112 patients with ulcerative colitis (UC) and 144 healthy controls. RESULTS: Patients with IBD showed significantly higher resistin levels compared with controls (P<0.0001). In both, patients with CD and UC, resistin concentrations were significantly associated with elevated white blood cell count (P<0.0001), C-reactive protein (CRP) (P<0.0001) and disease activity (P< or =0.0001). In multivariate logistic regression analysis, resistin levels were identified as an independent predictor of active disease (odds ratio 1.014, 95% confidence interval 1.002-1.027, P=0.02) in patients with CD after adjusting for sex, age, body mass index,

white blood cell count and CRP. In UC patients, resistin was associated with active disease in multivariate regression analysis after control for sex, age, body mass index and white blood cell count (odds ratio 1.015, 95% confidence interval 1.002-1.029, P=0.02). Addition of CRP, however, abolished this association. CONCLUSION: Resistin levels are an independent predictor of disease activity in patients with CD. Resistin may represent a novel link between inflammation and IBD.
European Journal of Gastroenterology & Hepatology

Mielck, A.
Erklärungsmodelle regionaler Gesundheitsunterschiede. Zusammenstellung der wissenschaftlichen Evidenz für das Projekt ´Gesundheit regional` - Eine bevölkerungsrepräsentative Befragung zum Gesundheitsverhalten in Bayern.
In: Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit* [Ed.]: Proceedings (Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit). Erlangen: 2007. 40 S.
Mielck, A.; Altgeld, T.; Reisig, V.; Kümpers, S.
Quantitative Zielvorgaben zur Verringerung der gesundheitlichen Ungleichheit. Erfahrungen aus England und Umsetzungsmöglichkeiten in Deutschland.
In: Gesundheit Berlin* [Ed.]: Proceedings (13. Bundesweiter Kongress Armut und Gesundheit). Berlin: 2007.
von Lengerke, T.; Rütten, A.; Vinck, J.; Lüschen, G.; Mielck, A.; Eller, M.; John, J.
Soziale und politische Partizipation als Parameter gesundheitsförderlicher Lebensstile: Ergebnisse zweier Bevölkerungssurveys.
In: von Lengerke, T.* [Eds.]: Public Health-Psychologie: Individuum und Bevölkerung zwischen Verhältnissen und Verhalten. Weinheim: Juventa, 2007. 207-215
von Lengerke, T.; Rütten, A.; Vinck, J.; Lüschen, G.; Mielck, A.; Eller, M.; John, J.
Adipositas bei Erwachsenen. Ein public health-psychologischer Überblick.
In: von Lengerke, T.* [Eds.]: Public Health-Psychologie: Individuum und Bevölkerung zwischen Verhältnissen und Verhalten. Weinheim: Juventa, 2007. 121-135
Schellhorn, M.
Vergleich der Wartezeiten von gesetzlich und privat Versicherten in der ambulanten ärztlichen Versorgung.
In: Böcken, J.*; Braun, B.*; Amhof, R.* [Eds.]: Gesundheitsmonitor 2007. Gütersloh: Bertelsmann Stiftung, 2007. 95-113 (Gesundheitsmonitor 2007)
Gesundheitsmonitor 2007
Mielck, A.; Bayerl, B.; Koller, D.
Soziale Ungleichheit, Umweltbedingungen und Gesundheit anhand eines regionalen Beispiels.
München: 2007. 68 S. (Gesundheitsberichtserstattung der Landeshauptstadt München)
Schellhorn, M.
Vergleich der Wartezeiten von gesetzlich und privat Versicherten in der ambulanten ärztlichen Versorgung.
In: Böcken, J.*; Braun, B.*; Amhof, R.* [Eds.]: Gesundheitsmonitor 2007: Gesundheitsversorgung aund Gestaltungsoptionen aus der Perspektive von Bevölkerung und Ärzten. Gütersloh: Bertelsmann, 2007. 95-113
Kim,T.S.; Schenk, A.; Lungeanu, D.; Reitmeir, P.; Eickholz, P.
Nonsurgical and surgical periodontal therapy in single-rooted teeth.
Clin. Oral Investig. 11, 391-399 (2007)
The purpose of this study was to compare the effect of tooth related and patient related factors on the success of non-surgical and surgical periodontal therapy. In 41 patients (22 female) with untreated and/or recurrent periodontitis, no therapy, scaling and root planing (SRP), or access flap (AF) were assigned according to probing pocket depth (PPD). PPD and vertical relative attachment level (RAL-V) were obtained initially, 3 and 6 months after therapy. Baseline data were compared according to therapy, jaw, tooth type, and site. Factors influencing clinical parameters were identified using multilevel analyses. Baseline PPDs were deeper interproximally, in the maxilla and at premolars compared to buccal/oral sites, mandibular, and anterior teeth. At 6 months, PPD reduction and RAL-V gain were significantly greater at sites receiving SRP and AF as compared to untreated sites ($p < 0.001$). PPD reduction and RAL-V gain were significantly less ($p < 0.005$) in smokers as compared to nosmokers and at interproximal sites ($p < 0.0001$) as compared to buccal/oral sites. RAL-V gain was less in aggressive periodontitis, and PPD reduction was less in the maxilla ($p < 0.001$). In sites with greater bone loss and infrabony defects, a poorer response was observed regarding RAL-V gain or PPD reduction, respectively. The conclusions of the study are the following: (1) Nonsurgical and surgical periodontal therapies are effective in single-rooted teeth; (2) severe interproximal bone loss and infrabony defects deteriorate clinical results; and (3) there seem to be more defect-associated (tooth, site) factors influencing treatment outcome than patient-associated factors.
Clinical Oral Investigations

Chen, C.M.; Mielck, A.; Fahlbusch, B.; Bischof, W.; Herbarth, O.; Borte, M.; Wichmann, H.-E.; Heinrich, J.
Social factors, allergen, endotoxin, and dust mass in mattress.
Indoor Air 17, 384-393 (2007)
Indoor environment has been associated with allergic disease. Further, it has been observed that the prevalences of allergic sensitization are different in different social groups. We therefore investigated the association between socioeconomic status (SES) and indoor bio-contaminants. House dust samples were collected from parents' and infants' mattress from 2166 families in Munich (62.2%) and Leipzig (37.8%), Germany. Major mite allergen Der p 1 and Der f 1, cat allergen Fel d 1, and endotoxin were extracted and quantified. Parental educational level and family equivalent income were used independently as socioeconomic indicators. Indoor endotoxin, mite allergen Der p 1, and the amount of sampled dust were not associated with the social factors. Mite allergen Der f 1 was slightly associated by family SES but without a consistent pattern. In families who are not cat owners, however, a negative association between the amount of cat allergen and family SES were observed. The observed negative association between cat allergen loads and concentrations in mattress and family SES in non-cat owners' homes indicated that community is an important source of cat allergen exposure. PRACTICAL IMPLICATIONS: The study indicated that community is a major source of cat allergen exposure especially in communities of low SES.
Indoor Air

Neubauer, S.; Steinle, T.; Gapp, O.; König, H.-H.; Leidl, R.
Informationsbasis für die Abschätzung von gesundheitspolitischen und wirtschaftlichen Folgen von Tabakkontrollmaßnahmen in Deutschland.

Soz. Fortschr. 11, 271-279 (2007)
Sozialer Fortschritt

Mielck, A.
Erklärungsmodelle regionaler Gesundheitsunterschiede : Fachinformation Gesundheit. Zusammenstellung der wissenschaftlichen Evidenz für das Projekt "Gesundheit regional" - eine bevölkerungsrepräsentative Befragung zum Gesundheitsverhalten in Bayern.
Erlangen: Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit (LGL), 2007. 42 S.
Diese Publikation fasst den Stand der wissenschaftlichen Diskussion zur Erklärung regionaler Unterschiede der Gesundheit, auch unter Berücksichtigung sozioökonomischer Einflussfaktoren, zusammen. Der Bericht zeigt, welchen Einfluss die individuellen und regionalen Merkmale des sozialen Status auf den Gesundheitszustand ausüben können. Es wird der Stand der wissenschaftlichen Diskussion aufgezeigt und dargestellt, welche Merkmale bisher untersucht wurden, wie sich die Auswahl der Merkmale theoretisch begründen lässt, wie die Merkmale in den empirischen Studien erfasst wurden, und welche Ergebnisse diese Studien gezeigt haben. Der Schwerpunkt liegt auf dem dritten Kapitel, in dem die Frage im Vordergrund steht, wie sich der regionale Einfluss auf den Gesundheitszustand theoretisch und empirisch erfassen lässt.
von Lengerke, T.
Individuum und Bevölkerung zwischen Verhältnissen und Verhalten : Was ist Public Health-Psychologie?
In: von, L.e.n.g.e.r.k.e.*; T, .* [Eds.]: Public Health-Psychologie: Individuum und Bevölkerung zwischen Verhältnissen und Verhalten. Weinheim: Juventa, 2007. 11-18
von Lengerke, T.; Rütten, A.; John, J.
Soziale und politische Partizipation als Parameter gesunder Lebensstile : Ergebnisse zweier Bevölkerungssurveys.
In: von, L.e.n.g.e.r.k.e.*; T, .* [Eds.]: Public Health-Psychologie: Individuum und Bevölkerung zwischen Verhältnissen und Verhalten. Weinheim: Juventa, 2007. 207-215
von Lengerke, T.; Klotter, C.
Adipositas bei Erwachsenen : ein public health-psychologischer Überblick.
In: von Lengerke, T.* [Eds.]: Public Health-Psychologie: Individuum und Bevölkerung zwischen Verhältnissen und Verhalten. Weinheim: Juventa, 2007. 121-135
von Lengerke, T.; Manz, R.
Krankheitsprävention und Gesundheitsförderung : Klassifikationen und eine dimensionale Systematik.
In: von, L.e.n.g.e.r.k.e.*; T, .* [Eds.]: Public Health-Psychologie: Individuum und Bevölkerung zwischen Verhältnissen und Verhalten. Weinheim: Juventa, 2007. 19-31
von Lengerke, T.; Abu-Omar, K.
Verhaltensepidemiologie : Einblicke in ein neues Wissensgebiet.
In: von, L.e.n.g.e.r.k.e.*; T, .* [Eds.]: Public Health-Psychologie: Individuum und Bevölkerung zwischen Verhältnissen und Verhalten. Weinheim: Juventa, 2007. 32-44
von Lengerke, T.
Die holy four". Rauchen, Alkoholkonsum, Bewegung und Ernährung (RABE). "
In: von, L.e.n.g.e.r.k.e.*; T, .* [Eds.]: Public Health-Psychologie: Individuum und Bevölkerung zwischen Verhältnissen und Verhalten. Weinheim: Juventa, 2007. 74-76
Mielck, A.; Bayerl, B.; Koller, D.
Soziale Ungleichheit, Umweltbedingungen und Gesundheit anhand eines regionalen Beispiels. Gesundheitsberichterstattung.
München: Referat für Gesundheit und Umwelt der Landeshauptstadt München, 2007. 68 S. (Stadt-Gesundheit)
Bremer, C.; von Lengerke, T.
Häufiges Überessen nach Reduktionsdiät bei Frauen und Männern: Eine Bevölkerungsstudie zur Rolle der Unzufriedenheit mit dem Körpergewicht.
Z. Med. Psychol. 16, 183-192 (2007)
Der Zusammenhang von Diätverhalten und häufigem Überessen und die Rolle der Unzufriedenheit mit dem eigenen Körpergewicht für Frauen und Männer werden untersucht. Daten des Survey 1999/2001 der Kooperativen Gesundheitsforschung in der Region Augsburg (KORA) wurden regressionsanalytisch analysiert. Diätverhalten (mindestens eine Diät in den letzten zwölf Monaten), Unzufriedenheit mit dem Körpergewicht und Überessen wurden mit KORA-Items in computergestützten persönlichen Interviews erhoben. Für Alter, Wohnort, Familienstand, Sozialschicht, den anthropometrisch gemessenen Body Massindex, Ernährungsmuster, Alkoholkonsum, Rauchen und Bewegungsverhalten wurde adjustiert. Diätverhalten war nur bei Männern prädiktiv für häufiges Überessen. Demgegenüber waren die Odds häufigen Überessens bei beiden Geschlechtern mehr als verdoppelt, wenn Unzufriedenheit mit dem Gewicht vorlag. Zugleich ging der Zusammenhang zwischen Diätverhalten und Überessen bei Männern auf die Gruppe zurück, die unzufrieden mit ihrem Gewicht war. Unzufriedenheit mit dem Körpergewicht war stärker als Diätverhalten mit häufigem Überessen assoziiert und bei Männern eine Bedingung für die Assoziation zwischen Diätverhalten und häufigem Überessen. Die Studie legt nahe, im Rahmen essverhaltensbezogener Interventionen beim Thema Körpererleben insbesondere bei Männern das Diätverhalten zu berücksichtigen.
Zeitschrift für Medizinische Psychologie

von Lengerke, T.; John, J.
Excess use of general practitioners by obese adults: Does health-related quality of life account for the association?
Psychol. Health Med. 12, 536-544 (2007)
As general practitioners (GP) are seeing, and are likely to continue to see, increasing numbers of obese patients in their practices, it is relevant to know with which needs these patients enter general practice. The present study aims to determine whether besides physical comorbidities, health-related quality of life (HRQOL) accounts for associations of obesity with GP use. In a general population survey in Augsburg, Germany (KORA-Survey S4 1999/2001), anthropometric body mass (BMI in kg/(m(2))), physical comorbidities, HRQOL (the 12-item Short Form; SF-12), and visits to GP were assessed, and analyzed by logistic and zero-truncated negative binomial regressions (two-part model). Gender, age, socio-economic status, marital status, health insurance, and place of residence were adjusted for. The sample consisted of N = 942 residents aged 25 - 74, who had been randomly sampled from 17 cluster-sampled communities, and were either normal-weight, overweight, moderately obese, or severely obese. The moderately obese group had higher odds than the normal-weight to report any GP use; however, while being predictive, neither physical comorbidity nor HRQOL mediated this. In contrast, with regard to number of GP visits among users, the severely obese group (BMI >/= 35) reported

significantly more visits than the normal-weight group, and both physical comorbidity and physical (but not mental) HRQOL accounted for this. In conclusion, physical comorbidity and HRQOL mediate excess use of GP by severely obese users in terms of number of visits. Thus, for this group, subjective physical health seems to be important besides physical comorbidities, suggesting for general practice to focus both on evaluated and perceived needs of these patients.
Psychology, Health & Medicine

Teipel, S.J.; Ewers, M.; Reisig, V.; Schweikert, B.; Hampel, H.; Happich, M.
Long-term cost-effectiveness of donepezil for the treatment of Alzheimer's disease.
Eur. Arch. Psychiatry Clin. Neurosci. 257, 330-336 (2007)
Acetyl-)cholinesterase (ChE) inhibitors have been approved for the treatment of mild to moderate Alzheimer's disease (AD). However, use of ChE inhibitors is limited by budget constraints and disincentives on the side of health insurances and nursing care insurances. OBJECTIVE: To analyse under what conditions the application of the acetylcholinesterase inhibitor donepezil is favourable for the treatment of patients with AD from the perspective of health insurance and nursing care insurance companies in Germany, taking into account factors such as start and duration of treatment, duration of follow-up, drug costs, internalization of opportunity costs and varying mortality and efficacy rates. METHODS: Transition probabilities from a Swedish study and German cost data for donepezil were merged in a Markov model to follow a cohort of patients over a period of 5-10 years. We defined a base case with 1 year treatment and follow-up over 5 years and varied treatment length, follow-up interval and cost factors in sensitivity analyses. RESULTS: In the base case, the ChE inhibitor donepezil did not lead to cost savings but to a cost-effective outcome on side of health insurances and nursing care insurances. Early treatment of AD and internalization of opportunity costs (caring time devoted to patients) led to less costs per quality adjusted life years gained. However, results are very sensitive with respect to varying mortality and efficacy rates. CONCLUSION: The application of donepezil may be cost-effective, but considerable uncertainties remain. Moreover, the way the reimbursement system in Germany is presently arranged does not support the application of ChE inhibitors.
European Archives of Psychiatry and Clinical Neuroscience

Vollmar, H.C.; Gräßel, E.; Neubauer, S.; Großfeld-Schmitz, M.; Koneczny, N.; Schürer-Maly, C.-C.; Koch, M.; Ehlert, N.; Holle, R.; Rieger, M.; Butzlaff, M.
Multimodale Schulung von Hausärzten - Evaluation und Wissenszuwachs im Rahmen der Initiative Demenzversorgung in der Allgemeinmedizin (IDA).
Z. Arztl. Fortbild. Qualitatssich. 101, 27-34 (2007)
In many industrialized countries diagnostic and therapeutic deficits in the management of patients with dementia are well documented. Due to demographic trends the next years will see a further rise in the number of affected patients. Accordingly, the knowledge and competence of the physicians taking care of these patients need to be keep up-to-date. In the context of the three-armed cluster-randomized IDA trial (IDA = "Initiative Demenzversorgung in der Allgemeinmedizin"; Dementia Management Initiative in General Medicine), general practitioners (GPs) from the trial area (Bavaria, Germany) were trained in the diagnosis and treatment of dementia. METHODS: The educational training concept was based on the evidence-based guideline of Witten/Herdecke University (UWH). All participating GPs (n = 137, January 2006) received three hours training in the diagnosis of dementia. In addition, a subgroup was trained for two hours in dementia therapy (n = 90). Both groups obtained information about the study design. The didactic concept included screen and oral presentations by opinion leaders, video and interactive elements. At the beginning of the training sessions participants had to fill in a pilot-tested questionnaire with 20 multiple choice questions addressing the diagnosis and therapy of dementia (pretest). The same questionnaire was completed at the end of the training session (posttest) complemented by an evaluation sheet. Overall and intergroup differences between pre- and post-test results (increase in knowledge) were compared using the Chi-Square test. RESULTS: Overall, the quality of the training received a positive rating by the participants. By the end of January 2006, 137 doctors had been trained. The mean knowledge gain was 4.0+2.6 correctly answered questions ($p<0.001$; CI 3.6 to 4.5) comparing pre- and posttest (n = 132). In the group trained on diagnosis alone (n = 45), the gain averaged 2.0+/-1.9 questions. The group with additional training on therapy (n = 87) achieved a difference of 5.1 -2.3 questions ($p<0.001$). DISCUSSION: Participants of the dementia training achieved a substantial gain of knowledge. The extent of this knowledge increase was associated with the attendance to respective training modules. An ongoing trial will add further information about knowledge translation in the field of dementia.
Zeitschrift für Ärztliche Fortbildung und Qualität im Gesundheitswesen

Lauterberg, J.; Grossfeld-Schmitz, M.; Ruckdäschel, S.; Neubauer, S.; Mehlig, H.; Gaudig, M.; Hruschka, D.; Vollmar, H.C.; Holle, R.; Grässel, E.
Projekt IDA - Konzept und Umsetzung einer cluster-randomisierten Studie zur Demenzversorgung im hausärztlichen Bereich.
Z. Arztl. Fortbild. Qualitatssich. 101, 21-26 (2007)
Given the multiple deficits in dementia care IDA is a health services research project that addresses the key role of general practitioners in the early detection of dementia, patient and family education, therapy and referral to further counseling and supportive measures. Mid 2005 IDA was started by the AOK Bavaria as a pilot project targeting patients living at home. This three-armed cluster-randomized trial--currently including 180 participating general practitioners--is to compare two supportive measures of different intensity (counseling for care-giving relatives and care management) with the usual care in terms of time to nursing home placement. Additional outcomes investigated include the development of the patient's cognitive status and his abilities to perform activities of daily living, burden and quality of life of care-giving relatives as well as healthcare costs and costs of institutional care. Participating patients with initially mild to moderate disease will be observed for a period of two years. Data collection will proceed via general practitioners and caregivers and also utilize routine data of statutory health insurances and long-term care insurances. Keeping in mind that patient recruitment is ongoing throughout 2006 the initial analysis of 254 patients' data shows an average 80-year old patient in the early phase of moderate dementia. One third of the participants are cases with a first- time diagnosis obtained from their general

practitioner. Final results for IDA are expected to be available in 2009.
Zeitschrift für Ärztliche Fortbildung und Qualität im Gesundheitswesen

Icks, A.; Rathmann, W.; Haastert, B.; Gandjour, A.; Holle, R.; John, J.; Giani, G.; KORA Study Group (Wichmann, H.-E.; Illig, T.; Meisinger, C.; Peters, A.; Holle, R.; John, J.)
Clinical and cost-effectiveness of primary prevention of Type 2 diabetes in a 'real world' routine healthcare setting: Model based on the KORA Survey 2000.
Diabetic Med. 24, 473-480 (2007)
To analyse the clinical and cost-effectiveness of the primary prevention of Type 2 diabetes in a 'real world' routine healthcare setting using population-based data (KORA Survey in Augsburg, Germany, total population approximately 600,000). METHODS: Decision analytic model, time horizon 3 years. INTERVENTIONS: Staff education, targeted screening and lifestyle modification or metformin in people aged 60-74 years with a body mass index of > or = 24 kg/m(2) and prediabetic status (fasting glucose 5.3-6.9 mmol/l and 2-h post load glucose 7.8-11.0 mmol/l) (target population approximately 72,500), according to the Diabetes Prevention Program trial. MAIN OUTCOME MEASURES: Cases of Type 2 diabetes prevented, cost (Euro), incremental cost-effectiveness ratios (ICERs). RESULTS: Under model assumptions, 14 908 people in the target population would develop diabetes if there was no intervention, 184 cases would be avoided with lifestyle intervention and 42 cases with metformin intervention. From the perspective of statutory health insurance and society, costs for lifestyle modification were 856,507 euro (574,241 pounds) and 4,961,340 euro (3,326,307 pounds), respectively, and for metformin 797,539 euro (534,706 pounds) and 1,335,204 euro(895,181 pounds). Up to 5% of the costs were due to staff education and up to 36% to screening. Lifestyle was more cost effective than metformin. ICERs for lifestyle vs. 'no intervention' were 4664 euro (3127 pounds) and 27,015 euro (18,112 pounds) per case prevented from the statutory health insurance and societal perspective. CONCLUSIONS: Total cost and cost per case of diabetes avoided was high. Staff education and screening had a considerable impact. In view of the low participation in a routine healthcare setting, with both strategies only a small number of cases of diabetes would be prevented. Before implementing the programme, efforts should be made to improve patient participation in order to achieve better clinical and cost-effectiveness of the prevention of Type 2 diabetes in 'real world' clinical practice.
Diabetic Medicine

Kainzinger, F.; Raible, C.
Optimales Management von klinischen Studien: Welche Organisationsmodelle offeriert die theoretische Analyse, wie sieht die praktische Umsetzung aus?
Gesundheitsökon. Qualitätsmanag. 12, 217-224 (2007)
Background: Germany as a R&D location is encountering a growing competition with other nations. Third-party funds play an important role in financing university hospitals. The pressure on universities to implement efficient structures for clinical research through organizational changes is increasing. Aim: Which organization models for optimal management of clinical studies are offered by a theoretical analysis and how are these models currently implemented in German universities? Method: Theoretical analysis of the interface between universities and industries, as well as of the organizational structure within the university hospital from an economic perspective. Explorative empirical comparison between theoretical results and practical implementation in German universities. Data: Organizational charts from ten “Coordination-Centers for Clinical trials” (KKS) are used for the census. Results: Derived from the theoretical inter-company analysis, the theoretical optimal alternative seems to be a joint venture between the university hospital and pharmaceutical manufacturer, which, however, is deemed not feasible in practice. The existing relationship between the client and contractor should be optimized. The organizational analysis within the university hospital indicated that the conduct of clinical trials should be organized within a “clinical trial department”. This department should be managed within a matrix-project regime and additional staff positions should be made available to co-ordinate central activities. The explorative empirical census shows that only three out of ten KKS can be considered similar to the theoretical model (Dresden, Halle, Cologne). Conclusions: The organization model deduced from the theoretical analysis provides an alternative for university hospitals to optimize the management of clinical trials. This model is partly implemented in German Coordination Centers for Clinical Trials (KKS). Further empirical research should concentrate on outcome-based criteria.
Gesundheitsökonomie & Qualitätsmanagement

Zietemann, V.; Machens, P.; Mielck, A.; Kwetkat, A.
Soziale Kontakte und Depression bei geriatrischen Patienten: Gibt es einen Einfluss von Geschlecht?
Gesundheitswesen 69, 345-352 (2007)
Depression gehört zu den häufigsten affektiven Erkrankungen. Die Ermittlung von beeinflussbaren Faktoren, die mit Depression assoziiert sind, stellt eine wichtige Voraussetzung für Präventionsmaßnahmen dar. Bei 580 geriatrischen Patienten des Klinikums Neuperlach wurden in einer Querschnittstudie Daten zu sozialen Faktoren erhoben. In der vorliegenden Arbeit ist mit Hilfe ordinaler logistischer Regression ihre Assoziation mit Depression (klinische Diagnose mittels ICD-10) und depressiven Symptomen (GDS) untersucht worden. Die Ergebnisse zeigen, dass das Auftreten von depressiven Symptomen und von Depression mit geringeren sozialen Kontakten und weniger Unterstützung assoziiert war, auch nach Adjustierung für andere Risikofaktoren (zum Beispiel körperliche Beeinträchtigung und Demenz). Dieser Zusammenhang war bei Frauen (zum Beispiel depressive Symptome: mäßig versus viel Kontakte: OR=2,7; 95% KI: 1,8-4,1) deutlicher ausgeprägt als bei Männern (OR=1,3; 95% KI: 0,7-2,4). Ob Frauen jedoch stärker von Programmen zur Förderung von sozialer Unterstützung profitieren könnten als Männer, ist ein wichtiger Aspekt, der zukünftig noch in prospektiven Studien zu klären ist.
Gesundheitswesen, Das

Quentin, W.; Neubauer, S.; Leidl, R.; König, H.-H.
Advertising bans as a means of tobacco control policy: A systematic literature review of time-series analyses.
Int. J. Public Health 52, 295-307 (2007)
This paper reviews the international literature that employed time-series analysis to evaluate the effects of advertising bans on aggregate consumption of cigarettes or tobacco. A systematic search of the literature was conducted. Three groups of studies representing analyses of advertising bans in the USA, in other

countries and in 22 OECD countries were defined. The estimated effects of advertising bans and their significance were analysed.
International Journal of Public Health

Reisig, V.; Reitmeir, P.; Döring, A.; Rathmann, W.; Mielck, A.; KORA Study Group (Wichmann, H.-E.; Holle, R.; John, J.; Illig, T.; Meisinger, C.; Peters, A.)
Social inequalities and outcomes in type 2 diabetes in the German region of Augsburg. A cross-sectional survey.
Int. J. Public Health 52, 158-165 (2007)
To assess the association of socioeconomic position with health (care) outcomes in type 2 diabetes with a particular focus on glycaemic control. A cross-sectional survey in the region of Augsburg (Germany) on 373 men and women with type 2 diabetes, drawn from representative MONICA surveys and the myocardial infarct register. Analysis of association of socioeconomic position with HbA1c levels, cardiovascular risk factors and long-term macro- and microvascular diabetes complications using logistic regression models. Glycaemic control, measured by HbA1c levels, is strongly associated with indicators of socioeconomic position favouring the better off. Comparison of the lowest with the highest socioeconomic group showed an odds ratio of 2.49 (95% CI: 1.22–5.07) for the MI register subgroup and 1.80 (95% CI: 0.80–4.06) for the survey subgroup for failure to achieve the recommended HbA1c target. This association could not be accounted for by differences across social groups in age, sex, diabetes duration, obesity, or physical activity. Social inequalities in glycaemic control do exist. This finding may indicate a level of diabetes care that is inappropriate to the need of socially disadvantaged groups.
International Journal of Public Health

von Lengerke, T.; Janssen, C.; John, J.
Sense of coherence, health locus of control, and quality of life in obese adults: Physical limitations and psychological normalcies.
Int. J. Public Health 52, 16-26 (2007)
To assess differences between overweight and normal- weight adults in sense of coherence (SOC), health locus of control (HLOC), and health-related quality of life (HQOL).Methods: Cross-sectional population study (Augsburg, Germany). Random sample aged 25–74 (N = 947). Body mass index (BMI) was categorized into four groups (normal-weight: 18.5–25; pre-obesity: 25–29.9; moderate obesity: 30–34.9; severe obesity: ? 35). The associations between obesity classification and SOC-13T, MHLOC-Scales, and SF-12 summary scores were estimated via analysis of covariance.Results: Adjusted for age and socio-economic status, no differences across BMI-groups related to SOC, internal HLOC, external HLOC-'chance', and SF-12-'mental health'. HLOC-'doctors' was marginally elevated in obese women. Larger differences pertained to SF-12-'physical health' in that it was considerably reduced in obese women and severely obese men.Conclusions: In this adult population sample, obesity is not associated with SOC, HLOC, and HQOL in terms of mental health, but is associated with poorer physical health, which was reported by all groups of obese women, and by severely obese men. These results underline the need to treat and prevent obesity to restore and promote physical HQOL, and to distinguish moderate vs. severe obesity in obesity research.
International Journal of Public Health

Weyers, S.; Lehmann, F.; Meyer-Nürnberger, M.; Reemann, H.; Altgeld, T.; Hommes, M.; Luig-Arlt, H.; Mielck, A.
Strategien zur Verminderung gesundheitlicher Ungleichheiten in Deutschland.
Bundesgesundheitsbl.-Gesund. 50, 484-491 (2007)
Vor dem Hintergrund gesundheitlicher Ungleichheiten koordiniert die Bundeszentrale für gesundheitliche Aufklärung (BZgA) das Europäische Projekt Closing the Gap: Strategies for Action to tackle Health Inequalities in Europe. Der Bericht zum Wissens- und Aktionsstand zur Verminderung gesundheitlicher Ungleichheiten in den verschiedenen europäischen Ländern ist ein Ergebnis des EU-Projektes. In diesem Beitrag sollen entsprechende aktuelle Informationen für Deutschland zu den Bereichen Forschung, politische Rahmenbedingungen, Initiativen, Qualität und Evaluation von Interventionen und Verständnis in der Öffentlichkeit dargestellt werden. Trotz des Fehlens einer konzertierten Regierungsstrategie zur Verminderung gesundheitlicher Ungleichheiten gibt es in Deutschland eine Reihe wichtiger, von der Bundesregierung unterstützter Initiativen, die bundesweit Akteure "an einen Tisch bringen". Bei der Konzipierung einer Gesamtstrategie kann der Wissenstransfer zwischen den europäischen Ländern hilfreich sein.
Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz

von Lengerke, T.; John, J.
General practitioners' opportunities for preventing ill health in healthy vs morbid obese adults: A general population study on consultations.
J. Public Health 15, 71-80 (2007)
To determine whether overweight and obese adults with and without physical morbidity show an excess utilization of general practitioners in terms of consultation and, among users, number of consultations. In a general adult population survey in the Augsburg region, Germany (KORA Survey S4 1999/2001), body mass index (BMI in kg/m2) was assessed anthropometrically, physical morbidity via computer-aided personal interview with an adapted version of the Functional Comorbidity Index (Groll et al., J Clin Epidemiol 58:595–602, 2005) and consultations with general practitioners in three computer-aided telephone interviews over half a year. Analysis was performed using multiple logistic and zero-truncated negative binomial regressions (two-part model). Data were adjusted for gender, age, socio-economic status, marital status, health insurance and place of residence. Among healthy respondents, i.e. those with no morbidity, neither moderately nor severely obese respondents had significantly higher odds for GP use, or higher numbers of consultations among users, than those in the normal weight range. In contrast, among respondents with any physical morbidity, obese respondents showed excess utilization of GP in that moderately obese adults had significantly higher odds of any GP contact (odds ratio=2.09, $p<0.01$), and, among users, the severely obese group showed an excess number of consultations [incident rate ratio=1.73, $p<0.05$ (adjusted: 1.59, $p<0.10$)]. Physical morbidity did not predict any GP use, but tended to be associated with number of consultations among users (incident rate ratio=1.84, $p<0.10$). Under the present conditions of utilization of general practitioners by obese adults in Germany, this group of physicians seems to have the most opportunities for secondary and tertiary prevention in this group of patients. With regard to obese adults who are as yet by and

large healthy (and usually of relatively young age), primary prevention efforts may be viable not predominantly by primary care, but community-oriented policies. How far general practice can be an integrative part of primary disease prevention by obesity management is an issue for further investigation.
Journal of Public Mental Health

Behrend, C.; Buchner, F.; Happich, M.; Holle, R.; Reitmeir, P.; Wasem, J.
Risk-adjusted capitation payments: How well do principal inpatient diagnosis-based models work in the German situation? Results from a large data set.
Eur. J. Health Econ. 8, 31-39 (2007)
Five models of risk adjusters were tested as a (proxy) measure for health status with data from a large German sickness fund. The first two models use standard demographic and socio-demographic variables. One model incorporates a simple binary indicator for hospitalization and the last two are based on the hierarchical coexisting conditions (HCCs: DxCG® Risk Adjustment Software Release 6.1) using in-patient diagnoses. Special investigations were done on the subgroups of insurees who left, joined or stayed with the fund over the observation period. Age and gender grouping accounted for 3.2% of the variation in total expenditure for concurrent as well as prospective models. The current German risk adjusters age, sex, and invalidity status account for 5.1 and 4.5% of the variance in the concurrent and prospective models, respectively. Age, gender, invalidity status and in-patient HCC covariates explain about 37% of the variations of the total expenditures in a concurrent model and roughly 12% of the variations of total expenditures in a prospective model. Only modest improvement can be achieved with the long-term-care (LTC) indicator. For high-risk (cost) groups, substantial under-prediction remains; conversely, for the low-risk group, represented by enrolees who did not show any health care expense in the base year, all of the models over-predict expenditure. Special investigations were done on the subgroups of insurees who left, joined or stayed with the fund over the observation period.
The European journal of health economics

Leidl, R.
Kritische Bewertung von gesundheitsökonomischen Studien.
In: Kunz, R.* [Eds.]: Lehrbuch Evidenz-basierte Medizin in Klinik und Praxis. Köln: Deutscher Ärzte-Verl., 2007. 205-215
Kuch, B.; von Scheidt, W.; Kling, B.; Heier, M.; Hörmann, A.; Meisinger, C.
Characteristics and outcome of patients with acute myocardial infarction according to presenting electrocardiogram (from the MONICA/KORA Augsburg Myocardial Infarction--Registry).
Am. J. Cardiol. 100, 1056-1060 (2007)
Acute myocardial infarctions (AMIs) are categorized according to presenting electrocardiography into ST-elevation (STE), non-STE, and bundle branch block AMIs. Data on the characteristics and risks of these categories originate mainly from voluntary registries or clinical trials and may be hampered by selection and information bias. This study evaluated these different categories, with the additional differentiation of non-STE AMIs into ST-depression (STD) AMIs and those with nonspecific electrocardiographic signs (no-ST) in an unselected cohort. From 1985 to 2004, all consecutive patients aged 25 to 74 years who were hospitalized with AMI at the study region's major clinic were registered prospectively. A total of 6,748 patients were identified, of whom 45.8% had STE, 14.0% STD, 32.4% no-ST, and 7.8% bundle branch block AMIs, respectively. There were substantial differences in medical history, presentation, and therapy among the AMI types. Even after adjusting for the latter factors, the odds ratios of 28-day case fatality compared with no-ST were 1.26 (95% confidence interval 1.01 to 1.59) for STE, 1.84 (95% confidence interval 1.39 to 2.44) for STD, and 3.18 (95% confidence interval 2.37 to 4.27) for bundle branch block. In conclusion, after considering in-hospital therapy, the difference between STE and no-ST was nonsignificant, whereas the case-fatality difference between no-ST and STD persisted, suggesting some other unknown underlying factors associated with STD.
American Journal of Cardiology, The

Vollmert, C.; Hahn, S.; Lamina, C.; Huth, C.; Kolz, M.; Schöpfer-Wendels, A.; Mann, K.; Bongardt, F; Mueller, J.C.; Kronenberg, F.; Wichmann, H.-E.; Herder, C.; Holle, R.; Löwel, H.; Illig, T.; Janssen, O.E; KORA Study Group (Wichmann, H.-E.; Holle, R.; John, J.; Illig, T.; Meisinger, C.)
Calpain-10 variants and haplotypes are associated with polycystic ovary syndrome in Caucasians.
Am. J. Physiol. Endocrinol. Metab. 292, E836-E844 (2007)
PCOS is known to be associated with an increased risk of T2DM and has been proposed to share a common genetic background with T2DM. Recent studies suggest that the Calpain-10 gene (CAPN10) is an interesting candidate gene for PCOS susceptibility. However, contradictory results were reported concerning the contribution of certain CAPN10 variants, especially of UCSNP-44, to genetic predisposition to T2DM, hirsutism, and PCOS. By means of MALDI-TOF MS technique, we genotyped an expanded single nucleotide polymorphism panel, including the CAPN10 UCSNP-44, -43, -56, ins/del-19, -110, -58, -63, and -22 in a sample of 146 German PCOS women and 606 population-based controls. Statistical analysis revealed an association between UCSNP-56 and susceptibility to PCOS with an odds ratio (OR) of 2.91 (95% CI=1.51-5.61) for women carrying an AA genotype compared with GG. As expected, the 22-genotype of the ins/del-19 variant, which is in high linkage disequilibrium (r2=0.98) with UCSNP-56, was also significantly associated (OR=2.98, 95% CI=1.55-5.73). None of the additionally tested variants alone showed any significant association with PCOS. A meta-analysis including our study (altogether 623 PCOS cases and 1,224 controls) also showed significant association only with ins/del-19. The most common haplotype TGG3AGCA was significantly associated with a lower risk for PCOS (OR=0.487, P=0.0057). In contrast, the TGA2AGCA haplotype was associated with an increased risk for PCOS (OR=3.557, P=0.0011). By investigating a broad panel of CAPN10 variants, our results pointed to an allele dose-dependent association of UCSNP-56 and ins/del-19 with PCOS.
American Journal of Physiology - Endocrinology and Metabolism

Sausenthaler, S.; Kompauer, I.; Mielck, A.; Borte, M.; Herbarth, O.; Schaaf, B.; von Berg, A.; Heinrich, J.; LISAplus Study Group (Wichmann, H.-E.; Heinrich, J.; Bolte, G.; Belcredi, P.; Jacob, B.; Schoetzau, A.; Mosetter, M.; Schindler, J.; Höhnke, A.)
Impact of parental education and income inequality on children's food intake.
Public Health Nutr. 10, 24-33 (2007)
OBJECTIVE: To analyse the association between socio-economic indicators and diet among 2-year-old children, by assessing the independent contribution of parental education

and equivalent income to food intake. DESIGN: The analysis was based on data from a prospective birth cohort study. Information on diet was obtained using a semi-quantitative food-frequency questionnaire. Low and high intake of food was defined according to the lowest and the highest quintile of food consumption frequency, respectively. SETTING: Four German cities (Munich, Leipzig, Wesel, Bad Honnef), 1999-2001.Subjects Subjects were 2637 children at the age of 2 years, whose parents completed questionnaires gathering information on lifestyle factors, including parental socio-economic status, household consumption frequencies and children's diet. RESULTS: Both low parental education and low equivalent income were associated with a low intake of fresh fruit, cooked vegetables and olive oil, and a high intake of canned vegetables or fruit, margarine, mayonnaise and processed salad dressing in children. Children with a low intake of milk and cream, and a high intake of hardened vegetable fat, more likely had parents with lower education. Low butter intake was associated with low equivalent income only. CONCLUSIONS: These findings may be helpful for future intervention programmes with more targeted policies aiming at an improvement of children's diets.
Public Health Nutrition

Rathmann, W.; Haastert, B.; Herder, C.; Hauner, H.; Koenig, W.; Meisinger, C.; Holle, R.; Giani, G.
Differential association of adiponectin with cardiovascular risk markers in men and women? The KORA survey 2000.
Int. J. Obes. 31, 770-776 (2007)
In men, high adiponectin concentrations were related to a lower risk of myocardial infarction, whereas no association with cardiovascular events was found in women.To investigate sex differences in the associations of adiponectin with cardiovascular risk factors.Design: Cross-sectional population-based KORA Survey 2000 in Southern Germany using the same study methods for cardiovascular risk factors as the former WHO MONICA project.Participants:A total of 697 men and 657 women, aged 55–74 years. Glucose tolerance status was assessed by oral glucose tolerance tests.Adiponectin (geometric mean, interquartile range; mug/ml) levels were significantly higher in women (11.1; 8.5–14.9) than in men (7.1; 5.2–9.6) ($P<0.05$). In univariate analyses, HDL-cholesterol and age were significantly positively correlated with adiponectin in both sexes. Negative correlations were observed with BMI, waist circumference, fasting and postchallenge glucose, insulin, HOMA-IR, HbA1c, triglycerides, uric acid and CRP ($P<0.01$). In sex-specific multivariate regression, age and HDL-cholesterol were independently positively, and fasting insulin and 2-h glucose were negatively related to adiponectin in both sexes. Uric acid was significantly inversely related to adiponectin in women only (sex interaction: P=0.02). Exploratory sex-specific factor analysis of adiponectin and the core components of the metabolic syndrome yielded four similar factors. Adiponectin loaded negatively on the 'lipids' factor in both sexes.The associations of adiponectin with cardiovascular risk factors showed a similar pattern in both sexes, except for uric acid. This small sex difference may not explain previous conflicting results on the association of adiponectin with cardiovascular events in men and women.
International Journal of Obesity

Neubauer, S.; Welte, R.; König, H.-H.; Leidl, R.
Die volkswirtschaftlichen Kosten des Zigarettenrauchens in Deutschland.
Public Health Forum 15, 14-16 (2007)
Public Health Forum

Happich, M.; von Lengerke, T.
Convergence of life expectancy in the European Union: A Markov approach.
Appl. Econ. Lett. 14, 175-178 (2007)
Given efforts of integration within the European Union (EU), convergence of life expectancies in member-states should be observed. A Markov approach classifying 15 EU member-states is applied to OECD data covering 1980 to 1989 and 1989 to 1998. The dynamics of cross-sectional distributions and the pace of their transitional processes are analyzed. In the 1980s slow convergence can be observed, whereas in the 1990s convergence is close to non-existent. Markov modelling shows that EU member states did not continue to converge in life expectancy following 1989, suggesting that efforts of socio-economic integration do not affect this public health indicator.
Applied Economics Letters

Eickholz, P.; Krigar, D.-M.; Kim, T.-S.; Reitmeir, P.; Rawlinson, A.
Stability of clinical and radiographic results after guided tissue regeneration in infrabony defects.
J. Periodontol. 78, 37-46 (2007)
BACKGROUND: The aim of this 5-year follow-up study was to evaluate clinically and radiographically the long-term results after guided tissue regeneration (GTR) therapy of infrabony defects using non-resorbable and bioabsorbable barriers. METHODS: Thirty-one patients with periodontitis and 50 infrabony defects that had been treated using GTR were recruited. Eleven defects were treated with non-resorbable expanded polytetrafluoroethylene membranes and 39 defects with bioabsorbable barriers. At baseline and 6 and 60 +/- 3 months after surgery, clinical parameters and standardized radiographs were obtained. During surgery and 60 +/- 3 months thereafter, the distance from the cemento-enamel junction to the base of the bony defect (vertical probing bone level [PBL-V]) was measured. Bone gain was evaluated using digital subtraction radiography. RESULTS: At 6 and 60 +/- 3 months after GTR, there was a statistically significant ($P<0.001$) reduction of probing depth (6 months: 4.31 +/- 1.76 mm; 60 months: 3.95 +/- 1.62 mm) and vertical clinical attachment level gains (CAL-V) (6 months: 3.34 +/- 1.66 mm; 60 months: 2.97 +/- 1.53 mm). From 6 to 60 months after GTR, three infrabony defects exhibited CAL-V loss >2 mm, and a small, statistically not significant mean CAL-V loss of 0.39 +/- 1.60 mm was observed. From baseline to 60 +/- 3 months, a significant PBL-V gain of 1.78 +/- 2.67 mm ($P<0.001$) and increase in bone density were observed ($P = 0.003$). CONCLUSION: The CAL-V gain achieved after GTR in infrabony defects using both non-resorbable and bioabsorbable barriers was stable after 5 years in 47 of 50 defects.
Journal of Periodontology

2006
Leu, R.E.; Schellhorn, M.
The evolution of income-related health inequalities in Switzerland over time.
CESifo Econ. Stud. 52, 666-690 (2006)

This article presents new evidence on income-related health inequality and its development over time in Switzerland. We employ the methods lined out in Van Doorslaer and Jones (2003, "Inequalities in self-reported health: validation of a new approach to measurement", Journal of Health Economics 22(1), 61–78) and Van Doorslaer and Koolman (2004, "Explaining the differences in income-related health inequalities across European Countries", Health Economics 22(7), 609–628) measuring health using an interval regression approach to compute concentration indices and decomposing inequality into its determining factors. Nationally representative survey data for 1982, 1992, 1997, and 2002 are used to carry out the analysis. Looking at each of the four years separately the results indicates the usual positive relationship between income and health, but the distribution is among the least unequal in Europe. No clear trend emerges in the evolution of the inequality indices over the two decades. A small but significant increase over the first 15 years is followed by stabilization if not a slight decrease in total income-related health inequality. The most important contributors to health inequality are income, education and activity status, in particular, retirement. Regional differences including the widely varying health care supply, in contrast, do not exert any systematic influence.
CESifo Economic Studies

Richter, M.; Mielck, A.
Gesundheitliche Ungleichheit im Jugendalter: Herausforderungen für die Prävention und Gesundheitsförderung.
Präv. Gesundheitsf. 1, 248-254 (2006)
Über das Ausmaß gesundheitlicher Ungleichheit in der Adoleszenz in Deutschland ist bisher nur wenig bekannt. Aktuelle Studien weisen darauf hin, dass sozioökonomische Unterschiede in der Gesundheit in dieser Lebensphase insgesamt eher inkonsistent und weniger stark ausgeprägt sind. Dieses Phänomen stellt die Planung von Strategien und Maßnahmen zur Reduzierung gesundheitlicher Ungleichheiten vor zahlreiche Herausforderungen. Um die Ursachen für den inkonsistenten Einfluss sozialer Ungleichheit auf die Gesundheit im Jugendalter zu verstehen, muss die Eigenständigkeit der Lebensphase ldquorJugendldquo stärker in den Fokus der Forschung gestellt werden. Das Verständnis, welche Rolle verschiedene sekundäre Sozialisationsinstanzen wie Schule, Gleichaltrigengruppe und Medien in der Beziehung zwischen sozialer Ungleichheit und Gesundheit im Jugendalter spielen, kann dabei helfen die theoretischen Ansätze zu sozialer Ungleichheit und Gesundheit besser als bislang zu fundieren und Interventionen zu entwickeln, die an eben diesen zentralen Schaltstellen ansetzen.
Prävention und Gesundheitsförderung

Bayerl, B.; Mielck, A.
Egalitäre und individualistische Gerechtigkeitsvorstellungen zur gesundheitlichen Versorgung: Ergebnisse einer Befragung von Patienten und Studenten.
Gesundheitswesen 68, 739-746 (2006)
Ziel der Studie: Die vorliegende Arbeit beschäftigt sich mit der Frage, welche Vorschläge zur Reform des Gesundheitssystems von welchen Versicherten akzeptiert werden. Dabei werden zwei Gerechtigkeitsvorstellungen gegenüber gestellt: Die „Egalitaristen" betonen das Ziel, die finanziellen Belastungen so gleich wie möglich zu verteilen und die Versorgungsangebote allen Versicherten in gleicher Weise anzubieten. Die „Individualisten" treten dafür ein, dass die gesundheitliche Versorgung so weit wie möglich von der individuellen Zahlungsbereitschaft und vom eigenen Gesundheitsverhalten des Versicherten abhängig ist. In der Arbeit wird untersucht, welche Versicherten der einen oder der anderen Zielsetzung zustimmen. Methodik: Mithilfe eines standardisierten Fragebogens wurden 343 zufällig ausgewählte Personen (175 ältere Patienten und 168 Studenten) im September 2003 schriftlich befragt. Zur Erfassung einer egalitären sind vier und zur Erfassung einer individuellen Auffassung sind fünf Fragen verwendet worden. Dabei kamen auch Vignetten zum Einsatz. Mit dieser Methode lässt sich untersuchen, welchen Einfluss das folgende „Framing" hat: Ist die Entscheidung für eine egalitaristische oder individuelle Zielsetzung davon abhängig, ob dabei an eine bestimmte Zielperson gedacht wird (z. B. einen reicheren oder ärmeren Versicherten). Ergebnisse: Die Analysen zeigen, dass die egalitäre Vorstellung vor allem bei den folgenden Patienten zu finden ist: Obere Altersgruppe, GKV-versichert, hohe Arzneimitteleinnahme, häufiger Arztbesuch. In der Gruppe der Studenten ist sie auch bei denjenigen besonders häufig, die selten Sport treiben. Die individualistische Vorstellung ist vor allem bei den folgenden Patienten zu finden: Männlich, obere Bildungsgruppe, erwerbstätig, PKV-versichert, sportlich aktiv, Nichtraucher; bei den Studenten zeigen sich ganz ähnliche Zusammenhänge. Deutlich wird auch, dass die Vignetten das Antwortverhalten stark beeinflussen. Diskussion: Die Zustimmung zu oder Ablehnung von Reformvorschlägen wird offenbar wesentlich durch die persönlichen Merkmale der Versicherten geprägt. Die Akzeptanz der Reformen wird wesentlich davon abhängen, ob es gelingt, diese unterschiedlichen Sichtweisen der Versicherten zu integrieren.
Gesundheitswesen, Das

Meisinger, C.; Hörmann, A.; Heier, M.; Kuch, B.; Löwel, H.
Admission blood glucose and adverse outcomes in non-diabetic patients with myocardial infarction in the reperfusion era.
Int. J. Cardiol. 113, 229-235 (2006)
International Journal of Cardiology

Schweikert, B.; Jacobi, E.; Seitz, R.; Cziske, R.; Ehlert, A.; Knab, J.; Leidl, R.
Effectiveness and cost-effectiveness of adding a cognitive behavioral treatment to the rehabilitation of chronic low back pain.
J. Rheumatol. 33, 2519-2526 (2006)
Journal of Rheumatology, The

Löwel, H.; Hörmann, A.; Döring, A.; Heier, M.; Meisinger, C.; Schneider, A.E.; Kaup, U.; Gösele, U.; Hymer, H.
Koronare Herzkrankheit und akuter Myokardinfarkt.
Gesundheitsberichterstatt. Bundes 33, 1-35 (2006)
Gesundheitsberichterstattung des Bundes: Themenhefte

Mielck, A.; Eller, M.; Bayerl, B.
Soziale Ungleichheit, Armut und Gesundheit in München.
In: Referat für Gesundheit und Umwelt der Landeshauptstadt München* [Ed.]: Gesundheitsberichtserstattung der Landeshauptstadt München. 2006. 12-30
Stark, R.G.; König, H.H.; Leidl, R.
Kosten und gesundheitliche Effekte messen - KN Chronisch entzündliche Darmerkrankung / KN-CED.

In: Proceedings (Von der Forschung in die Versorgung - Kompetenznetze in der Medizin). Berlin: Bundesministerium für Bildung und Forschung (BMBF) [Hrsg.], 2006. 78-79
Mielck, A.; Helmert, U.
Vergleich zwischen GKV- und PKV-Versicherten: Unterschiede bei Morbidität und gesundheitlicher Versorgung.
In: Böcken, J.*; Braun, B.*; Amhof, R.*; Schnee, M.* [Eds.]: Gesundheitsmonitor 2006: Gesundheitsversorgung und Gestaltungsoptionen aus der Perspektive von Bevölkerung und Ärzten. Gütersloh: Bertelsmann Stiftung, 2006. 32-52
Hintergrund und Fragestellung: Es gibt kaum wissenschaftliche Untersuchungen über Unterschiede zwischen gesetzlich und privat Versicherten. Der Artikel untersucht die Unterschiede in der Morbidität und der Inanspruchnahme medizinischer Versorgung, aber auch in den Einstellungen zu gesundheitspolitischen Themen. Methode: Datenbasis sind rund 12.000 Befragungsteilnehmer des Gesundheitsmonitors (repräsentativer Bevölkerungsquerschnitt im Alter von 18-79 Jahren). Erhebungen von Herbst 2001 bis Frühjahr 2005. Analysemethoden: Deskriptive Statistik, bi- und multivariate Analysen zur Feststellung der Einflüsse von sozio-ökonomischen Merkmalen. Ergebnisse: PKV-Versicherte sind häufiger männlich, jünger und verfügen über ein höheres Haushaltseinkommen. Die Morbidität der GKV-Versicherte ist fast doppelt so hoch wie bei PKVVersicherten. Sie gehen häufiger zum Arzt und nehmen mehr Medikamente ein. GKV-Versicherte haben häufiger Probleme mit Selbstbeteiligungen, mit schlechter Qualität der Versorgung und machen sich daher größere Sorgen um ihre zukünftige medizinische Versorgung. Sie sind eher bereit bei Beitragssatzsenkungen auf die freie Arztwahl zu verzichten. Die Zustimmung zu den Solidarprinzipien ist bei GKV-Versicherten höher. Auch unter Kontrolle der Einflüsse von Alter, Geschlecht und Einkommen bleiben all diese Unterschiede bestehen. Schlussfolgerungen: Bei der Diskussion um die zu künftige Gestaltung der medizinischen Versorgung muss über die Abgrenzung zwischen PKV und GKV gesprochen werden. Fragen der Verteilungsgerechtigkeit, aber auch der Zumutbarkeit von finanziellen Belastungen müssen diskutiert werden. Angemessenheit und Qualität der medizinischen Versorgung müssen in diesem Zusammenhang ebenfalls thematisiert werden. Im Sinne des Solidarprinzips müssten die teilweise erheblichen Unterschiede zwischen privat und gesetzlich Versicherten abgebaut werden.
Neubauer, S.; Welte, R.; Beiche, A.; Koenig, H.-H.; Buesch, K.; Leidl, R.
Mortality, morbidity and costs attributable to smoking in Germany: Update and a 10-year comparison.
Tob. Control 15, 464-471 (2006)
Tobacco Control

Mielck, A.; Helmert, U.
Vergleich zwischen GKV- und PKV-Versicherten : Unterschiede bei Morbidität und gesundheitlicher Versorgung.
In: Böcken, J.* [Eds.]: Gesundheitsmonitor 2006: Gesundheitsversorgung und Gestaltungsoptionen aus der Perspektive von Bevölkerung und Ärzten. Gütersloh: Bertelsmann, 2006. 32-52
Mielck, A.
Quantitative Zielvorgaben zur Verringerung der gesundheitlichen Ungleichheit: Lernen von anderen westeuropäischen Staaten .
In: Richter, M.*; Hurrelmann, K.* [Eds.]: Gesundheitliche Ungleichheit - Grundlagen, Probleme, Perspektiven. Wiesbaden: GWV Fachverl., 2006. 439-451
In einigen westeuropäischen Staaten wird schon seit geraumer Zeit versucht, das Ziel „Verringerung der gesundheitlichen Ungleichheit" so genau wie möglich zu definieren. Dabei wird auch vor einer Quantifizierung dieser Zielsetzung nicht zurückgeschreckt. Mit „Quantifizierung" sind hier zahlenmäßig fixierte Vorgaben gemeint wie: Die zurzeit vorhandenen Unterschiede in der Mortalität zwischen Statusgruppe A und Statusgruppe B sollen in zehn Jahren 15% kleiner sein. Derartige Vorgaben bergen für die gesundheitspolitischen Akteure erhebliche Risiken. Nach Ablauf der gesetzten Frist kann überprüft werden, wie gut dieses Ziel erreicht worden ist, und auch schon in den Jahren bis zum Ablauf der Frist ist abzusehen, ob die Entwicklung in die vorgesehene Richtung geht. Diesen Risiken steht jedoch ein wichtiger Vorteil gegenüber: Die Planung von Maßnahmen wird zielgerichtet fokussiert. Quasi von selbst stellen sich sehr praxisnahe konkrete Fragen wie z.B.: Welche Maßnahme hat welchen Effekt auf die gesundheitliche Ungleichheit? Wer ist für welche Maßnahme verantwortlich? Wie können diese Maßnahmen fachlich und zeitlich koordiniert werden? Wer ist für die Koordination verantwortlich? Wie kann der Erfolg der Maßnahmen dadurch abgesichert werden, dass die Personengruppe, deren Gesundheitszustand verbessert werden soll, in die Planung und Durchführung der Maßnahmen eingebunden wird? Wie wirken sich die sozialen und politischen Entwicklungen, die außerhalb des geplanten Maßnahme-Katalogs liegen (Arbeitsmarkt, Reform der Krankenversicherung etc.) auf die gesundheitliche Ungleichheit aus?
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Quantitative Zielvorgaben zur Verringerung der gesundheitlichen Ungleichheit : Lernen von anderen westeuropäischen Staaten.
In: Richter, M.*; Hurrelmann, K.* [Eds.]: Gesundheitliche Ungleichheit: Grundlagen, Probleme, Perspektiven. Wiesbaden: GWV Fachverl., 2006. 439-451
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Nonparametric bounds on the effect of deductibles in health care insurance on doctor visits - Swiss evidence.
Health Econ. 15, 1011-1020 (2006)
We evaluate the effect of the size of deductibles in the basic health insurance in Switzerland on the probability of a doctor visit. We employ nonparametric bounding techniques to minimise statistical assumptions. In order to tighten the bounds we consider two further assumptions: mean independence of an instrument and monotone treatment response. Under these two assumption we are able to bound the causal effect of high deductibles compared to low deductibles below zero. We conclude that the difference in health care utilisation is partly due to a reduction of moral hazard effects.
Health Economics

Stark, R.G.; König, H.-H.; Leidl, R.
Costs of inflammatory bowel disease in Germany.
Pharmacoeconomics 24, 797-814 (2006)
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Die Wirtschaftlichkeit der Versorgung im Alter.
In: Rebscher, H.* [Eds.]: Gesundheitsökonomie und Gesundheitspolitik im Spannungsfeld zwischen Wissenschaft

und Politikberatung. Heidelberg: Economica-Verl., 2006. 495-504
Wolfenstetter, S.B.
Adipositas und die Komorbidität Diabetes mellitus Typ 2 bei Kindern und Jugendlichen in Deutschland: Entwicklung und Krankheitskostenanalyse.
Gesundheitswesen 68, 600-612 (2006)
Einleitung: Der Anstieg der Prävalenz der Adipositas und des adipositasbasierten Diabetes mellitus Typ 2 (DMT2) bei Kindern und Jugendlichen in Deutschland entwickelt sich aufgrund der psychischen und physischen Folgeerkrankungen zu einem großen gesundheitspolitischen Problem. Das Ziel dieses Artikels ist es, die Anzahl der übergewichtigen und adipösen Kinder und Jugendlichen mit und ohne DMT2 und die derzeitigen (Jahr 2003) und zukünftigen Kosten für das Gesundheitssystem in Deutschland zu schätzen. Methode: Die Daten zu den Krankheitskosten im Erwachsenenalter und zur Prävalenz der Adipositas im Kindes- und Jugendalter sind englischen und deutschen wissenschaftlichen Fachzeitschriften sowie einer umfassenden Internetrecherche entnommen. Die Kosten zur Adipositas und des DMT2 im Kindes- und Jugendalter basieren auf dem Top-Down-Ansatz und auf der Prävalenzmethode. Diese direkten Kosten wurden mittels aggregierter statistischer Daten (ICD 10: Adipositas E65 - 68; DMT2 E11) verschiedener wissenschaftlicher Publikationen und mithilfe von Telefoninterviews ermittelt. Außer der Erkrankung DMT2 wurden weitere Folgeerkrankungen der Adipositas in diesen Kostenberechnungen vernachlässigt. Ergebnisse: Im Jahr 1999 waren in Deutschland eigenen Berechnungen zufolge 1,3 Millionen Kinder und Jugendliche übergewichtig und 594 000 Kinder und Jugendliche in der Altersgruppe von fünf bis 17 Jahren adipös. Die höchsten Prävalenzwerte wurden in der Altersgruppe der 14- bis 17-Jährigen ermittelt. Die Prävalenz bei Übergewicht stieg hier von 8,9 % im Jahr 1994 auf 15,7 % im Jahr 1999 und bei Adipositas im Zeitraum von 1994 bis 1998 von 10,1 % auf 13,1 % an. Die Prävalenz des DMT2 liegt bei adipösen Kindern und Jugendlichen ungefähr bei 1 %. Die Kosten, die dem Gesundheitssystem durch diese Veränderungen und durch den erhöhten BMI-Index von Kindern und Jugendlichen entstehen, betrugen 2003 insgesamt rund 44 Millionen €, mit 36,4 Millionen € für die Rehabilitation, 3,6 Millionen € für den Krankenhausaufenthalt und 3,9 Millionen € für spezielle ambulante Programme für adipöse Kinder. Die Kosten für den bei Kindern und Jugendlichen diagnostizierten DMT2 betrugen im Jahr 2003 1,4 Mio. €. Die durchschnittlichen Kosten für medizinische Behandlungen eines adipösen Kindes in der Altersgruppe von 5 bis 20 Jahren betrugen 2003 im Mittel 3484 € und circa 8539 € pro behandeltes adipöses Kind mit DMT2. Die inkrementellen Kosten liegen dementsprechend bei 2489 € oder 7544 € im Vergleich zu den durchschnittlichen Krankheitskosten eines Kindes in Deutschland. Die zukünftigen jährlichen attributablen Kosten allein für die Behandlung der Fettleibigkeit der hier beschriebenen Kohorte von bis zu 6,4 Millionen € für das Gesundheitssystem entsprechen 7,3 bis 10,1 % der gesamten adipositasbasierten Kosten, die auch alle weiteren Kosten der Komorbiditäten mit einschließen. Die zukünftigen jährlichen Kosten des adipositasinduzierten DMT2 von bis zu 17,3 Millionen € (ohne diabetesbedingte Folgeerkrankungen) und von bis zu 92,1 Millionen € (inklusive diabetesinduzierte Folgeerkrankungen) machen einen Anteil von 7,0 bis 55,6 % an den gesamten adipositasinduzierten Kosten inklusive der Kosten aller adipositasassoziierten Folgeerkrankungen aus. Schlussfolgerungen: Adipositas und DMT2 im Kindes- und Jugendalter sind schnell zunehmende Erkrankungen, die aufgrund der Folgeerkrankungen große Kostentreiber für das Gesundheitssystem darstellen. Die Datenlage über die Kosten der Adipositas und des adipositasbasierten DMT2 sind sehr rudimentär, und weitere Forschungs- und Interventionsprogramme, die diese Krankheiten untersuchen und eventuell dagegen angehen, scheinen notwendig zu sein, um eine öffentliche Gesundheitskrise zu verhindern. Die Herausforderung für die Gesundheitspolitik ist es, die effektivsten und effizientesten Präventionsmaßnahmen zu identifizieren.
Gesundheitswesen, Das

Icks, A.; Rathmann, W.; Haastert, B.; Mielck, A.; Holle, R.; Löwel, H.; Giani, G.; KORA Study Group (Meisinger, C.; Holle, R.; Wichmann, H.-E.; John, J.; Illig, T.; Peters, A.)
Versorgungsqualität und Ausmaß von Komplikationen an einer bevölkerungsbezogenen Stichprobe von Typ 2-Diabetespatienten. Der KORA-Survey 2000.
Dtsch. Med. Wochenschr. 131, 73-78 (2006)
BACKGROUND AND OBJECTIVE: The aim of this study was to analyse health care processes and outcomes in type 2 diabetes in a representative population sample of persons, aged 25-74 years, in the region of Augsburg, Germany. PATIENTS AND METHODS: Based on the KORA Survey 2000, indicators of health care services and outcomes were analysed for all study subjects with known type 2 diabetes (n=149; 80 males (54%)) , mean age 62 +/- 9 years; total random population sample: 4,261 persons). Means and prevalences were calculated, including 95% confidence intervals (CI). Associated factors were analysed using multivariate regression models. RESULTS: 57% of the patients had not received adequate drug treatment concerning hypertension and 43% concerning hypercholesterolemia. 63% (CI: 54-70 %) and 38% (CI: 30-47%), respectively, reported that their eyes or feet had been examined during the past 12 months. 47% (CI: 39-56%) had been instructed about their diabetes. 69% (CI: 61-76%) of the subjects did not know the term "HbA(1c)", the proportion being higher among subjects without diabetes education or those of a low social status. 13% (CI: 8-20%) of the subjects had been told by their medical practitioner that they had a retinopathy, 5% (CI: 2- 10%) a foot ulcer, 19% (CI: 12-28%) proteinuria. Two persons were blind, one had been on renal dialysis, and 5% (CI: 2-10%) had undergone amputation of a limb. 6% (3-12%) had at least one of the end-stage diabetic complications. The mean HbA(1c) was 7.2 +/- 1.6%, significantly higher in those with a diabetes for >10 years. CONCLUSIONS: The population-based data regarding indicators of type 2 diabetes care processes and outcome in a defined region in Germany show that the treatment of hypertension and hypercholesterolemia was highly inappropriate, as was the frequency of medical control investigations. The high proportion of subjects who did not know the term "HbA(1c)" was striking, particularly among those of a low social status. A significant proportion had severe late complications. The mean HbA(1c), however, was better than had been reported in some previous German practice-based studies.
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Epidemiologic Perspectives and Innovations

Blankenfeld, H.; Mielck, A.; Schumm-Draeger, P.M.; Siegmund, T.
Wie viel wissen stationär behandelte Diabetiker über ihre Erkrankung?: Eine empirische Untersuchung in einem städtischen Klinikum in München.
Gesundheitswesen 68, 557-565 (2006)
Gesundheitswesen, Das

Holle, R.; Hochadel, M.; Reitmeir, P.; Meisinger, C.; Wichmann, H.-E.; KORA Study Group (Holle, R.; John, J.; Illig, T.; Peters, A.; Meisinger, C.; Wichmann, H.-E.)
Prolonged recruitment efforts in health surveys: Effects on response, cost and potential bias.
Epidemiology 17, 639-643 (2006)
BACKGROUND: In health surveys, considerable effort and expense are invested to achieve a high response proportion and thereby to reduce selection bias. We investigated the interrelation of recruitment efforts and expense with potential nonresponse bias based on data from a large health survey. METHODS: In a population-based health survey, a stratified sample of 6640 residents of the Augsburg (Germany) region was selected, of whom 4261 attended the main study between October 1999 and April 2001. A short telephone interview yielded additional information on nearly half of the nonparticipants. All recruitment contacts were documented, and expenses were estimated on the basis of unit costs. Different recruitment strategies were modeled retrospectively. We compared their cost savings as well as their influence on the response proportion and on prevalence estimates. RESULTS: The distribution of total contacting cost per individual was highly skewed with 50% of the total sum spent on 17% of the sample. Late responders showed many similarities with nonresponders; both included a higher percentage of people with impaired health and with greater behavioral health risks. We were able to identify recruitment strategies that may save up to 25% of the recruitment costs without significant shift in the parameter estimates. Data collected in the short nonresponder interview proved to be important to correct for possible nonresponse bias. CONCLUSIONS: In general, prolonged recruitment efforts lead to a larger and more representative sample but at increasing marginal costs. Specific cost-saving recruitment strategies that do not enhance response bias can be suggested. Interviews of nonresponders are also useful.
Epidemiology

von Lengerke, T.; John, J.; KORA Study Group (Wichmann, H.-E.; Holle, R.; John, J.; Illig, T.; Meisinger, C.)
Use of medical doctors, physical therapists and alternative practioners by obese adults: Does body weight dissatisfaction mediate extant associations?
J. Psychosomat. Res. 61, 553-560 (2006)
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Soziale Ungleichheit und Gesundheit.
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Patientenorientierung durch Patientenbefragungen als ein Qualitätsmerkmal der Krankenversorgung.
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Herder, C.; Hauner, H.; Haastert, B.; Röhrig, K.; König, W.; Kolb, H.; Müller-Scholze, S.; Thorand, B.; Holle, R.; Rathmann, W.
Hypoadiponectinemia and proinflammatory state: Two sides of the same coin?
Diabetes Care 29, 1626-1631 (2006)
OBJECTIVE - Previous studies have yielded conflicting results on the association of adiponectin levels and inflammation. Low systemic concentrations of adiponectin, as well as elevated levels of immune mediators, represent risk factors for the development of type 2 diabetes and coronary artery disease. The major aim of this cross-sectional study was to investigate the interdependence of hypoadiponectinemia and low-grade systemic inflammation. RESEARCH DESIGN AND METHODS - The study sample consisted of 606 participants aged 55-74 years (244 with normal glucose tolerance, 242 with impaired glucose tolerance, and 120 with newly diagnosed type 2 diabetes) of the population-based KORA S4 (Cooperative Health Research in the Region of Augsburg Survey 4; 1999-2001). Systemic concentrations of adiponectin and a wide range of anthropometric, metabolic, and inflammatory variables were available for analyses. The association of adiponectin with 15 immunological markers, including leukocyte count, acute-phase proteins, cytokines, cytokine receptors, and chemokines, was assessed using univariable and multivariable models. RESULTS - No evidence for a significant correlation between adiponectin and all immunological parameters except eotaxin could be found after multivariable adjustments, whereas multiple strong correlations with obesity and metabolic factors were present. CONCLUSIONS - From these data, we conclude that hypoadiponectinemia and a proinflammatory state are largely independent from each other. © 2006 by the American Diabetes Association.
Diabetes Care

Mielck, A.
Wie lassen sich die Zielgruppen für Interventionsmaßnahmen bestimmen?
In: Altgeld, T.*; Bächlein, B.*; Deneke, C.* [Eds.]: Diversity Management in der Gesundheitsförderung: Nicht nur die leicht erreichbaren Zielgruppen ansprechen!. Frankfurt, Main: Mabuse Verl., 2006. 85-99
Auf dem Hintergrund zunehmender Berichte über den Zusammenhang zwischen der sozialen Lage in Deutschland einerseits und dem Gesundheitszustand andererseits befasst sich der Beitrag mit der Frage, wie gesundheitliche Ungleichheit verringert werden kann. Dabei wird insbesondere untersucht, ob und wie sich die Merkmale des sozialen Status (Bildung, berufliche Stellung und Einkommen) für die Definition von Zielgruppen eignen. Ziel ist es, die soziale Lage noch detaillierter zu erfassen und eine Differenzierung nach weiteren sozialen Faktoren etwa durch die Bildung von alters- und geschlechtsspezifischen Untergruppen vorzunehmen, um konkrete Maßnahmen zur Verringerung des Problems abzuleiten. In einem abschließenden Ausblick geht es um den Wechsel der Perspektive - weg von der wissenschaftlichen Frage nach den Ursachen hin zur Planung und Durchführung

konkreter Interventionsmaßnahmen sowie um eine bessere Kommunikation und Kooperation zwischen Wissenschaftlern und gesundheitspolitischen Akteuren. (ICH).

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Wie lassen sich die Zielgruppen für Interventionsmaßnahmen bestimmen?
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Soziale Netzwerke und der Gesundheitszustand von Typ 2 Diabetikern und Nicht-Diabetikern unter Längsschnitt-Betrachtung - Ergebnisse einer bevölkerungsbezogenen Fall-Kontroll-Studie.
München, Ludwig-Maximilians-Universität, Medizinische Fakultät, Diss., 2006, 124 S.
Vor allem bei der Bewältigung einer chronischen Krankheit wie Diabetes mellitus treten neben medizinischen Behandlungskonzepten auch psychosoziale Mechanismen in den Vordergrund. Gerade das soziale Umfeld von Diabetespatienten kann diese beim täglichen Leben mit der Krankheit in praktischer wie emotionaler Hinsicht unterstützen, was sich günstig auf das subjektive Befinden sowie den Krankheitsverlauf auswirkt. Dies hat sich in zahlreichen Studien aus dem Ausland gezeigt. Die Untersuchung des Zusammenhangs zwischen sozialem Netzwerk (gemessen mit dem Social Network Index von Berkman und Syme) und selbst eingeschätzter Gesundheit („self rated health") bei Patienten mit Typ 2 Diabetes (N=164) und Nicht-Diabetikern (N=207) ist Ziel dieser Arbeit. Im deutschsprachigen Raum gibt es bislang noch keine Studie, die sich mit dieser Fragestellung beschäftigt. Die Daten stammen aus der 1998 durchgeführten KORA-A Studie, in der insgesamt 1003 im Raum Augsburg lebende Fälle und nach Alter und Geschlecht gematchte Kontrollen untersucht wurden, die bereits an einem MONICA Survey (1989/90 bzw. 1994/95) teilgenommen hatten oder ins Augsburger Herzinfarktregister aufgenommen worden waren. In den explorativen Analysen zeigt sich kein konsistenter Zusammenhang zwischen dem Netzwerk und der Blutzuckereinstellung (gemessen mit dem HbA1c-Wert). Deskriptive Analysen zeigen, dass Diabetiker im Vergleich zu Nicht-Diabetikern in jedem Alter deutlich kleinere Netzwerke haben sowie ihren Gesundheitszustand schlechter einschätzen. Anhand von logistischen Regressionen betrachtet, sind umfangreiche soziale Beziehungen der Kontrollen, aber nicht der Diabetiker mit guter Gesundheit zu demselben Messzeitpunkt assoziiert. Unter Längsschnitt-Betrachtung zeigt sich nur bei den Patienten mit Diabetes, dass ein großes soziales Netz zum ersten Messzeitpunkt mit guter Gesundheit vier bzw. acht Jahre später verbunden ist („Social Causation"). Dieses Ergebnis lässt auf den sogenannten Puffereffekt sozialer Beziehungen schließen, die somit unter Anwesenheit (diabetesbedingter) Stressoren protektiv auf die Gesundheit wirken. Hinweise auf das „Social Selection"-Modell (Zusammenhang zwischen dem früheren Gesundheitsstatus und dem späteren Netzwerk) können in den Analysen nicht gefunden werden. Aus den Ergebnissen lässt sich schließen, dass gerade die Gruppe der Diabetiker (ebenso wie andere chronisch Kranke) folglich an Programme zum Aufbau neuer sozialer Kontakte bzw. zur Mobilisierung bereits bestehender Netzwerke herangeführt werden sollte.

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Knowledge about diabetes and participation in diabetes training courses : The need for improving health care for diabetes patients with low SES.
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Kosten und gesundheitliche Effekte messen - KB Chronisch entzündliche Darmerkrankungen (KB-CED).
In: Von der Forschung in die Versorgung : Kompetenznetze in der Medizin. Bonn: Bundesministerium für Bildung und Forschung, 2006. 78-79

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Systemic monocyte chemoattractant protein-1 concentrations are independent of type 2 diabetes or parameters of obesity: Results from the Cooperative Health Research in the Region of Augsburg survey S4 (KORA S4).
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Herzinfarkt und koronare Sterblichkeit in Süddeutschland: Ergebnisse des bevölkerungsbasierten MONICA/KORA-Herzinfarktregisters 1991 bis 1993 und 2001 bis 2003.
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Gesundheitswesen, Das

Stratmann-Schoene, D.; Kuehn, T.; Kreienberg, R.; Leidl, R.
A preference-based index for the SF-12.
Health Econ. 15, 553-564 (2006)
Background: The SF-12 is a widely used generic measure of subjective health. As the scoring algorithms of the SF-12 do not include preference values, different approaches to assign a preference-based index are available that should be tested regarding their feasibility and validity. Objectives: To develop a concept for a preference-based index for the SF-12 on the basis of multi-attribute decision analysis and to perform initial tests of its feasibility and validity in an empirical study. Methods: A multi-attribute preference function for the SF-12 was developed, estimated and tested for validity. Two mail surveys (n = 100, 200) and an interview (n = 72) were conducted with women who had an operation for breast cancer. Visual analogue scale (VAS) and standard gamble (SG) measures elicited preference-based valuations. Results: Eight attributes were identified in the SF-12. Validity tests showed an average difference of 8 VAS score points between directly measured and predicted values for given health states. Conclusion: The initial results show that this approach might allow the direct assignment of a preference-based valuation to the SF-12. The quality of the psychometric features of the multi-attribute value function is encouraging. Future studies should test this concept more extensively, especially by determining parameters for a representative sample of the general population and by comparing performance with other approaches to value the SF-12.
Health Economics

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Direkte medizinische Kosten der (starken) Adiposias: Ein Buttom-up-Vergleich über- vs. normalgewichtiger Erwachsener in der KORA-Studienregion.
Gesundheitswesen 68, 110-115 (2006)
Ziel der Studie: Schätzung und Vergleich der direkten medizinischen Krankheitskosten bei Erwachsenen in verschiedenen BMI-Klassen und unterschiedlichen Graden von Adipositas. Methodik: In einer Teilstichprobe (n = 947) des KORA-Survey S4 1999/2001 (Region Augsburg, Alter: 25 - 74 Jahre) wurden Arztkontakte, Medikamentenkäufe und -erhalt sowie Tage stationären Aufenthalts im Krankenhaus über einen Zeitraum von einem œ Jahr in drei computergestützten Telefoninterviews erhoben. Der Body-Mass-Index (BMI in kg/m^2) wurde anthropometrisch bestimmt. Personen mit Normalgewicht ($18,5 \le BMI < 25$), Präadipositas ($25 \le BMI < 30$), moderater Adipositas (Grad 1: $30 \le BMI < 35$) und starker Adipositas (Grade 2 - 3: $BMI \ge 35$) wurden mittels auf allgemeinen linearen Modellen basierenden Kovarianz- und Regressionanalysen bzgl. ihrer Gesundheitskosten verglichen. Arztkontakte und Krankenhaustage wurden gemäß des Vorschlags der AG MEG bewertet, Medikamente mit den tatsächlichen Kosten. Für Geschlecht, Alter, sozioökonomischen Status (Helmert-Index), Krankenkasse (GKV vs. PKV) und Wohnort (Stadt Augsburg vs. Landkreis Augsburg oder Aichach-Friedberg) wurde adjustiert. Ergebnisse: Während sich Personen mit moderater Adipositas in ihren direkten medizinischen Kosten im Mittel statistisch nicht signifikant von Normalgewichtigen bzw. Präadipösen unterschieden (1 080,14 € vs. 847,60 € bzw. 830,59 €; für Versorgungsnutzer: 1 215,55 € vs. 993,18 € bzw. 1 003,23 € [alle Werte adjustiert und per annum]), ergaben sich für Personen mit starker Adipositas deutlich erhöhte Kosten (2 572,19 €; Versorgungsnutzer: 2 964,87 €). Subanalysen einzelner Inanspruchnahmeparameter ergaben, dass dieses Muster vor allem auf stationäre Krankenhausaufenthalte und den Erhalt/Kauf rezeptpflichtiger Medikamente zurückzuführen ist. Schlussfolgerung: Die Ergebnisse sprechen für im Mittel höhere direkte medizinische Kosten vor allem bei Personen mit starker, weniger mit moderater Adipositas. Sie unterstreichen, dass die Unterscheidung moderater vs. starker Adipositas (Grade 1 vs. 2 - 3) in der Gesundheitsökonomie und Versorgungsforschung von besonderer Bedeutung ist.
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Public health is an interdiscipline, and about wholes and parts: Indeed, critical health psychology needs to join forces.
J. Health Psychol. 11, 395-399 (2006)
Hepworth's assessment of critical health psychology's capacity to contribute to public health promotion (this issue) is commented on and supplemented by selected issues relevant to Hepworth's timely call for interdisciplinary research and action in this context. Drawing on eco-epidemiology, multilevel research strategies are suggested that comprehensively account for individual/psychological and population/sociological factors. It is delineated how health promotion policies may be backed by psychologically informed policy analysis. Regarding health, it is argued to keep scrutinizing ill-health and to resist simplistic notions of quality of life or wellness but also to enhance these by incorporating concepts from positive psychology. Finally, it is considered whether trans disciplinarity may be in aid of fully realizing the potentials of blending the merits of health psychology and public health.

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Ambient Air Pollution is Associated with Increased Risk of Hospital Cardiac Readmissions of Myocardial Infarction Survivors in Five European Cities.
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Background— Ambient air pollution has been associated with increases in acute morbidity and mortality. The objective of this study was to evaluate the short-term effects of urban air pollution on cardiac hospital readmissions in survivors of myocardial infarction, a potentially susceptible subpopulation. Methods and Results— In this European multicenter cohort study, 22 006 survivors of a first myocardial infarction were recruited in Augsburg, Germany; Barcelona, Spain; Helsinki, Finland; Rome, Italy; and Stockholm, Sweden, from 1992 to 2000. Hospital readmissions were recorded in 1992 to 2001. Ambient nitrogen dioxide, carbon monoxide, ozone, and mass of particles <10 μm (PM10) were measured. Particle number concentrations were estimated as a proxy for ultrafine particles. Short-term effects of air pollution on hospital readmissions for myocardial infarction, angina pectoris, and cardiac causes (myocardial infarction, angina pectoris, dysrhythmia, or heart failure) were studied in city-specific Poisson regression analyses with subsequent pooling. During follow-up, 6655 cardiac readmissions were observed. Cardiac readmissions increased in association with same-day concentrations of PM10 (rate ratio [RR] 1.021, 95% CI 1.004 to 1.039) per 10 μg/m3) and estimated particle number concentrations (RR 1.026 [95% CI 1.005 to 1.048] per 10 000 particles/cm3). Effects of similar strength were observed for carbon monoxide (RR 1.014 [95% CI 1.001 to 1.026] per 200 μg/m3 [0.172 ppm]), nitrogen dioxide (RR 1.032 [95% CI 1.013 to 1.051] per 8 μg/m3 [4.16 ppb]), and ozone (RR 1.026 [95% CI 1.001 to 1.051] per 15 μg/m3 [7.5 ppb]). Pooled effect estimates for angina pectoris and myocardial infarction readmissions were comparable. Conclusions— The results suggest that ambient air pollution is associated with increased risk of hospital cardiac readmissions of myocardial infarction survivors in 5 European cities.
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Übergewicht gilt sowohl in der klinischen Medizin als auch in der bevölkerungsbezogenen Gesundheitswissenschaft (Public Health) als einer der bedeutendsten Risikofaktoren. Das hat vor allem drei Gründe: Zum einen erhöht insbesondere deutliches Übergewicht (Adipositas) die Wahrscheinlichkeit zahlreicher schwerwiegender Krankheiten, besonders im Herz-Kreislauf- und Stoffwechselbereich (z. B. Myokardinfarkt und Typ-2-Diabetes).Zum anderen hat auch in Deutschland die Zahl Übergewichtiger und Adipöser in den vergangenen Jahrzehnten deutlich zugenommen, etwa bei Kindern und Jugendlichen, aber auch bei jüngeren Frauen und Männern mittleren Alters.Schließlich gilt Übergewicht als zumindest teilweise vermeid- und behandelbar, da es unter anderem mit beeinflussbaren Faktoren wie dem Ernährungsverhalten (inklusive Alkoholkonsum) sowie körperlicher (In-)Aktivität zusammenhängt. All das macht Übergewicht auch für die Versorgungsforschung und Gesundheitsökonomie zu einem höchst aktuellen Thema. So hat das Robert-Koch-Institut in einer Analyse der Daten des Bundes-Gesundheitssurvey 1998 zu den Einflussfaktoren der Inanspruchnahme im ambulanten Bereich festgestellt, dass Adipositas (definiert als ein Body-Mass-Index [BMI] ≥ 30) mit einer erhöhten Inanspruchnahme von Allgemeinärzten (allerdings nicht Fachärzten) einhergeht. Die volkswirtschaftlichen Kosten der Adipositas wurden kürzlich in einer Top-Down-Analyse auf 530 Mio. Euro geschätzt, wohlgemerkt ohne Komorbiditäten (mit Letzteren waren es über fünf Mrd. Euro). Dabei sind die spezifischen direkten Kosten der Versorgung vor allem auf Allgemeinarztbesuche zurückzuführen, und die indirekten Kosten (im Sinne arbeitsunfähigkeitsbedingter Produktivitätsverluste) machten ungefähr 50 % aus.
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Background: Atopic disorders are the result of complex interactions between genetic and environmental factors. Associations analyses between the promoter polymorphism rs1800875 in the mast cell chymase gene (CMA1) and atopy-related phenotypes have yielded inconsistent results. Methods: We sequenced the CMA1 locus in 24 unrelated healthy individuals with serum IgE levels <50% percentile and 24 individuals with atopic eczema and serum IgE levels >90% percentile. Seven CMA1 single nucleotide polymorphisms (SNPs) were evaluated for evidence of associations with atopic phenotypes within a large population of German adults (n = 1875). Subjects were phenotyped by standardized questionnaires and interviews, skin prick testing and serum IgE measurements. Genotyping was performed using MALDI-TOF MS (Matrix-Assisted Laser Desorption Ionization–Time of Flight mass spectrometry). Results: Promoter polymorphism rs1800875 was significantly associated with atopic eczema. No associations between any other single SNP and atopic phenotypes could be detected. Haplotype reconstruction revealed four of 128 possible haplotypes reaching estimated frequencies of 3% or more. Two of these haplotypes showed a borderline-significant association with atopic eczema, which did not remain significant after correction for multiple testing. Conclusions: Results confirm previous observations of a significant association between the CMA1 promoter polymorphism rs1800875 and atopic eczema, but not with serum IgE levels, and support the hypothesis that CMA1 serves as candidate gene for atopic eczema.
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Latent membrane protein 1 (LMP-1) of Epstein-Barr virus (EBV) promotes tumorigenesis by inhibiting apoptosis. We show that an important antiapoptotic activity of LMP-1 is the inhibition of Bcl2-associated protein X (Bax), a potent proapoptotic protein. BAX expression was regulated by LMP-1 activation of nuclear factor κB (NF-κB) via the C-terminal activation region 1 (CTAR-1) and CTAR-2. Interestingly, p65/p50 inhibited, whereas p50/p50

increased, BAX promoter activity as demonstrated by overexpression and selective inhibition of these NF-κB isoforms. Electrophoretic mobility shift analysis revealed that LMP-1 activates 2 of the 3 NF-κB binding sites (κB1-κB3) in the BAX promoter. LMP-1 induced binding of the NF-κB heterodimer p65/p50 to the κB2 site and of the p50/p50 homodimer to the κB3 site. Promoter mutation analysis revealed that the κB2 site is necessary for inhibition of BAX promoter activity and the κB3 site, for its activation. However, the activation of the BAX promoter by LMP-1 was observed only in the presence of specific inhibitors of p65/p50. In all other cases, LMP-1 inhibited BAX promoter activity. Most importantly, the antiapoptotic activity of LMP-1 was considerably decreased in cells deficient for BAX. These results indicate that the inhibition of Bax may be an important antiapoptotic activity of LMP-1.
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Altered myocardial repolarization is one of the important substrates of ventricular tachycardia and fibrillation. The influence of rare gene variants on repolarization is evident in familial long QT syndrome. To investigate the influence of common gene variants on the QT interval we performed a linkage disequilibrium based SNP association study of four candidate genes. Using a two-step design we analyzed 174 SNPs from the KCNQ1, KCNH2, KCNE1, and KCNE2 genes in 689 individuals from the population-based KORA study and 14 SNPs with results suggestive of association in a confirmatory sample of 3277 individuals from the same survey. We detected association to a gene variant in intron 1 of the KCNQ1 gene (rs757092, +1.7 ms/allele, P=0.0002) and observed weaker association to a variant upstream of the KCNE1 gene (rs727957,

+1.2 ms/allele, P=0.0051). In addition we detected association to two SNPs in the KCNH2 gene, the previously described K897T variant (rs1805123, −1.9 ms/allele, P=0.0006) and a gene variant that tags a different haplotype in the same block (rs3815459, +1.7 ms/allele, P=0.0004). The analysis of additive effects by an allelic score explained a 10.5 ms difference in corrected QT interval length between extreme score groups and 0.95% of trait variance (P<0.00005). These results confirm previous heritability studies indicating that repolarization is a complex trait with a significant heritable component and demonstrate that high-resolution SNP-mapping in large population samples can detect and fine map quantitative trait loci even if locus specific heritabilities are small.
Circulation Research

Rathmann, W.; Martin, S; Haastert, B.; Icks, A.; Holle, R.; Löwel, H.; Giani, G.; KORA Study Group (Holle, R.; Wichmann, H.-E.; John, J.; Illig, T.; Meisinger, C.; Peters, A.)
Performance of screening questionnaires and risk scores for undiagnosed diabetes.
Arch. Intern. Med. 165, 436-441 (2005)
BACKGROUND: Validation of published screening questionnaires and risk scores for undiagnosed diabetes has typically not been performed in independent population samples. METHODS: Oral glucose tolerance tests were performed in 1353 participants (aged 55-74 years) without known diabetes in the Cooperative Health Research in the Region of Augsburg (KORA) Survey 2000, Augsburg, Germany. Sensitivity, specificity, and the area under the receiver operating characteristic curve (AUC) for undiagnosed diabetes were calculated for various screening questionnaires. RESULTS: Four screening tests (Rotterdam Diabetes Study, Cambridge Risk Score, San Antonio Heart Study, and Finnish Diabetes Risk Score) were applied to the KORA data. The AUCs were 61% (95% confidence interval [CI], 56%-66%) for the Rotterdam Diabetes Study, 65% (95% CI, 60%-69%) for the Finnish Diabetes Risk Score (P=.10 vs Rotterdam), and 67% (95% CI, 62%-72%) for the Cambridge Risk Score (P<.001 vs Rotterdam). A predictive model including fasting glucose level (San Antonio Heart Study) yielded an AUC of 90% (P<.01 vs all 3 questionnaires); however, this was not significantly different from fasting glucose level alone (AUC, 89%; P=.46). The sensitivities, specificities, and predictive values of questionnaires were substantially lower than originally described, which was mainly due to population variation of risk factors compared with the KORA sample (age, body mass index, antihypertensive medication, and smoking). CONCLUSIONS: Currently proposed questionnaires yielded low validity when applied to a new population, most likely due to differences in population characteristics. Performance of diabetes risk questionnaires or scores must be assessed in the target population where they will be applied.
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Trends in socioeconomic inequalities in self-assessed health in 10 European countries.
Int. J. Epidemiol. 34, 295-305 (2005)
Background: Changes over time in inequalities in self-reported health are studied for increasingly more countries, but a comprehensive overview encompassing several countries is still lacking. The general aim of this article is to determine whether inequalities in self-assessed health in 10 European countries showed a general tendency either to increase or to decrease between the 1980s and the 1990s and whether trends varied among countries. Methods: Data were obtained from nationally representative interview surveys held in Finland, Sweden, Norway, Denmark, England, The Netherlands, West Germany, Austria, Italy, and Spain. The proportion of respondents with self-assessed health less than 'good' was measured in relation to educational level and income level. Inequalities were measured by means of age-standardized prevalence rates and odds ratios (ORs). Results: Socioeconomic inequalities in self-assessed health showed a high degree of stability in European countries. For all countries together, the ORs comparing low with high educational levels remained stable for men (2.61 in the 1980s and 2.54 in the 1990s) but increased slightly for women (from 2.48 to 2.70). The ORs comparing extreme income quintiles increased from 3.13 to 3.37 for men and from 2.43 to 2.86 for women. Increases could be demonstrated most clearly for Italian and Spanish men and women, and for Dutch women, whereas inequalities in health in the Nordic countries showed no tendency to increase. Conclusions: The results underscore the persistent nature of socioeconomic inequalities in health in modern societies. The relatively favourable trends in the Nordic countries suggest that these countries' welfare states were able to buffer many of the adverse effects of economic crises on the health of disadvantaged groups. © The Author 2004; all rights reserved.
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Mobilization of exogenous and endogenous selenium to bile after the intravenous administration of environmentally relevant doses of arsenite to rabbits.
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Extending our studies of the effect of arsenite on the metabolism of inorganic selenium (selenite and selenate) to lower doses, we intravenously injected New Zealand white rabbits with aqueous solutions of arsenite, selenite, arsenite + selenite, selenate and selenate + arsenite at 50 µg and 5 µg metalloid per kilogram body weight. Bile samples were collected for 25 min, acid-digested and analyzed for total arsenic and selenium by double focusing magnetic sector field inductively coupled plasma mass spectrometry. At both dose levels, and in accord with previous observations, an increased mutual biliary excretion of arsenic and selenium was observed regardless of whether selenium was coadministered with arsenite in the form of selenite or selenate. Based on our previous investigations into the in vivo interaction between arsenite and selenite (or selenate), these findings can be rationalized in terms of the biliary excretion of the seleno-bis(S-glutathionyl) arsinium ion, $[(GS)_2AsSe]^-$. In addition, the treatment of rabbits with 50 µg arsenic per kilogram body weight in form of arsenite alone also resulted in a significantly increased bile selenium concentration compared with bile from untreated animals ($p < 0.05$), which implies a mobilization of endogenous selenium to bile. Combined, these results establish a causal relationship between the exposure of mammals to arsenite and selenium deficiency.
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Schulz, E.; Leidl, R.; König, H.H.
The impact of ageing on hospital care and long-term care--the example of Germany.
Health Policy 67, 57-74 (2004)
BACKGROUND: In the next few decades the population in all EU-countries will age rapidly. This could have a major impact on the health care sector. This study analyses the effect of population ageing on utilisation in two key sectors of the health care system, namely hospital care and long-term care in Germany, up to 2020 with an outlook to 2050. METHODS: Two population scenarios, one with constant, one with increasing life expectancy, were combined with constant age and gender specific utilisation rates of hospital and long-term care. In the case of hospital care two projection methods were used: Method A differentiates between age-groups, gender and main diagnosis. Method B differentiates between age-groups, survivors and decedents. RESULTS: Population ageing was found to cause a moderate increase in hospital days, but was associated with substantial changes in the disease and age structure. In the case of increasing life expectancy, method B lead to a lower growth in hospital days than method A. The number of persons receiving long-term care will increase strongly, associated with a shift to more severe disability and institutional care. Changes in the composition of private households and the increasing labour participation of women will lead to additional demand for professional caregivers at home and in institutions. CONCLUSIONS: Changes in the number and disease structure of hospital days due to population ageing will require reorganisation and restructuring of hospital departments. In the case of long-term care a high increase in professional home care and institutional care will be required. Health policy has to take into account these developments in order to adequately deal with future demand for these services.
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Corzillius, M.; Mühlberger, N.; Sroczynski, G.; Jaeger, H.; Wasem, J.; Siebert, U.
Cost effectiveness analysis of routine use of genotypic antiretroviral resistance testing after failure of antiretroviral treatment for HIV.
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OBJECTIVES: Single use of genotypic antiretroviral resistance testing (GART) after first failure of highly active antiretroviral therapy (HAART) was reported to be cost effective; its use prior HAART initiation is unknown. Guidelines recommend GART after each treatment failure. We assessed the cost effectiveness of GART used routinely after first and subsequent treatment failures. Furthermore, we determined the minimum effectiveness required for GART prior to the first HAART to be as cost effective as after treatment failure. DESIGN AND METHODS: We developed a decision-analytic Markov model to estimate lifetime clinical and economic outcomes in a cohort of HIV patients starting HAART. Rates of treatment failure, estimates of GART effectiveness and data on disease progression were derived from published trials and observational studies. A cost effectiveness analysis was performed from the perspective of the healthcare system using cost data from a Central European healthcare setting. Deterministic and probabilistic sensitivity analyses using Monte Carlo technique were performed. RESULTS: GART after treatment failures increased life expectancy by 9 months and undiscounted life-time costs per case by 16,406 euros. The discounted incremental cost effectiveness ratio was 22,510 euros per life-year gained (euros/LY). Best- and worst-case scenarios yielded 16,512 euros/LY and 42,900 euros/LY, respectively. GART prior to the initiation of HAART would be equally cost effective if it could reduce the probability of first HAART failure by at least 36%. CONCLUSION: Routine use of GART after treatment failures is cost effective. GART prior to the first HAART would be equally cost effective if it could lower the probability of first HAART failure by approximately a third.
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Fröhlich, M.; Mühlberger, N.; Hanke, H.; Imhof, A.; Döring, A.; Pepys, M.P.; Koenig, W.
Markers of inflammation in woman on different hormone replacement therapies.
Ann. Med. 35, 353-361 (2003)
BACKGROUND AND AIM. To measure in¯ammatory markers in postmenopausal women on different forms of hormone in postmenopausal women on different forms of hormone replacement therapy (HRT). replacement therapy (HRT). METHOD. C-reactive protein (CRP), ®brinogen, plasma METHOD. C-reactive protein (CRP), ®brinogen, plasma viscosity (PV), albumin and white blood cell (WBC) count viscosity (PV), albumin and white blood cell (WBC) count were determined in 749 postmenopausal women. were determined in 749 postmenopausal women. RESULTS. CRP concentration was signi®cantly higher in RESULTS. CRP concentration was signi®cantly higher in women on estrogen monotherapy (difference of the median women on estrogen monotherapy (difference of the median (d) 0.96 (d) 0.96 mg/l, mg/l, P P = = 0.013), compared to those without HRT, 0.013), compared to those without HRT, but there was no difference in women on combined HRT. but there was no difference in women on combined HRT. Fibrinogen concentration was signi®cantly lower in women Fibrinogen concentration was signi®cantly lower in women on estrogen monotherapy (d 0.25 on estrogen monotherapy (d 0.25 g/l, g/l, P P = = 0.004) and 0.004) and combined HRT (d 0.4 combined HRT (d 0.4 g/l, g/l, P P < < 0.001), compared to women 0.001), compared to women without HRT. Similarly, PV was signi®cantly lower in women without HRT. Similarly, PV was signi®cantly lower in women on estrogen monotherapy (d 0.017 on estrogen monotherapy (d 0.017 mPa mPa · · s, s, P P = = 0.007) and 0.007) and women

on combined HRT (d 0.039 women on combined HRT (d 0.039 mPa mPa · · s, s, P P < < 0.001), 0.001), compared to those without HRT. No differences were found compared to those without HRT. No differences were found for WBC count and the negative acute phase marker for WBC count and the negative acute phase marker albumin in the various treatment groups. In contrast to albumin in the various treatment groups. In contrast to oral estrogen administration, levels o fCRP, ®brinogen and oral estrogen administration, levels o fCRP, ®brinogen and PV in women on transdermal estrogen therapy did not differ PV in women on transdermal estrogen therapy did not differ from the no-HRT group. There was no association between from the no-HRT group. There was no association between these markers o fin¯ammation and plasma estrogen levels. these markers o fin ¯ammation and plasma estrogen levels. CONCLUSION. Oral estrogen monotherapy was associated CONCLUSION. Oral estrogen monotherapy was associated with highest concentrations o fCRP. In contrast, other with highest concentrations o fCRP. In contrast, other markers o fin¯ammation were either similar or lower in the markers o fin¯ammation were either similar or lower in the oral HRT group, compared to the group o fwomen without oral HRT group, compared to the group o fwomen without HRT, suggesting that higher CRP concentrations re¯ect HRT, suggesting that higher CRP concentrations re¯ect estrogen effects on CRP expression rather than a systemic estrogen effects on CRP expression rather than a systemic pro-in¯ammatory effect. pro-in¯ammatory ef
Annals of Medicine

Koenig, W.; Sund, M.; Fröhlich, M.; Löwel, H.; Hutchinson, W.L.; Pepys, M.B.
Refinement of the Association of Serum C-reactive Protein Concentration and Coronary Heart Disease Risk by Correction for Within-Subject Variation over Time : The MONICA Augsburg Studies,1984-1987.
Am. J. Epidemiol. 158, 357-364 (2003)
The authors sought to assess the repeatability of measurements of C-reactive protein, an independent predictor of coronary heart disease, in a large cohort of apparently healthy men and to correct earlier estimates of the association of C-reactive protein and coronary heart disease for the measurement error in this protein. They measured C-reactive protein by a high-sensitivity assay in 936 men aged 45–64 years in the MONICA (Monitoring of Trends and Determinants in Cardiovascular Disease) Augsburg cohort in 1984–1985 and remeasured it 3 years later. All men were subjected to an 8-year follow-up of their cardiovascular status. The analytical variation of the assay was small, with the analytical variance component at 1 percent of the within-subject variance component, a repeatability coefficient of 25 percent, and a reliability coefficient of 1.00. In contrast, the within- subject variation of C-reactive protein corresponded to a repeatability coefficient of 740 percent and a reliability coefficient of 0.54, indicating considerable within-subject variation. Based on the authors' estimates, three serial determinations of C-reactive protein should be done to achieve a reliability of 0.75, the value they found for total cholesterol. Correcting the hazard ratios in their original analysis of the association of coronary heart disease and high-sensitivity-assay C-reactive protein for the measurement error in C-reactive protein and covariables leads to a considerably larger estimate. The results suggest that the true association between C-reactive protein and cardiovascular risk is underestimated by a single C-reactive protein determination, and that several serial C- reactive protein measurements should be taken.
American Journal of Epidemiology

Fröhlich, M.; Sund, M.; Löwel, H.; Imhof, A.; Hoffmeister, A.; Koenig, W.
Independent association of various smoking characteristics with markers of systemic inflammation in men. Results from a representative sample of the general population (MONICA Augsburg Survey 1994/95).
Eur. Heart J. 24, 1365-1372 (2003)
AIMS: Aim of the study was to investigate the association between various markers of systemic inflammation and a detailed history of smoking in a large representative sample of the general population. METHODS AND RESULTS: The effects of chronic smoking on white blood cell (WBC) count, fibrinogen, albumin, plasma viscosity (PV), and high-sensitivity C-reactive protein (CRP) were measured in 2305 men and 2211 women, age 25-74 years, participating in the third MONICA Augsburg survey 1994/95. In men, current smokers showed statistically significantly higher values for WBC count, fibrinogen, PV, and CRP, compared to never smokers, with intermediate, but only slightly increased values for ex-smokers and for occasional smokers. No consistent associations were seen with albumin. Duration of smoking was positively associated with markers of inflammation as were pack-years of smoking. Conversely, duration of abstinence from smoking was inversely related to these markers. Except for WBC count, no such associations were found in women. CONCLUSION: Data from this large representative population show strong associations between smoking and various markers of systemic inflammation in men. They also show that cessation of smoking is associated with a decreased inflammatory response, which may represent one mechanism responsible for the reduced cardiovascular risk in these subjects.
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We apply a high-throughput protocol of chip-based mass spectrometry (matrix-assisted laser desorption/ionization time-of-flight; MALDI-TOF) as a method of screening for differences in single-nucleotide polymorphism (SNP) allele frequencies. Using pooled DNA from individuals with asthma, Crohn's disease (CD), schizophrenia, type 1 diabetes (T1D), and controls, we selected 534 SNPs from an initial set of 1435 SNPs spanning a 25-Mb region on chromosome 6p21. The standard deviations of measurements of time of flight at different dots, from different PCRs, and from different pools indicate reliable results on each analysis step. In 90% of the disease-control comparisons we found allelic differences of <10%. Of the T1D samples, which served as a positive control, 10 SNPs with significant differences were observed after taking into account multiple testing. Of these 10 SNPs, 5 are located between DQB1 and DRB1, confirming the known association with the DR3 and DR4 haplotypes whereas two additional SNPs also reproduced known associations of T1D with DOB and LTA. In the CD pool also, two

earlier described associations were found with SNPs close to DRB1 and MICA. Additional associations were found in the schizophrenia and asthma pools. They should be confirmed in individual samples or can be used to develop further quality criteria for accepting true differences between pools. The determination of SNP allele frequencies in pooled DNA appears to be of value in assigning further genotyping priorities also in large linkage regions.
Genomics

Kim, T.S.; Knittel, M.; Dörfer, C.; Steinbrenner, H.; Holle, R.; Eickholz, P.
Comparison of two types of synthetic biodegradable barriers for GTR in interproximal infrabony defects: Clinical and radiographic 24-month results.
Int. J. Periodontics Restor. Dent. 23, 481-489 (2003)
The aim of the present study was to compare the efficacy of guided tissue regeneration (GTR) using two different biodegradable barriers (polylactide acetyltributyl citrate; polydioxanon) in three- and two-walled infrabony defects. The polydioxanon barrier is an experimental GTR membrane that consists of a continuous occlusive barrier with a layer of slings on the side that is meant to face the mucoperiosteal flap. Fifteen patients provided 15 pairs of similar contralateral periodontal defects: 12 predominantly two-walled and 18 predominantly three-walled infrabony defects. Each defect was randomly assigned to treatment with polylactide acetyltributyl citrate (control) or polydioxanon (test) devices. At baseline, 6, 12, 18, and 24 months after surgery, clinical measurements were performed and standardized radiographs obtained (not at 18 months). Both treatments revealed a significant Gingival Index reduction, probing depth reduction, and vertical probing attachment level gain 24 months after surgery. Both treatments showed slight resorption of the crestal alveolar ridge after 24 months, which failed to reach statistical significance. A statistically significant bone gain within the infrabony pockets was measured for both treatment options 24 months postsurgical. Regarding Gingival Index and probing depth reduction as well as vertical probing attachment level and bone gain, there were neither statistically significant nor clinically relevant differences between test and control barriers. The use of both biodegradable barriers in GTR therapy may be recommended.
International Journal of Periodontics & Restorative Dentistry, The

Mackenbach, J.P.; Bakker, M.J.
Tackling socioeconomic inequalities in health: analysis of European experiences.
Lancet 362, 1409-1414 (2003)
Effective strategies must be developed to reduce socioeconomic inequalities in health. Most efforts take place in isolation, and only the UK experience has been discussed widely in international published work. We therefore analysed policy developments on health inequalities in different European countries between 1990 and 2001. We noted that countries are in widely different phases of awareness of, and willingness to take action on, inequalities in health. We identified innovative approaches in five main areas: policy steering mechanisms; labour market and working conditions; consumption and health-related behaviour; health care; and territorial approaches. National advisory committees in the UK, the Netherlands, and Sweden have proposed comprehensive strategies to reduce health inequalities. Variations between these packages suggest that policymaking in this area still is largely intuitive and would benefit from incorporation of more rigorous evidence-based approaches. Further international exchanges of experiences with development, implementation, and evaluation of policies and interventions to reduce health inequalities can help to enhance learning speed.
Lancet, The

Rathmann, W.; Haastert, B.; Icks, A.; Löwel, H.; Meisinger, C.; Holle, R.; Giani, G.
High prevalence of undiagnosed diabetes mellitus in Southern Germany: Target populations for efficient screening. The KORA survey 2000.
Diabetologia 46, 182-189 (2003)
AIMS/HYPOTHESIS: To estimate the prevalence of undiagnosed diabetes mellitus, impaired glucose tolerance (IGT) and impaired fasting glucose (IFG), and their relations with cardiovascular risk factors in the general population aged 55 to 74 years in Southern Germany. METHODS: Oral glucose tolerance tests were carried out in a random sample of 1353 subjects aged 55 to 74 years participating in the KORA (Cooperative Health Research in the Region of Augsburg) Survey 2000. Prevalences of glucose tolerance categories (1999 WHO criteria) were adjusted for sample probabilities. The numbers needed to screen (NNTS) to identify one person with undiagnosed diabetes were estimated from age-adjusted logistic regression models. RESULTS: Sample design-based prevalences of known and unknown diabetes, IGT, and IFG were 9.0%, 9.7%, 16.8%, 9.8% in men, and 7.9%, 6.9%, 16.0%, 4.5% in women, respectively. In both sexes, participants with undiagnosed diabetes had higher BMI, waist circumference, systolic blood pressure, triglycerides, uric acid, and lower HDL-cholesterol than normoglycaemic subjects. A combination of abdominal adiposity, hypertension, and parental diabetes in men resulted in a NNTS of 2.9 (95%CI: 2.0-4.6). In women, the combination of increased triglycerides, hypertension and parental diabetes history yielded a NNTS of 3.2 (95%CI: 2.2-5.1). CONCLUSION/INTERPRETATION: About 40% of the population aged 55 to 74 years in the Augsburg region have disturbed glucose tolerance or diabetes. Half of the total cases with diabetes are undiagnosed. Cardiovascular risk factors worsen among glucose tolerance categories, indicating the need for screening and prevention. Screening for undiagnosed diabetes could be most efficient in individuals with abdominal adiposity (men), hypertriglyceridaemia (women), hypertension, and parental diabetes history.
Diabetologia

Rütten, A.; Lüschen, G.; von Lengerke, T.; Abel, T.; Kannas, L.; Rodríguez Diaz, J.A.; Vinck, J.; van der Zee, J.
Determinants of health policy impact: A theoretical framework for policy analysis.
Soz. Präventivmed. 48, 293-300 (2003)
This paper addresses the role of policy and evidence in health promotion. The concept of von Wright's "logic of events" is introduced and applied to health policy impact analysis. According to von Wright (1976), human action can be explained by a restricted number of determinants: wants, abilities, duties, and opportunities. The dynamics of action result from changes in opportunities (logic of events). Applied to the policymaking process, the present model explains personal wants as

subordinated to political goals. Abilities of individual policy makers are part of organisational resources. Also, personal duties are subordinated to institutional obligations. Opportunities are mainly related to political context and public support. The present analysis suggests that policy determinants such as concrete goals, sufficient resources and public support may be crucial for achieving an intended behaviour change on the population level, while other policy determinants, e.g., personal commitment and organisational capacities, may especially relate to the policy implementation process. The paper concludes by indicating ways in which future research using this theoretical framework might contribute to health promotion practice for improved health outcomes across populations.
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Sozialepidemiologische Erklärungsansätze im Spannungsfeld zwischen Schicht-und Lebensstilkonzeptionen Plädoyer für eine integrative Betrachtung auf der Grundlage der Bourdieuschen Habitustheorie.
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Mielck, A.
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Gesundheits- und Sozialpolitik

John, J.; Holle, R.
Probleme der Erschließung und Nutzung von Daten der Gesetzlichen Krankenversicherung für bevölkerungsbezogene gesundheitsökonomische Evaluationsstudien : Erfahrungen aus KORA.
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Courté-Wienecke, S.
Externe Qualitätssicherung für Managed-Care-Organisationen : Erfahrungen aus den USA.
Gesundheitsökon. Qualitätsmanag. 8, 52-59 (2003)
Experience with external quality assurance of managed care organizations has been gained in the United States since the 1990's. The leading organization in this respect is the National Committee for Quality Assurance (NCQA) a private, not-for-profit organization with the aim of improving the quality of health care by assessing and reporting on the quality of managed care organizations. The NCQA's two complementary strategies are the accreditation of managed care organizations and performance measurement using a standardized set of measures of structure, process and outcomes of care (HEDIS). Use of this information by the various user groups and effects of the external quality assurance activities are described. If following the recent years' changes in legislation an increased diversification of sickness funds takes place in Germany, e. g., through selective contracting with distinct groups of providers or health care delivery organizations, or through a widespread establishment of integrated care networks using managed care tools, then - complementary to the quality management within these organizations - measures of external quality assurance and an increased transparency of care should be implemented. These should allow monitoring the effects of managed care instruments on the quality of care and facilitate informed choices of sickness funds and provider networks by consumers. In developing such concepts it can be very helpful to evaluate the described instruments and the experience with their application.
Gesundheitsökonomie & Qualitätsmanagement

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Frauen und koronare Herzkrankheit : Epidemiologische Besonderheiten im Vergleich zu Männern.
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Löwel, H.; Trentinaglia, I.; Heier, M.; Hörmann, A.
Der prähospitale Herzstillstand : eine Herausforderung an die Notfallmedizin: Ergebnisse aus dem Augsburger Herzinfarktregister.
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Löwel, H.; Meisinger, C.; Heier, M.; Hörmann, A.; Kuch, B.; Gostomzyk, J.; Koenig, W.
Geschlechtsspezifische Trends von plötzlichem Herztod und akutem Herzinfarkt : Ergebnisse des bevölkerungsbasierten KORA / MONICA Augsburg Herzinfarkt-Registers 1985 bis 1998.
Dtsch. Med. Wochenschr. 127, 2311-2316 (2002)
Hintergrund und Fragestellung: Der akute Herzinfarkt (HI) ist die Haupttodesursache im Erwachsenenalter. Die Arbeit untersucht in der Region Augsburg die zeitlichen Trends der HI-Morbidität und Mortalität der Bevölkerung und die 28-Tage-Letalität der Erkrankten sowie deren Determinanten nach Geschlecht. Ziel ist die Ableitung datenbasierter Vorschläge für eine verbesserte Akutversorgung von HI-Patienten. Patienten und Methoden: Von 1985 - 1998 wurden 13 499 25 - 74jährige Patienten (9537 Männer; 3962 Frauen) mit HI registriert; 7873 (5300 Männer, 2573 Frauen) Personen verstarben innerhalb von 28 Tagen. Die Datenerhebung zu den Verstorbenen erfolgte über die regionalen Gesundheitsämter und durch schriftliche Befragung der behandelnden und Leichenschauärzte (>90 % Beteiligung). Anamnestische und Behandlungsdaten der Krankenhauspatienten (ein Tag überlebend) basieren auf Interviews und den Krankenakten. Die Prähospitalphase, der 1. Tag sowie der 2.-28. Tag nach Hospitalisierung wurden gesondert analysiert. Ergebnisse: Die HI-Morbidität je 100 000 Einwohner nahm bei Männern von 560 auf 397 und bei Frauen von 161 auf 145 HI ab, die Mortalität reduzierte sich von 317 auf 232 bei Männern und von 101 auf 96 koronare Todesfälle bei Frauen. Bei Männern nahmen die Inzidenz und die Reinfarktrate und bei Frauen nur die Reinfarktrate ab. Unverändert verstarb ein Drittel der Erkrankten prähospital und zumeist zu Hause. Die Letalität am ersten Kliniktag nahm zu. Bis 1996/98 hatte sich die Akuttherapie im Krankenhaus stark verbessert, wodurch die Letalität von 13,0 % auf 8,4 % bei Männern und von 12,5 % auf 10,7 % Frauen gesunken ist. Folgerung: Eine weitere Abnahme des HI-Risikos erfordert intensivierte präventive Bemühungen bei Patient und Arzt. Eine verbesserte Aufklärung insbesondere von alleinstehenden HI-Gefährdeten ließe im Akutfall einen früheren Arztkontakt, eine schnellere Hospitalisierung und damit bessere Überlebenschancen erwarten. Background and aim: Myocardial infarction (MI) is the main single cause of death in adult populations. For the MONICA Augsburg population, MI-morbidity, mortality, and 28-day case fatality and their determinants were assessed by gender, and suggestions for an intensified acute care program were presented. Patients and methods: From 1985 to 1998, 13 499 25- to 74-year-old MI cases (9537 men, 3962 women) were registered; 7873 cases (5300 men, 2573 women) died within 28 days. Cardiac deaths were identified by regional health departments; causes of death were validated by the last treating physician and the coroner (response > 90 %). Hospitalized patients were interviewed about history and circumstances of the acute event; treatment data were abstracted from hospital charts. The prehospital phase, the first and the 2nd to 28thday after hospitalization were analyzed separately. Results: MI-morbidity per 100 000 population declined from 560 to 397 MI cases in men and from 161 to 145 in women; mortality decreased from 317 to 232 in men and from 101 to 96 in women. The decline in men was due to decreasing incident and recurrent MI whereas in women it was only due to a reduction of recurrent MI. One third died before hospitalization, mainly at home. Case fatality (CF) on the first day in hospital increased. In 24 hour survivors, evidence based treatment increased considerably, and was accompanied by decreasing 28-day-CF from 13.0 % to 8.4 % in men, and from 12.5 % to 10.7 % in women. Conclusion: Aggressive risk factor management and education of patients with cardiovascular risk factors concerning acute symptoms and the use of the emergency system will consequently improve pre-hospital and 28-day survival of the population.
Deutsche Medizinische Wochenschrift - DMW

Kuch, B.; Bolte, H.-D.; Hoermann, A.; Meisinger, C.; Löwel, H.
What is the real hospital mortality from acute myocardial infarction ? : Epidemiological vs clinical view.
Eur. Heart J. 23, 714-720 (2002)
Aims To examine the general influence of the definition of fatal and non-fatal acute myocardial infarction and coronary deaths on the estimation of in-hospital case- fatality, and to show how the definition of acute myocardial infarction influences time-trends of hospital mortality over 11 years. Methods and Results As part of the World Health Organization's MONICA (multinational Monitoring of Trends and Determinants in Cardiovascular Disease) Project in Augsburg all patients aged 25–74 years with a suspected diagnosis of acute myocardial infarction who were hospitalized in the study region's major clinic were registered prospectively between 1985 to 1995 (n = 4889). Patient information, including short-term survival status, was obtained from medical records, by interview of surviv- ing patients, and municipal death certificate files which were validated by an extended identification and validation pro- cess. In-hospital case fatality was estimated according to di ff erent definitions which closely followed the international MONICA criteria. Epidemiological definitions comprised definite and possible acute myocardial infarction, and events with unclassifiable deaths, while the clinical defi- nition was restricted to definite infarction. Overall, case fatality by the epidemiological definitions was 28 to 29·8% (23·5% of those treated in a coronary care unit) compared to 13·5% using the clinical definition. While over the

11 years, the reduction in case fatality according to the epi- demiological definitions was modest, highly significant decreases were observed by applying the clinical definition (from 15·8% in 1985–1988 to 10·8% in 1993–1995, P <0·001 adjusted for age and sex). The discrepancy in case fatality between the definitions is explained by the high proportion of patients who die very early (about 70% of all fatal events during the first 24 h) with the consequence of missing data which may preclude a definite diagnosis of acute myocardial infarction. Conclusions Applying a broader definition of acute myo- cardial infarction reveals that in-hospital mortality is higher than believed until now, and it implies that our e ff orts must be intensified to reduce overall in-hospital coronary heart disease mortality.
European Heart Journal

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Kim, T.S.; Holle, R.; Hausmann, E.; Eickholz, P.
Long-term results of guided tissue regeneration therapy with non-resorbable and bioabsorbable barriers. II. A case series of infrabony defects.
J. Periodontol. 73, 450-459 (2002)
BACKGROUND: The aim of this 5-year follow-up case series was to clinically and radiographically evaluate the long-term results after guided tissue regeneration (GTR) therapy of infrabony defects using non-resorbable and bioabsorbable barriers. METHODS: In 12 patients with advanced chronic periodontitis 12 pairs of contralateral infrabony defects were treated. Within each patient one defect received a non-resorbable (expanded polytetrafluoroethylene [ePTFE]; control: C) and the other a bioabsorbable (polyglactin 910; test: T) barrier by random assignment. At baseline and at 6 and 60 +/- 3 months after surgery clinical parameters and standardized radiographs were obtained. Gain of bone density within infrabony defects was assessed using subtraction radiography. RESULTS: Eight of 12 patients were available for the 60-month reexaminations. Six and 60 +/- 3 months after GTR therapy statistically significant (P < 0.05) vertical attachment (CAL-V) gain was observed in both groups (C6:2.6 +/- 1.4 mm; C60: 1.6 +/- 1.5 mm; T6:3.0+/- 1.7 mm; T60: 3.0 +/- 0.7mm). However at 60 months, 2 infrabony defects in the control group had lost all the attachment that had been gained 6 months after therapy and a clinically relevant but statistically in significant mean CAL-V loss of 1.0 +/- 2.1 mm was observed from 6 to 60 months. The case series failed to show statistically significant differences between test and control regarding CAL-V gain 60 months after surgery. Also subtraction analysis failed to reveal statistically significant differences regarding density gain between both groups 6 and 60 months postsurgically (C6: 26.4 +/- 54.2; C60 62.8 +/- 112.7; T6: 68.7 +/- 72.8; T60. 84.1 +/- 83.6). CONCLUSIONS: CAL-V gain achieved after GTR therapy in infrabony defects using both non-resorbable and bioabsorbable barriers was quite stable after 5 years in 14 of 16 defects.
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Respiratory mechanics in mice : Strain and sex specific differences.
Acta Physiol. Scand. 174, 367-375 (2002)
To assess the contribution of genetic background to respiratory mechanics, we developed a ventilator unit to measure lung function parameters in the mouse. We studied two commonly used inbred mice strains originating from Mus musculus domesticus (C57BL/6 and C3HeB/FeJ) and a third strain derived from Mus musculus molossinus [Japanese fancy mouse 1 (JF1)]. The ventilator allows for accurate performance of the different breathing manoeuvres required for measuring in- and expiratory reserve capacity, quasi-static and dynamic compliance, and airway resistance. In combination with a mass spectrometer for monitoring gas concentrations, single-breath manoeuvres were performed and He-expirograms obtained, from which dead space volume and slope of phase III were determined. From each strain and each sex, 10, 2-month old animals were studied immediately after being killed by an intraperitoneal overdose of xylazine and ketamine. C3HeB/FeJ and C57BL/6 exhibited

comparable lung volumes. In male C3HeB/FeJ mice, e.g. vital capacity (VC) was 1072?±?79?µL, inspiratory reserve capacity 782?±?88?µL, and dead space volume at total lung inflation 216?±?18?µL. Lung volumes of JF1 were significantly lower (e.g. VC 611?±?53?µL, P?
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Winkelhake, O.; John, J.
Aktuelle Reformvorschläge zur GKV-Finanzierung : Königs- oder Irrweg.
Soz. Fortschr. 51, 181-183 (2002)
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Mielck, A.; Heinrich, J.
Soziale Ungleichheit und die Verteilung umweltbezogener Expositionen (Environmental Justice).
Gesundheitswesen 64, 405-416 (2002)
The paper deals with the following question: How are the environmental risks distributed across different social groups? Using the term 'environmental justice', it has been discussed in the USA for more than 15 years already that environmental risks are not distributed evenly (i.e., justly). Public attention concentrates on the high environmental burden of the black community, but differences by social status are also addressed. In Germany, there is as yet no comparable discussion. In order to contribute to its development, we focus mainly on the following topics: empirical data from Germany on socio-economic differences in environmental risks concerning the home and the home environment, combination with the discussion on environmental justice, recommendations for research and health policy. The results indicate that also in Germany the lower status groups are exposed to greater environmental risks, and that regional measures of health promotion provide a good chance of reducing this inequality.
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Children, an important target group for the reduction of socioeconomic inequalities in health.
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Non-surgical periodontal therapy with adjunctive topical doxycycline : A double-blind randomized controlled multicenter study. (I). Study design and clinical results.
J. Clin. Periodontol. 29, 108-117 (2002)
Aim: Evaluation of the clinical effect of topical application of doxycycline adjunctive to non-surgical periodontal therapy.Methods: A total of 111 patients suffering from untreated or recurrent moderate to severe periodontitis at 3 different centers (Heidelberg, Frankfurt, Nijmegen) were treated in this double-blind split-mouth study. In each patient, 3 different treatment modalities were assigned randomly to 3 test teeth: scaling and root planing alone (SRP), SRP with subgingival vehicle control (VEH), and SRP with subgingival application of a newly developed biodegradable 15% doxycycline gel (DOXI). At baseline, clinical parameters were measured at all single rooted teeth using a reference splint: PlI, PPD, relative attachment level (RAL-V), GI. 3 strata were generated according to baseline PPD: (i) 5-6 mm, (ii) 7-8 mm, (iii) greater than or equal to9 mm. Not more than 50% active smokers were allowed to each stratum. 3 and 6 months after therapy re-examination was performed by examiners blinded to baseline data and test sites. The statistical comparison of RAL-V gain and PPD reduction between the treatments was based on a repeated measures ANOVA with correction according to Huynh & Feldt. The comparison of SRP versus DOXI was considered as the main study question.Results: 110 patients finished the 3 months and 108 the 6 months examination. The study did not show adverse effects of VEH or DOXI except for one singular inflammation that occurred 2 months after application of the doxycycline gel. DOXI provided statistically significantly more favorable PPD reduction (SRP: -2.4+/-1.4 mm, VEH: -2.7+/-1.6 mm, DOXI: -3.1+/-1.2 mm; SRP versus DOXI VEH versus DOXI p=0.0066) and RAL-V gain (SRP: 1.6+/-1.9 mm, VEH: 1.6+/-2.2 mm, DOXI: 2.0+/-1.7 mm; SRP versus DOXI p=0.027, VEH versus DOXI p=0.038) than SRP and VEH after 6 months.Conclusions: Adjunctive topical subgingival application of a biodegradable 15% doxycycline gel was safe and provided more favorable RAL-V gain and PPD reduction than SRP alone and VEH. Thus, by use of topical doxycycline the threshold for surgical periodontal therapy might be moved toward deeper pockets.
Journal of Clinical Periodontology

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Informationen für das Qualitätsmanagement im Krankenhaus : Zur Funktion und Methodik von Patienten- und Personalbefragungen.
Med. Klin. Intensivmed. Notfmed. 97, 104-110 (2002)
Background: For quality management to be both systematic and realistic, a wealth of information is needed on the experiences patients as well as staff have in the hospital's daily running. This makes patient and staff surveys imperative to prudent quality management.Topic: The following article describes essential points for such studies to become methodologically sound and for their results to be of practical relevance. It is emphasized that the surveys' main purpose - i.e, to stimulate measures for improving the quality of care - can only be fulfilled when hospital staff, with the resolute support by its directors, is being successfully involved in these studies during all stages.
Medizinische Klinik - Intensivmedizin und Notfallmedizin

Zahlmann, G.; Mertz, M.; Fabian, E.; Holle, R.; Kaatz, H.; Neubauer, L.; Strobl, H.; Walther, H.-D.
Perioperative cataract OP management by means of teleconsultation.

Graefes Arch. Clin. Exp. Ophthalmol. 240, 17-20 (2002)
Background: Teleconsultation services have the potential to improve the communication among different medical care providers and between them and the patient. Increasing effectiveness in the shape of a savings in time or cost is often the result of better communication. Methods: A study was performed in order to demonstrate the feasibility of teleconsultation services, using the perioperative management of cataract patients as an example, and to provide data on the quality, acceptance and effectiveness of these services in comparison with a control group experiencing normal treatment. Results: Over a period of 3 months 42 patients of the teleconsultation group and 20 controls were studied. There were two referring ophthalmologists and three surgeons. The teleconsultation group had one consultation fewer with the ophthalmic surgeon because of the teleconsultation service. Patient satisfaction was slightly higher using the new technology. Patients would like to see this technique used again should surgery on the second eye become necessary. Conclusions: Teleconsultation services are ready to support and improve perioperative cataract management. Patients' confidence in their medical treatment was increased by using teleconsultation services. Physicians will expand the use of teleconsultation.
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Mielck, A.
Soziale Ungleichheit und Gesundheit : Die regionale Konzentration eines gesamtgesellschaftlichen Problems.
In: Mielck, A.* [Eds.]: Städte und Gesundheit : Projekte zur Chancengleichheit. Lage: Jacobs, 2002. 41-67 (Gesundheit-Pflege-Soziale Arbeit; 17)
The paper deals with the following question: How are the environmental risks distributed across different social groups? Using the term 'environmental justice', it has been discussed in the USA for more than 15 years already that environmental risks are not distributed evenly (i.e., justly). Public attention concentrates on the high environmental burden of the black community, but differences by social status are also addressed. In Germany, there is as yet no comparable discussion. In order to contribute to its development, we focus mainly on the following topics: empirical data from Germany on socio-economic differences in environmental risks concerning the home and the home environment, combination with the discussion on environmental justice, recommendations for research and health policy. The results indicate that also in Germany the lower status groups are exposed to greater environmental risks, and that regional measures of health promotion provide a good chance of reducing this inequality.
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Indien : Private Dienstleister als Stütze des Gesundheitssystems.
In: Holz, D.-U.*; Streicher, J.*; Wünsche, K.* [Eds.]: Gesundheitswesen : Perspektiven für private Unternehmen. Hamburg: manager magazin Verl.-Ges. mbH, 2002. 89-94
Lecher, S.; Satzinger, W.; Trojan, A.; Koch, U.
Patientenorientierung durch Patientenbefragungen als ein Qualitätsmerkmal der Krankenversorgung.
Bundesgesundheitsbl.-Gesund. 45, 3-12 (2002)
Gegenläufig zur Dominanz ökonomischer und fiskalischer Aspekte des Gesundheitssystems gewinnt "Patientenorientierung" als ein Qualitätskriterium der Krankenversorgung auch in Deutschlands gesundheitspolitischer Debatte zunehmend an Bedeutung. Immer deutlicher wird, dass sie eine zentrale Handlungsmaxime für alle Einrichtungen und Professionen des Gesundheitswesens zu sein hat und dass es gilt, ihre wesentlichen Elemente – Transparenz des Versorgungsangebots und -geschehens sowie Partizipation der Betroffenen an deren Gestaltung – auf allen Ebenen des Gesundheitswesens umzusetzen. Ein Instrumentarium zur Einbeziehung der Bürger in die Gestaltung des Gesundheitssystems, zum Leistungsvergleich zwischen seinen Einrichtungen und zur Ermittlung von Qualitätsdefiziten stellen Nutzer-, Versicherten- und Patientenbefragungen dar. Systematische Patientenbefragungen sind allerdings nicht in allen Einrichtungsarten gleichermaßen gut möglich, und auch dort, wo ihnen keine schwer überwindbaren situativen und patientenbedingten Hindernisse im Wege stehen, nämlich in Krankenhäusern und Rehabilitationskliniken, werden die Befragungen und ihre Ergebnisse oft dadurch entwertet, dass sie methodisch nicht solide angelegt sind bzw. aus ihnen keine praktischen Konsequenzen gezogen werden. Es gibt aber auch Befragungstechniken, mit deren Hilfe methodische Schwierigkeiten oder praktische Verwertungsdefizite so minimiert werden können, dass Patientenbefragungen durchaus einen profunden Beitrag zur Förderung der Patientenorientierung und Verbesserung der Versorgungsqualität in Gesundheitseinrichtungen leisten können.
Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz

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Soziale Ungleichheit und Gesundheit : Die regionale Konzentration eines gesamtgesellschaftlichen Problems.
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The influence of autologous tumor fibroblasts on the radiosensitivity of squamous cell carcinoma megacolonies.
Int. J. Radiat. Oncol. Biol. Phys. 50, 229-237 (2001)
Purpose: To study the influence of tumor fibroblasts on radiosensitivity and stem cell fraction of tumor cells in squamous

cell carcinoma megacolonies by determining colony cure and clonogen survival, Methods and Materials: Murine squamous cell carcinoma cells (AT478c) grown as flat but multilayered megacolonies were co-cultured with pre-irradiated tumor fibroblasts derived from the same carcinoma, and irradiated with 1, 2, 4, or 8 fractions. Recurrent clones and their growth pattern in situ were recorded. From megacolony cure data and clonogen survival data, the clonogen number and the parameters of cellular radiosensitivity were calculated, Results: The curability of the co-cultured megacolonies, as determined by TCD50 values, was significantly increased compared to the megacolonies without fibroblasts ($p < 0.01$). Both the megacolony cure and clonogen survival data suggested a decrease of the clonogen fraction in the so-cultured megacolonies, Conclusion: The presence of tumor fibroblasts increases megacolony radiosensitivity. This is due to a decrease in the fraction of clonogens in the tumor megacolony, apparently caused by a downregulation of the stem cell fraction of the tumor cells.
International Journal of Radiation Oncology, Biology, Physics

Satzinger, W.
Patienten zu Wort kommen lassen ! Zur Funktion von Patientenbefragungen für Qualitätsmanagement im Krankenhaus.
In: Brand, H.* [Eds.]: Proceedings (Qualitätsmanagement im ÖGD. 3. Jahrestagung des lögd, Dortmund, Germany, 16. -17. März 2000). Bielefeld: lögd, 2001. 52-67 (Wissenschaftliche Reihe; 9)
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Nachwort oder : Was ist zu beachten, damit Patientenbefragungen die Patientenversorgung verbessern helfen?
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Kinder im Krankenhaus. Zur Methodik einer Kinder- und Elternbefragung.
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Weder Kinderspiel noch Quadratur des Kreises. Eine Übersicht über methodische Grundprobleme bei Befragungen von Krankenhauspatienten.
In: Satzinger, W.*; Trojan, A.*; Kellermann-Mühlhoff, P.* [Eds.]: Patientenbefragungen in Krankenhäusern : Konzepte, Methoden, Erfahrungen. Sankt Augustin: Asgard-Verl., 2001. 41-80 (Schriftenreihe Forum Sozial- und Gesundheitspolitik; 15)
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Klein, F.; Kim, T.-S.; Hassfeld, S.; Staehle, H.-J.; Reitmeir, P.; Holle, R.; Eickholz, P.
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Der Gesundheitszustand von deutschen und ausländischen Kindern : Warum ist Mehmet gesünder als Maximilian ?
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Eickholz, P.; Kim, T.-S.; Holle, R.; Hausmann, E.
Long-term results of guided tissue regeneration therapy with non-resorbable and bioabsorbable barriers.I. Class II furcations.
J. Periodontol. 72, 35-42 (2001)
Background: The aim of this 5-year follow-up study was to clinically and radiographically evaluate the long-term results after guided tissue regeneration (GTR) therapy of Class II furcation defects using non-resorbable and bioabsorbable barriers. Methods: Nine pairs of contralateral Class II furcation defects were treated in 9 patients with advanced periodontitis. Within each patient, one defect received a non-resorbable (expanded polytetrafluoroethylene [ePTFE]; control, C) barrier and the other a bioabsorbable (polyglactin 910; test, T) barrier by random assignment. At baseline, 6, and 60 +/- 3 months after surgery, clinical parameters and standardized radiographs were obtained. Gain of bone density within furcation areas was assessed using subtraction radiography. Results: Six and 60 months after GTR therapy, statistically significant (P <0.05) horizontal attachment (CAL-H) gain was observed in both groups (C6: 1.7 +/- 0.8 mm; C60: 1.6 +/- 1.2 mm; T6: 2.0 +/- 0.7 mm; T60: 2.2 +/- 0.9 mm). However, 1 furcation assessed as Class I six months after GTR therapy with a bioabsorbable barrier had progressed to Class III after 5 years, and in another patient, 5 years after placement of an ePTFE barrier, 1 furcation had lost all the CAL-H gain that had been observed at 6 months. Subtraction analysis revealed similar area gain in both groups 6 and 60 months postsurgically (C6: 0.3 +/- 0.5; C60 1.0 +/- 1.7; T6: 0.4 +/- 0.4; T60: 1.1 +/- 1.7). Conclusions: CAL-H gain achieved after GTR therapy in Class II furcations was stable after 5 years in 16 of 18 defects. The study failed to show a statistically significant difference in stability of CAL-H gain between control and test groups 5 years after GTR therapy.
Journal of Periodontology

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Mielck, A.; Bloomfield, K.
Verringerung der Einkommens-Ungleichheit und Verstärkung des sozialen Kapitals : Neue Aufgaben der sozial-epidemiologischen Forschung.
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Gesundheitswesen, Das

Hellbrück, R.P.; Schoder, D.
Stimulating the diffusion of EDI in health care.
Int. J. Healthcare Technol. Manag. 3, 191-202 (2001)
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Mielck, A.
Armut und Gesundheit bei Kindern und Jugendlichen : Ergebnisse der sozial-epidemiologischen Forschung in Deutschland.
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Mielck, A.
Die Verminderung sozial bedingter Ungleichheit von Gesundheits-Chancen als Aufgabe für Public Health.
Bundesgesundheitsbl.-Gesund. 44, 804-812 (2001)
Der Beitrag konzentriert sich auf die Unterschiede im Gesundheitszustand nach den Merkmalen des sozio-ökonomischen Status, d. h. den Unterschieden nach Bildung, beruflichem Status und Einkommen. Inzwischen ist auch in Deutschland vielfach empirisch belegt worden, dass Personen mit niedriger Bildung, niedrigem beruflichen Status und/oder niedrigem Einkommen zumeist eine erheblich höhere Morbidität und Mortalität aufweisen als Personen aus den oberen Statusgruppen. In den Mittelpunkt der Diskussion ist daher immer mehr die Frage gerückt, wie diese “gesundheitliche Ungleichheit” erklärt und verringert werden kann. Die meisten empirischen Studien liegen zu den folgenden Erklärungsansätzen vor: belastende Arbeits- und Wohnbedingungen, unzureichendes Gesundheitsverhalten, Mängel in der gesundheitlichen Versorgung. Die Ergebnisse

weisen eindeutig auf eine höhere Gesundheitsgefährdung bei status-niedrigen Personen hin. Konkrete Maßnahmen zur Verringerung der gesundheitlichen Ungleichheit sind bisher jedoch nur ansatzweise zu finden. Um die Entwicklung dieser Maßnahmen zu unterstützen, wäre es z. B. notwendig, die Zielgruppen genauer zu beschreiben (sozio-ökonomischer Status, Alter, Geschlecht, Wohnort etc.), und die bereits durchgeführten Gesundheitsförderungsmaßnahmen für sozial Benachteiligte genauer zu erfassen und zu evaluieren.
Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz

Kersting-Dürrwächter, G.; Mielck, A.
Unfälle von Vorschulkindern im Landkreis Böblingen - Unfallursachen und Risikogruppen.
Gesundheitswesen 63, 335-342 (2001)
Gesundheitswesen, Das

John, J.; Wismar,, M.; Geraedts, M.
Aktuelle Forschungsperspektiven von Gesundheitssystemforschung und Gesundheitsökonomie in Deutschland.
Gesundheitswesen 63 (Sonderh.1), 73-78 (2001)
Gesundheitswesen, Das

von Koskull, St.; Truckenbrodt, H.; Holle, R.; Hörmann, A.
Incidence and prevalence of juvenile arthritis in an urban population of Southern Germany : A prospective study.
Ann. Rheum. Dis. 60, 940-945 (2001)
Objective-To ascertain the incidence and prevalence of juvenile arthritis in a German urban population. Methods-All 766 paediatricians, orthopaedists, and rheumatologists working in practices or outpatient clinics in 12 south German towns were asked to report all patients who consulted them for juvenile arthritis during the year 1995. Patients with continuing symptoms were followed up for 9-12 months to obtain a final diagnosis. Extended measures of quality control were taken to control for known biases. Results-Of 457 reported cases, 294 were diagnosed with para-/postinfectious arthritis (PPA), 78 with juvenile chronic arthritis (ICA), and IS with other forms of arthritis. Half of the PPA cases were classified as transient synovitis of the hip (SH). For JCA the reported annual incidence was 6.6 and the prevalence 14.8 per 100 000 subjects under 16 years of age. For PPA the reported incidence was 76 and the prevalence 4.4 per 100 000 subjects under 16. The incidence of rheumatic fever was clearly below 1 per 100 000 people under 16. A correction model was used to control for known biases and to adjust the estimates accordingly. Conclusions-The results of this first prospective study on the incidence and prevalence of juvenile arthritis in Germany are consistent with a retrospective study performed in the Berlin area. Based on these results it was estimated that the annual frequency of juvenile arthritis in Germany is as follows: 750-900 incident JCA cases, 21 000 incident SH cases, and 21 000 incidence cases of other forms of PPA a year. The number of incidence cases of rheumatic fever is expected to be markedly lower than 150 a year. The total prevalence is expected to be 3600-4350 JCA cases, 2250-3000 SH cases, and the same number of other forms of PPA.
Annals of the Rheumatic Diseases : ARD online

Thorand, B.; Liese, A.D.; Metzger, M.-H.; Reitmeir, P.; Schneider, A.E.; Löwel, H.
Can inaccuracy of reported parental history of diabetes explain the maternal transmission hypothesis for diabetes?
Int. J. Epidemiol. 30, 1084-1089 (2001)
BACKGROUND: The mode of inheritance of type 2 diabetes mellitus is still under discussion. Several studies have suggested an excess maternal transmission, however, more recent studies could not always confirm these findings. METHODS: We investigated the frequency of a maternal and paternal history of diabetes among diabetic and non-diabetic subjects and assessed the association between diabetes and a parental history of diabetes among participants of the MONICA Augsburg study. As an extension to previous studies, unknown parental status was taken into account. RESULTS: Of the 542 diabetic probands, 25.3% reported a positive maternal history of diabetes and 10.9% reported a positive paternal history of diabetes. Among the 12,209 non-diabetic participants a positive maternal history was also more common than a positive paternal history (12.5% versus 7.1%). Conversely, an unknown paternal status was more common than an unknown maternal status in both groups (diabetic subjects: 27.9% versus 16.8%, non-diabetic subjects: 16.8% versus 8.4%). Adjusted odds ratios (OR) for the association between a parental history of diabetes and diabetes status were similar for a positive maternal (OR = 2.9, 95% CI : 2.3-3.6) and paternal history (OR = 2.8, 95% CI : 2.1-3.8) and for an unknown maternal (OR = 1.3, 95% CI : 1.0-1.8) and paternal history (OR = 1.5, 95% CI : 1.2-1.9). CONCLUSION: Our findings do not support a strong excess maternal transmission of diabetes. Epidemiological biases and failure to account for 'don't know' responses may in part explain the previously observed predominance of a maternal history of diabetes.
International Journal of Epidemiology

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The impact of diabetes mellitus on survival after myocardial infarction: can it be modified by drug treatment ? : Results of a population-based myocardial infarction register follow-up study.
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Aims/hypothesis. Mortality of diabetic patients after myocardial infarction remains high despite recent improvement in their management. This study population-based evaluates the impact of cardiovascular drug therapy on mortality within 28 days and during 5-year follow-up in diabetic compared with non-diabetic patients.¶Methods. Using the MONICA Augsburg register from 1985 to 1992, 2210 inpatients with incident Q-wave myocardial infarction aged 25–74 years were included, of whom 468 had diabetes. Primary end point was mortality within 28 days and over 5 years. General linear model procedures were used for age-adjustment, controlling for sex, and testing significance; hazard risk ratios were calculated using multivariable Cox proportional hazards model procedures.¶Results. During the 5-year follow-up, 598 subjects died (396 diabetic, 202 non-diabetic). The mortality rate within 28 days was 12.6 % in diabetic patients (women 18.0 %, men 9.9 %) and 7.3 % in non-diabetic patients (p = 0.001). Mortality in diabetic patients over 5 years was increased by 64 % (95 % confidence interval 1.39–1.95) compared with non-diabetic patients. This was considerably reduced (p < 0.001) in patients treated with thrombolytic drugs (risk ratio: diabetes 0.57, no diabetes 0.65) and with beta blockers (0.62 and 0.64) and antiplatelets (0.76 and 0.74) at hospital discharge. Mortality of diabetic patients treated with these drugs was reduced to that of non-diabetic

patients without such treatment (risk ratio 1.01 to 1.27; p > 0.1).¶Conclusion/interpretation. Diabetic patients after myocardial infarction are at particularly high risk of dying, but benefit clearly from treatment with thrombolytics, beta blockers and antiplatelets. This study does not, however, allow any inferences to be drawn for treatment with angiotensin converting enzyme inhibitors or the impact of left ventricular function.
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Guided Tissue Regeneration with Bioabsorbable Barries: Intrabony Defects and Class II Furcations.
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Cavelaars, A.E.J.M.; Kunst, A.E.; Geurts, J.J.M.; Crialesi, R.; Grötvedt, L.; Helmert, U.; Lahelma, E.; Lundberg, O.; Mielck, A.; Rasmussen, N.; Regidor, E.; Spuhler, Th.; Mackenbach, J.P.
Persistent variations in average height between countries and between socio-economic groups: an overview of 10 European countries.
Ann. Hum. Biol. 27, 407-421 (2000)
PRIMARY OBJECTIVES: This paper aims to provide an overview of variations in average height between 10 European countries, and between socio-economic groups within these countries. DATA AND METHODS: Data on self-reported height of men and women aged 20-74 years were obtained from national health, level of living or multipurpose surveys for 1987-1994. Regression analyses were used to estimate height differences between educational groups and to evaluate whether the differences in average height between countries and between educational groups were smaller among younger than among older birth cohorts. RESULTS: Men and women were on average tallest in Norway, Sweden, Denmark and the Netherlands and shortest in France, Italy and Spain (range for men: 170-179 cm; range for women: 160-167 cm). The differences in average height between northern and southern European countries were not smaller among younger than among older birth cohorts. In most countries average height increased linearly with increasing birth-year (approximately 0.7-0.8 cm/5 years for men and approximately 0.4 cm/5 years for women). In all countries, lower educated men and women on average were shorter than higher educated men (range of differences: 1.6-3.0 cm) and women (range of differences: 1.2-2.2 cm). In most countries, education-related height differences were not smaller among younger than among older birth cohorts. CONCLUSIONS: The persistence of international differences in average height into the youngest birth cohorts indicates a high degree of continuity of differences between countries in childhood living conditions. Similarly, the persistence of education-related height differences indicates continuity of socio-economic differences in childhood living conditions, and also suggests that socio-economic differences in childhood living conditions will continue to contribute to socio-economic differences in health at adult ages.
Annals of Human Biology

Mackenbach, J.P.; Cavelaars, A.E.J.M.; Kunst, A.E.; Groenhof, F.
Socioeconomic inequalities in cardiovascular disease mortality: An international study.
Eur. Heart J. 21, 1141-1151 (2000)
Background Differences between socioeconomic groups in mortality from and risk factors for cardiovascular diseases have been reported in many countries. We have made a comparative analysis of these inequalities in the United States and 11 western European countries. The aims of the analysis were (1) to compare the size of inequalities in cardiovascular disease mortality between countries, and (2) to explore the possible contribution of cardiovascular risk factors to the explanation of between-country differences in inequalities in cardiovascular disease mortality. Data and Methods Data on ischaemic heart disease, cerebrovascular disease and total cardiovascular disease mortality by occupational class and/or educational level were obtained from national longitudinal or unlinked cross-sectional studies. Data on smoking, alcohol consumption, overweight and infrequent consumption of fresh vegetables by occupational class and/or educational level were obtained from national health interview or multipurpose surveys and from the European Union's Eurobarometer survey. Age-adjusted rate ratios for mortality were correlated with age-adjusted odds ratios for the behavioural risk factors. Results In all countries mortality from cardiovascular diseases is higher among persons with lower occupational class or lower educational level. Within western Europe, a north–south gradient is apparent, with relative and absolute inequalities being larger in the north than in the south. For ischaemic heart disease, but not for cerebrovascular disease, an even more striking north–south gradient is seen, with some ‘reverse’ inequalities in southern Europe. The United States occupy intermediate positions on most indicators. Inequalities in cardiovascular disease mortality are associated with inequalities in some risk factors, especially cigarette smoking and excessive alcohol consumption. Conclusions Socioeconomic inequalities in cardiovascular disease mortality

are a major public health problem in most industrialized countries. Closing the gap between low and high socioeconomic groups offers great potential for reducing cardiovascular disease mortality. Developing effective methods of behavioural risk factor reduction in the lower socioeconomic groups should be a top priority in cardiovascular disease prevention.
European Heart Journal

Richter, M.; Mielck, A.
Strukturelle und verhaltensbezogene Determinanten gesundheitlicher Ungleichheit.
J Public Health =Z. Gesundheitswiss. 8 (H.3), 198-215 (2000)
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Liesenfeld, B.; Kohner, E.; Piehlmeier, W.; Kluthe, S.; Aldington, S.; Porta, M.; Bek, T.; Obermaier, M.; Mayer, H.; Mann, G.; Holle, R.; Hepp, K.-D.
A telemedical approach to the screening of diabetic retinopathy: Digital fundus photography.
Diabetes Care 23, 345-348 (2000)
OBJECTIVE: The importance of screening for diabetic retinopathy has been established, but the best method for screening has not yet been determined. We report on a trial of assessment of digital photographs by telemedicine compared with standard retinal photographs of the same fields and clinical examination by ophthalmologists. RESEARCH DESIGN AND METHODS: A total of 129 diabetic inpatients were screened for diabetic retinopathy by slit-lamp biomicroscopy performed by an ophthalmologist and by two-field 50 degrees non-stereo digital fundus photographs assessed by six screening centers that received the images by electronic mail. Conventional 35-mm transparencies of the same fields as the digital photographs were assessed by a retinal specialist and served as the reference method for detection of diabetic retinopathy. Slit-lamp biomicroscopy was the reference method for the detection of macular edema. RESULTS: The prevalence of any form of diabetic retinopathy was 30% (n = 35); of sight-threatening retinopathy including macular edema, the prevalence was 6% (n = 7). The assessment of digital images by the six screening centers resulted in a median sensitivity of 85% and a median specificity of 90% for the detection of moderate nonproliferative or sight-threatening diabetic retinopathy. Clinically significant macular edema (n = 4) was correctly identified in 15 of the 24 grading reports. An additional seven reports referred the patients for further investigation because of concurrent diabetic retinopathy. CONCLUSIONS: Telescreening for diabetic retinopathy by an assessment of two-field 50 degrees non-stereo digital images is a valid screening method. Although detection of clinically significant macular edema using biomicroscopy is superior to digital or standard non-stereo photographs, only few patients with sight-threatening diabetic retinopathy are missed.
Diabetes Care

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Equity in the delivery of health care in Europe and the US.
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This paper presents a comparison of horizontal equity in health care utilization in 10 European countries and the US. It does not only extend previous work by using more recent data from a larger set of countries, but also uses new methods and presents disaggregated results by various types of care. In all countries, the lower-income groups are more intensive users of the health care system. But after indirect standardization for need differences, there is little or no evidence of significant inequity in the delivery of health care overall, though in half of the countries, significant pro-rich inequity emerges for physician contacts. This seems to be due mainly to a higher use of medical specialist services by higher-income groups and a higher use of GP care among lower-income groups. These findings appear to be fairly general and emerge in countries with very diverse characteristics regarding access and provider incentives.
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Koenig, W.; Sund, M.; Löwel, H.; Döring, A.; Ernst, E.
Association between plasma viscosity and all-cause mortality: results from the MONICA- Augsburg Cohort Study 1984-92.
Br. J. Haematol. 109, 453-458 (2000)
Several studies have reported a strong association between various markers of the acute-phase response and death from cardiovascular diseases and all-cause mortality. Inflammation at a low level of intensity may be a common phenomenon associated with the majority of causes of death owing to chronic diseases. We sought to investigate the association of plasma viscosity with all-cause mortality in a cohort of apparently healthy men. The study population consisted of 964 men aged 45-64 years at entry, randomly selected from the general population and taking part in the first MONICA-Augsburg survey 1984-85. The main outcome measure was all-cause mortality. During 8 years of follow-up, there were 81 deaths (37 cardiovascular deaths, 23 deaths from cancer and 21 deaths from other causes). There was a strong positive and statistically significant age-adjusted relationship between plasma viscosity and all-cause mortality. The relative risk of death for a one standard deviation increase in plasma viscosity (0.070 mPa/s) was 1.45 [95% confidence interval (CI) 1.19-1.76]. After further adjusting for smoking, total cholesterol, body mass index, blood pressure and education, a relative risk of 1.41 (95% CI 1.14-1.74) resulted. Other risk variables had only negligible confounding effects. The relative risk of the median of the top quintile of the plasma viscosity distribution compared with the median of the bottom quintile, computed from the adjusted model, was 2.68 (95% CI 1.63-4.42). These findings suggest that plasma viscosity may have considerable potential to predict death from all causes in middle-aged men.
British Journal of Haematology

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Educational differences in smoking: International comparison.
BMJ:Br. Med. J. 320, 1102-1107 (2000)
OBJECTIVE: To investigate international variations in smoking associated with educational level. DESIGN: International comparison of national health, or similar, surveys. SUBJECTS: Men and women aged 20 to 44 years and 45 to 74 years. SETTING: 12 European countries, around 1990. MAIN OUTCOME MEASURES: Relative differences (odds ratios) and absolute differences in the prevalence of ever smoking and current smoking for men and women in each age group by educational level. RESULTS: In the 45 to 74 year age group, higher rates of current and ever smoking among lower educated subjects were found in some countries only. Among women this was found in Great Britain, Norway, and Sweden, whereas an opposite pattern, with higher educated women smoking more, was found in southern Europe. Among men a similar north-south pattern was found but it was less noticeable than among women. In the 20 to 44 year age group, educational differences in smoking were generally greater than in the older age group, and smoking rates were higher among lower educated people in most countries. Among younger women, a similar north-south pattern was found as among older women. Among younger men, large educational differences in smoking were found for northern European as well as for southern European countries, except for Portugal. CONCLUSIONS: These international variations in social gradients in smoking, which are likely to be related to differences between countries in their stage of the smoking epidemic, may have contributed to the socioeconomic differences in mortality from ischaemic heart disease being greater in northern European countries. The observed age patterns suggest that socioeconomic differences in diseases related to smoking will increase in the coming decades in many European countries.
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Editorial
Editorial
Ladwig, K.-H.; Mühlberger, N.; Walter, H.; Schumacher, K.; Popp, K.; Holle, R.; Zitzmann-Roth, E.M.; Schömig, A.
Gender differences in emotional disability and negative health perception in cardiac patients 6 months after stent implantation.
J. Psychosomat. Res. 48, 501-508 (2000)
Objectives: In this study we evaluate gender differences in affective adaptation and health perception in patients 6 months after stent implantation. Background: Assessment of gender-specific behavioral strategies to cope with serious cardiac disease conditions has not been given much attention until now. Preliminary data suggest greater impairments in female patients, which might be of clinical relevance. Methods: Three hundred seventeen patients were eligible for the 6-month follow-up investigation, 78 (24.6%) of whom were women. The women were significantly older but did not differ from men in their cardiac risk features and treatment procedures. There were no gender differences in prevalence of hypertension, hypercholesterolemia, and family history. Men had a significantly higher prevalence of smoking than women, whereas women had a significantly higher prevalence of diabetes than men. A structured interview and a standardized psychodiagnostic assessment was carried out, which covered domains of affective dysfunction (depression, anxiety, intrusion, and avoidance), vegetative symptoms (sleeping disorders), and parameters of negative health perception. Results: There were no significant gender differences in the prevalence of depressive symptoms. Women exhibited higher mean values of anxiety than men, which did not reach significance. Sleeping disorders were significantly more prevalent in women. The absolute level of being distressed by intrusive thoughts and avoidance behavior related to the severe underlying disease process was low in the total group of patients examined. Measurable gender differences did not emerge. Fifty-one (16.5%) patients exhibited pessimistic anticipation of dire consequences and severe signs of negative health perception (NHP group). There was a trend, although not statistically significant, toward more women being in the NHP group. The distribution of cardiac risk factors, however, was completely balanced in the NHP+ and NHP- patient groups. Objective somatic cardiac disease parameters did not account for the negative health perception. NHP was, however, associated with significantly more prestent angina pectoris ($p < 0.040$) and poststent angina pectoris ($p < 0.0001$). High levels of anxiety, depression, and of disturbed sleep also led to a sharp separation between patients with high degrees of an anticipated incapacitation due to the disease process. Univariate regression analysis suggested an effect of female gender on the occurrence of NHP (odds ratio 1.70; 95% CI 0.88 to 3.25), which was of borderline significance. Control for confounders in a multiple regression model, however, eliminated the gender effect (odds ratio 1.04, 95% CI 0.48 to 2.23). Poststent chest pain (odds ratio 7.75, 95% CI 3.28 to 18.32) and sleeping disorders (odds ratio 1.32, 95% CI 1.16 to 1.51) were identified as the most powerful confounders of the gender-NHP association. Conclusion: Contrary to expectation, women were not per se more distressed than men in all areas of adaptation of the midterm course after stent implantation, although the higher levels of anxiety and sleeping disorders in women deserve attention. A considerable proportion of patients exhibited a pessimistic disease perspective independent of their somatic status, which was associated with affective morbidity. The tendency toward more negative health perception in women may be due to their more frequent occurrence of chest pain and sleeping disorders.
Journal of Psychosomatic Research

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Interexaminer reliability of the assessment of clinical furcation parameters as related to different probes.
Eur. J. Oral Sci. 107, 2-8 (1999)
The aim of this study was to investigate the interexaminer reliability of the assessment of clinical furcation diagnosis. Horizontal attachment level (PAL-H) measurements were obtained by 3 examiners in 6 molars in each of 10 patients with advanced periodontitis. In each patient, 3 molars were examined using a 3 mm incrementally marked Nabers probe, and 3 molars were examined using a pressure-calibrated plastic probe (TPS). Assignment of the probe was random, and the schedule of examiners was changed for each patient. Clinical assessments were validated by intrasurgical measurements in 6 patients. Sixty molars with 152 furcations were investigated. Multifactorial analysis of variance revealed that PAL-H measurements were significantly influenced by examiner and furcation location, whereas type of probe and schedule of examination had no influence. The overall intraclass correlation coefficient was $r = 0.695$. The difference between clinical and intrasurgical PAL-H assessment was influenced by examiner and location but not by type of probe. Approximately 70% of the total variance of PAL-H measurements was due to the variance of true values, whereas 30% of the variance may be explained by interexaminer and intraexaminer variance. The pressure-calibrated TPS probe failed to increase the interexaminer reliability of PAL-H measurements when compared to a Nabers probe.
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Extracardiac contributions to chest pain perception in patients 6 months after acute myocardial infarction.
Am. Heart J. 137, 528-534 (1999)
OBJECTIVES: The amount of perceived anginal pain in patients after infarction deserves the attention of the physician. This study sought to identify the modulating influence of extracardiac factors on persistent angina pectoris after myocardial infarction. METHODS AND RESULTS: A total of 552 male survivors of acute myocardial infarction (age 29 to 65 years, median 54 years) were followed for a period of 6 months; the affective state was assessed immediately after the acute event. The prognostic importance of postinfarction depression on chest pain perception was evaluated 6 months after the cardiac event in 376 patients. After the 6-month follow-up period, 199 (53%) of the patients with myocardial infarction had angina pectoris. Somatic risk factors and electrocardiographic data at initial testing did not contribute to the risk of having chest pain. However, patients with high levels of depression at initial testing had an almost 3-fold risk of having angina pectoris 6 months after the index event. Older age, lower social class status, and preinfarction angina were also significantly related to angina pectoris at the end of the study. Patients who were pain free before the index infarction reported significantly more symptoms of chest pain at the study end point (P </=.02), when they had moderate to high degrees of postinfarction depression. In the logistic regression model, depression, then followed by preinfarction angina pectoris and low social class index, contributed significantly to the prediction of follow-up angina pectoris. CONCLUSIONS: The results of this study add evidence to the hypothesis that the perception of chest pain may be triggered not only by the nociceptive stimulation of the ischemic heart but also by extracardiac sources. Depressive mood state, when concomitant with cardiac disease, is shown to intensify perceived chest pain.
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Heyder, J.; Beck-Speier, I.; Busch, B.; Dirscherl, P.; Heilmann, P.; Ferron, G.A.; Josten, M.; Karg, E.W.; Kreyling, W.G.; Lenz, A.-G.; Maier, K.L.; Miaskowski, U.; Platz, S.; Reitmeir, P.; Schulz, S.; Takenaka, S.; Ziesenis, A.
Health effects of sulfur-related environmental air pollution. I. Executive summary.
Inhal. Toxicol. 11, 343-359 (1999)
The motivation of simulating real-world environmental exposure in a number of long-term studies with dogs was to address the question of whether or not perpetual inhalation of air pollutants can initiate diseases in healthy lungs and can thus contribute to the increasing prevalence of respiratory diseases in industrialized countries. The major conclusion of this article is that this question has to be answered in the negative for the simultaneous inhalation of the major constituents of combustion-related air pollution, particle-associated sulfur(IV), and particle-associated hydrogen ions. Over 13 mo, 8 healthy beagle dogs were exposed in 2 whole-body chambers daily for 16.5 h to 1 microm neutral sulfite [sulfur(IV)] particles at a mass concentration of 1.5 mg m-3 and for 6 h to 1.1 microm acidic sulfate particles carrying 15 micromol m-3 hydrogen ions into the canine lungs. This longitudinal study was characterized by repeated observations of individual respiratory response patterns. To establish baseline data the dogs were repeatedly examined preexposure while the chambers were ventilated over 16 mo with clean air. Each individual served thus as its own control. Another eight dogs served as additional controls. They were housed in 2 chambers ventilated with clean air over the entire study period of 29 mo. To assess response patterns, respiratory lung function tests were performed pre- and postexposure, segmental lung lavages were repeatedly performed to obtain epithelial lining fluid from the lungs for

analysis of cell content, cell function, and biochemical indicators of lung injury, and radiolabeled test particles were used to study pathways of intrapulmonary particle elimination. At the end of the study, the lungs of all animals were morphologically and morphometrically examined. Functional and structural responses were finally compared to those observed previously as a result of a sole exposure of canine lungs to neutral sulfite particles over 10 mo (Heyder et al., 1992). Interactions between responses induced by neutral sulfite and acidic sulfate particles occurred, but antagonism rather than synergism was observed. The responses induced by sulfur(IV) were less pronounced, not detectable, or even reversed when hydrogen ions were also delivered to the lungs. On the other hand, responses not induced by the sole exposure to sulfur(IV) were observed: The activity of alkaline phosphatase was elevated and type II pneumocytes proliferated. It can, however, be concluded that long-term exposure of healthy lungs to particle-associated neutral sulfur(IV) and hydrogen ions at concentration close to ambient levels causes subtle respiratory responses but does not initiate pathological processes in the lungs. In other words, the perpetual inhalation of sulfur(IV) and hydrogen ions from the atmospheric environment presents no health risk to the healthy lungs. It is thus also very unlikely that respiratory diseases can be initiated by the inhalation of these pollutants.
Inhalation Toxicology

Maier, K.L.; Beck-Speier, I.; Dayal, N.; Dirscherl, P.; Griese, M.; Heilmann, P.; Hinze, H.; Josten, M.; Karg, E.W.; Kreyling, W.G.; Lenz, A.-G.; Leuschel, L.; Meyer, B.; Miaskowski, U.; Reitmeir, P.; Ruprecht, L.; Schumann, G.; Ziesenis, A.; Heyder, J.
Health effects of sulfur-related environmental air pollution. II. Cellular and molecular parameters of injury.
Inhal. Toxicol. 11, 361-389 (1999)
Recently, concern has been raised about effects related to environmental sulfur and/or acidic aerosols. To assess long-term effects on nonrespiratory lung function, 8 beagle dogs were exposed over a period of 13 mo for 16.5 h/day to a neutral sulfite aerosol at a sulfur(IV) concentration of 0.32 mg m(-3) and for 6 h/day to an acidic sulfate aerosol providing a hydrogen concentration of 15.2 micromol m(-3) for inhalation. Prior to exposure the dogs were kept under clean air conditions for 16 mo to establish physiological baseline values for each animal. A second group of eight dogs (control) was kept for the entire study under clean air conditions. No clinical symptoms were identified that could be related to the combined exposure. Biochemical and cellular parameters were analyzed in sequential bronchoalveolar lavage (BAL) fluids. The permeability of the alveolo-capillary membrane and diethylenetriaminepentaacetic acid (DTPA) clearance was not affected. Similarly, oxidant burden of the epithelial lining fluid evaluated by levels of oxidation products in the BAL fluid protein fraction remained unchanged. Both the lysosomal enzyme beta-N-acetylglucosaminidase and the alpha-1-AT were increased ($p < .05$). In contrast, the cytoplasmic marker lactate dehydrogenase remained unchanged, indicating the absence of severe damages to epithelial cells or phagocytes. Various surfactant functions were not altered during exposure. Three animals showed elevated levels of the type II cell-associated alkaline phosphatase (AP), indicating a nonuniform response of type II cells. Significant correlations were found between AP and total BAL protein, but not between AP and lactate dehydrogenase, suggesting proliferation of alveolar type II cells. Absolute and relative cell counts in the BAL fluid were not influenced by exposure. Alveolar macrophages showed no alterations with regard to their respiratory burst upon stimulation with opsonized zymosan. The percentage of alveolar macrophages capable of phagocytozing latex particles was significantly decreased ($p<.05$), while the phagocytosis index was not altered. In view of the results of this and previous studies, we conclude that there is no synergism of effects of these two air pollutants on nonrespiratory lung functions. It is hypothesized that antagonistic effects of these air pollutants on phospholipase A2-dependent pathways account for compensatory physiological mechanisms. The results emphasize the complexity of health effects on lung functions in response to the complex mixture of air pollutants and disclose the precariousness in the risk assessment of air pollutants for humans.
Inhalation Toxicology

Kreyling, W.G.; Dirscherl, P.; Ferron, G.A.; Heilmann, P.; Josten, M.; Miaskowski, U.; Neuner, M.; Reitmeir, P.; Ruprecht, L.; Schumann, G.; Takenaka, S.; Ziesenis, A.; Heyder, J.
Health effects of sulfur-related environmental air pollution. III. Nonspecific respiratory defense capacities.
Inhal. Toxicol. 11, 391-422 (1999)
Recently concern has been raised about health effects related to environmental sulfur and/or acidic aerosols. To assess long-term effects on respiratory lung function, 8 beagle dogs were exposed over a period of 13 mo for 16.5 h/day to 1.0 microm neutral sulfite aerosol with a particle associated sulfur(IV) concentration of 0.32 mg m(-3) and for 6 h/day to 1.1 microm acidic sulfate aerosol providing an hydrogen ion concentration of 15.2 micromol m(-3) for inhalation. Prior to exposure the dogs were kept under clean air conditions for 16 mo to establish physiological baseline values for each dog. A second group of eight dogs (control) was kept for the entire study under clean air conditions. Nonspecific defense mechanisms in the airways and in the peripheral lung were studied during chronic exposure of the combination of neutral sulfur(IV) and acidic sulfur(VI) aerosols. No functional changes of tracheal mucus velocity were found, in agreement with unchanged morphometry of the airways. However, the exposure resulted in changes of several alveolar macrophage (AM) mediated particle clearance mechanisms: (1) Based on in vivo clearance analysis and cultured AM studies using moderately soluble cobalt oxide particles, intracellular particle dissolution was significantly reduced since phagolysosomal proton concentration was decreased. We deduce exposure-related malfunction of proton pumps bound to the phagolysosomal membrane as a result of an increase of cytosolic proton concentration. (2) Based on in vivo clearance analysis using insoluble polystyrene particles, AM-mediated particle transport from the lung periphery toward ciliated terminal bronchioli and further to the larynx was significantly reduced. Activation of epithelial type II cells at the entrance of alveoli was inferred from observed type II cell proliferation at those alveolar ridges and enhanced secretion of alkaline phosphatase in the fluid of bronchoalveolar lavages. As a result, hypersecretion of chemotactic mediators by activated type II cells at these loci led to the observed decrease of particle transport toward ciliated bronchioli. (3) Based on in vivo clearance analysis using insoluble polystyrene particles, particle transport from the alveolar epithelium into interstitial tissues was increased and (4) particle transport to the tracheobronchial lymph nodes was significantly enhanced. Particle transport into

interstitial tissues is the most prominent clearance pathway from the canine alveolar epithelium. We conclude that the deteriorated particle transport toward ciliated terminal bronchioli resulted in an enhanced particle transport across the epithelial membrane into interstitial tissues and the lymphatic drainage. The observed alterations in alveolar macrophage-mediated clearance mechanisms during chronic exposure of these air pollutants indicate an increased risk of health.
Inhalation Toxicology

Schulz, S.; Eder, G.; Heilmann, P.; Karg, E.W.; Meyer, T.; Schulz, A.; Ziesenis, A.; Heyder, J.
Health effects of sulfur-related environmental air pollution. IV. Respiratory lung function.
Inhal. Toxicol. 11, 423-438 (1999)
Recently concern has been raised about health effects related to environmental sulfur and/or acidic aerosols. To assess long-term effects on respiratory lung function, 8 beagle dogs were exposed over a period of 13 mo for 16.5 h/day to 1-microm neutral sulfite aerosol with a particle-associated sulfur(IV) concentration of 0.32 mg m(-3) and for 6 h/day to 1.1-microm acidic sulfate aerosol providing an hydrogen ion concentration of 15.2 micromol m(-3) for inhalation. Prior to exposure the dogs were kept under clean air conditions for 16 mo to establish physiological baseline values for each dog. A second group of eight dogs (control) was kept for the entire study under clean air conditions. Before and at the end of exposure, respiratory lung function was evaluated in both groups in anesthetized and mechanically ventilated animals. Lung volumes as well as static and dynamic lung compliances were measured. Series dead-space volumes and slopes of the alveolar plateau for respiratory (O_2, CO_2) and inert test gases (He, SF_6) were determined from single-breath washout tracings. Monodisperse 0.9-microm DEHS droplets were used to assess convective mixing in the lungs and to evaluate airway dimensions in vivo. Gas exchange across the alveolar-capillary layer was characterized by membrane diffusing capacity for carbon monoxide and alveolar-arterial pressure differences for respiratory gases. A bronchial challenge with carbachol was used to assess airway responsiveness. In comparison to the control group, dogs exposed to sulfur(IV) and acidic aerosol exhibited no significant changes in any respiratory lung function parameter. Also the responsiveness of the bronchial airways to carbachol was not affected. In view of the results obtained in this and previous studies, we conclude that anticipated synergistic effects of the two air pollutants on pulmonary lung function were not observed. It is hypothesized that antagonistic effects of the air pollutants on the activity of phospholipase A2 play an important role and account for counteracting physiological compensatory mechanisms. The results emphasize the complexity of health effects on lung function in response to the complex mixtures of ambient air pollutants and witness the precariousness in the risk assessment of air pollutants for humans.
Inhalation Toxicology

Takenaka, S.; Godleski, J.J.; Heini, A.; Karg, E.W.; Kreyling, W.G.; Ritter, B.; Schulz, S.; Ziesenis, A.; Heyder, J.
Health effects of sulfur-related environmental air pollution. V. Lung structure.
Inhal. Toxicol. 11, 439-454 (1999)
The lungs of 8 male beagle dogs were examined morphologically and morphometrically after exposure for 13 mo to a respirable sulfur(IV) aerosol at a mass concentration of 1.53 mg m(-3) (16.5 h/day), and to an acidic sulfate aerosol carrying 15.2 micromol m(-3) hydrogen ions into the lungs (6 h/day). An additional eight dogs served as unexposed controls. Standard morphometric analyses of both the surface epithelia of the conducting airways and the alveolar region were performed. These analyses showed no difference between the exposure group and control group. However, there was a tendency to an increase in the volume density of bronchial glands in the exposure group. Five of eight exposed animals showed thickened ridges (knob-like structures) at the entrance to alveoli in the alveolar duct and alveolar sac. Transmission electron microscopy revealed that the thickening was mainly due to type II cell proliferation. As the previous experiment using sulfite aerosol only showed no alterations in the proximal alveolar regions, the changes observed may be considered as effects of acidic sulfate aerosol alone or in combination with sulfite. These findings suggest that sulfur aerosols have the potential to induce epithelial alterations in the proximal alveolar region, which is a primary target for air pollutants.
Inhalation Toxicology

Klingberg, S.; Buchkremer, G.; Holle, R.; Schulze Mönking, H.; Hornung, W.P.
Differential therapy effects of psychoeducational psychotherapy for schizophrenic patients - results of a 2-year follow-up.
Eur. Arch. Psychiatry Clin. Neurosci. 249, 66-72 (1999)
There is increasing evidence of the efficacy and effectiveness of psychosocial interventions in schizophrenic patients. However, little research has been done on differential therapy effects. In a prospective, randomized clinical trial we carried out psychoeducational medication management training, cognitive psychotherapy, and key-person counseling. The patients of the control group participated in structured free-time activities for control of therapeutic commitment. Data from a total of 156 schizophrenic patients (DSM-III-R, no first-admissions) were available at 2-year follow-up. We analyzed in this study whether there are differential therapy effects of these interventions, depending on patient characteristics at baseline. There was a significant statistical interaction between treatment condition (specific/non-specific) and prognosis with respect to treatment outcome. Patients with a favorable prognosis and better social functioning had a better course under the specific treatment but a less favorable outcome in the non-specifically treated control group. These results suggest that more vulnerable patients are not sufficiently capable of learning and using coping strategies for relapse prevention. We need to learn more about differential indications for psychosocial treatment.
European Archives of Psychiatry and Clinical Neuroscience

Koenig, W.; Sund, M.; Fröhlich, M.; Fischer, H.G.; Löwel, H.; Döring, A.; Hutchinson, W.L.; Pepys, M.B.
C-Reactive protein, a sensitive marker of inflammation, predicts future risk of coronary heart disease in initially healthy middle-aged men: Results from the MONICA (Monitoring Trends and Determinants in Cardiovascular Disease) Augsburg Cohort Study, 1984 to 1992.
Circulation 99, 237-242 (1999)
BACKGROUND: Inflammatory reactions in coronary plaques play an important role in the pathogenesis of acute atherothrombotic events; inflammation elsewhere is also associated with both atherogenesis generally and its thrombotic

complications. Recent studies indicate that systemic markers of inflammation can identify subjects at high risk of coronary events. METHODS AND RESULTS: We used a sensitive immunoradiometric assay to examine the association of serum C-reactive protein (CRP) with the incidence of first major coronary heart disease (CHD) event in 936 men 45 to 64 years of age. The subjects, who were sampled at random from the general population, participated in the first MONICA Augsburg survey (1984 to 1985) and were followed for 8 years. There was a positive and statistically significant unadjusted relationship, which was linear on the log-hazards scale, between CRP values and the incidence of CHD events (n=53). The hazard rate ratio (HRR) of CHD events associated with a 1-SD increase in log-CRP level was 1.67 (95% CI, 1.29 to 2. 17). After adjustment for age, the HRR was 1.60 (95% CI, 1.23 to 2. 08). Adjusting further for smoking behavior, the only variable selected from a variety of potential confounders by a forward stepping process with a 5% change in the relative risk of CRP as the selection criterion, yielded an HRR of 1.50 (95% CI, 1.14 to 1.97). CONCLUSIONS: These results confirm the prognostic relevance of CRP, a sensitive systemic marker of inflammation, to the risk of CHD in a large, randomly selected cohort of initially healthy middle-aged men. They suggest that low-grade inflammation is involved in pathogenesis of atherosclerosis, especially its thrombo-occlusive complications.
Circulation

[Eds.]
The proportion of high risk preterm infants with postoperative apnea and bradycardia is the same after general and spinal anesthesia.
Can. J. Anaesth. 46, 94-95 (1999)
Canadian journal of anesthesia
Letter to the Editor
Letter to the Editor
Löwel, H.; Stieber, J.; Koenig, W.; Thorand, B.; Hörmann, A.; Gostomzyk, J.G.; Keil, U.
Das Diabetes-bedingte Herzinfarktrisiko in einer süddeutschen Bevölkerung: Ergebnisse der MONICA-Augsburg-Studien 1985-1994.
Diabetes Stoffwechs. 8, 11-21 (1999)
Background: The population-based MONICA Augsburg studies (age 25-74 years) were used to quantify the impact of diabetes mellitus (DM) on the risk of myocardial infarction (MI) and 28-day case fatality. Methods and results: During the 10-year MONICA study period a total of 12,766 persons took part in the CVD risk factor surveys; 551 (men 4.2%, women 3.6%) had DM. A parental history of DM was observed in 33% of the DM and 19% of the non-DM participants with a significantly increased risk profil. During 1985-1994 a total of 9,662 cases with fatal and non-fatal MI were registered; 2,775 (men 24.8%, women 38.2%) had DM. Men with DM showed a 3.7-fold (95% Confidence-Interval 3.5-3.9) and diabetic women showed a 5.9-fold (95% CI 5.5-6.4) increased risk of MI. The diabetic MI patients had a 50% (women) to 70% (men) increased 28-day case fatality ($p < 0.001$). Conclusions: Aggressive strategies of risk factor prevention should be implemented even in the prediabetic stage, especially in subjects with a positive parental history. Diagnostic guidelines and treatment strategies for DM patients with CHD should be issued by the diabetological and cardiological physicians' associations.
Diabetes und Stoffwechsel

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Rev. Int. Pol. Comp. 5(3), 639-668 (1998)
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Die Verkleinerung des "Healty-Migrant-Effects": Entwicklung der Morbidität von ausländischen und deutschen Befragten im sozioökonomischen Panel 1984-1992.
Gesundheitswesen 60, 715-720 (1998)
Gesundheitswesen, Das

Altenstetter, C.
Collective action of the medical device industry at the transnational level.
Curr. Politics Econ. Europe 8, 39-60 (1998)
Current Politics and Economics of Europe

Cavelaars, A.E.; Kunst, A.E.; Geurts, J.J.; Crialesi, R.; Grötvedt, L.; Helmert, U.; Lahelma, E.; Lundberg, O.; Matheson, J.; Mielck, A.; Mizrahi, A.; Rasmussen, N.K.; Regidor, E.; Spuhler, T.; Mackenbach, J.P.
Differences in self reported morbidity by educational level: A comparison of 11 western European countries.
J. Epidemiol. Community Health 52, 219-227 (1998)
STUDY OBJECTIVE: To assess whether there are variations between 11 Western European countries with respect to the size of differences in self reported morbidity between people with high and low educational levels. DESIGN AND METHODS: National representative data on morbidity by educational level were obtained from health interview surveys, level of living surveys or other similar surveys carried out between 1985 and 1993. Four morbidity indicators were included and a considerable effort was made to maximise the comparability of these indicators. A standardised scheme of educational levels was applied to each survey. The study included men and women aged 25 to 69 years. The size of morbidity differences was measured by means of the regression based Relative Index of Inequality. MAIN RESULTS: The size of inequalities in health was found to vary between countries. In general, there was a tendency for inequalities to be relatively large in Sweden, Norway, and Denmark and to be relatively small in Spain, Switzerland, and West Germany. Intermediate positions were observed for Finland, Great Britain, France, and Italy. The position of the Netherlands strongly varied according to sex: relatively large inequalities were found for men whereas relatively small inequalities were found for women. The relative position of some countries, for example, West Germany, varied according to the morbidity indicator. CONCLUSIONS: Because of a number of unresolved problems with the precision and the international comparability of the data, the margins of uncertainty for the inequality estimates are somewhat wide. However, these problems are unlikely to explain the overall pattern. It is remarkable that health inequalities are not necessarily smaller in countries with more egalitarian policies such as the Netherlands and the Scandinavian countries. Possible explanations are discussed.
Journal of Epidemiology and Community Health

Cavelaars, A.E.; Kunst, A.E.; Geurts, J.J.; Helmert, U.; Lundberg, O.; Mielck, A.; Matheson, J.; Mizrahi, A.; Rasmussen, N.; Spuhler, T.; Mackenbach, J.P.
Morbidity differences by occupational class among men in seven European countries: An application of the Erikson-Goldthorpe social class scheme.
Int. J. Epidemiol. 27, 222-230 (1998)
BACKGROUND: This paper describes morbidity differences according to occupational class among men from France, Switzerland, (West) Germany, Great Britain, the Netherlands, Denmark, and Sweden. METHODS: Data were obtained from national health interview surveys or similar surveys between 1986 and 1992. Four morbidity indicators were included. For each country, individual-level data on occupation were recorded according to one standard occupational class scheme: the Erikson-Goldthorpe social class scheme. To describe the pattern of morbidity by occupational class, odds ratios (OR) were calculated for each class using the average of the population as a reference. The size of morbidity differences was summarized by the OR of two broad hierarchical classes. All OR were age-adjusted. RESULTS: For all countries, a lower than average prevalence of morbidity was found for higher and lower administrators and professionals as well as for routine nonmanual workers, whereas a higher than average prevalence was found for skilled and unskilled manual workers and agricultural workers. Self-employed men were in general healthier than the average population. The relative health of farmers differed between countries. The morbidity difference between manual workers and the class of administrators and professionals was approximately equally large in all countries. Consistently larger inequality estimates, with no or slightly overlapping confidence intervals, were only found for Sweden in comparison with Germany. CONCLUSIONS: Thanks to the use of a common social class scheme in each country, a high degree of comparability was achieved. The results suggest that morbidity differences according to occupational class among men are very similar between different European countries.
International Journal of Epidemiology

Eickholz, P.; Kim, T.S.; Holle, R.
Regenerative periodontal surgery with non-resorbable and biodegradable barriers: Results after 24 months.
J. Clin. Periodontol. 25, 666-676 (1998)
The aim of the present study was to compare the effects of guided tissue regeneration (GTR) with non-resorbable (ePTFE) and biodegradable barriers (Polyglactin 910). 23 patients provided 29 pairs of similar contralateral periodontal defects (12 pairs of interproximal intrabony lesions, 11 pairs of degree II and 6 pairs of degree III furcation defects). Each defect was randomly assigned to treatment with either non-resorbable (control [c]) or biodegradable (test [t]) devices. At baseline, 6, 12, 18, and 24 months after surgery, clinical measurements (PlI, GI, PPD, PAL-V, PAL-H) were performed. Standardized radiographs were obtained at baseline 12 and 24 months postsurgically. On the radiographs, the linear distances from the cemento-enamel junction (CEJ) to the alveolar crest (AC) and from the CEJ to bottom of the bony defect (BD) were measured using a computer-assisted analysing method (LMSRT). Both treatments revealed a significant ($p<0.05$) PPD reduction [all defects: -2.97 +/- 1.90 mm (t), -2.21 +/- 1.73 mm (c); intrabony defects: -4.00 +/- 1.96 mm (t), -3.00 +/- 1.87 mm (c); degree II furcations: -2.67 +/- 0.97 mm (t), -2.08 +/- 1.54 mm (c)], PAL-V gain [all defects: 2.02 +/- 1.83 mm (t), 1.18 mm +/- 1.50 (c); intrabony defects: 3.45 +/- 1.48 mm (t), 1.95 +/- 1.64 mm (c); degree II furcations: 1.33 +/- 0.94 mm (t), 0.92 +/- 1.47 mm (c)], PAL-H gain [degree II furcations: 2.22 +/- 0.94 mm (t), 1.86 +/- 0.60 mm (c)], and radiographic changes [CEJ-AC: -0.56 +/- 1.98 mm (t), -0.06 +/- 1.19 mm (c); CEJ-BD: 2.10 +/- 1.92 mm (t), 1.24 +/- 2.04 mm (c)] after 24 months. For degree III furcations, neither statistically significant PPD reduction nor PAL-V gain was observed. Similar clinical and radiographic results were found 12 and 24 months after surgical treatment using either non-resorbable or biodegradable barriers. More favorable results concerning PAL-V gain in interproximal intrabony defects could be observed with biodegradable barriers after 24 months than using nonresorbable membranes. Whereas interproximal intrabony lesions and degree II furcation defects responded favorably to GTR therapy, through-and-through furcations must be looked upon as a contraindication for this regenerative technique. Based on the results of the present study, the use of biodegradable barriers in GTR may be recommended and, thereby, a surgical re-entry to remove nonresorbable barriers can be avoided.
Journal of Clinical Periodontology

Koenig, W.; Sund, M.; Filipiak, B.; Döring, A.; Löwel, H.; Ernst, E.
Plasma viscosity and the risk of coronary heart disease: Results from the MONICA-Augsburg cohort study, 1984 to 1992.
Arterioscler. Thromb. Vasc. Biol. 18, 768-772 (1998)
Plasma viscosity is determined by various macromolecules, eg, fibrinogen, immunoglobulins, and lipoproteins. It may therefore reflect several aspects involved in cardiovascular diseases, including the effects of classic risk factors, hemostatic disturbances, and inflammation. We examined the association of plasma viscosity with the incidence of a first major coronary heart disease event (CHD; fatal and nonfatal myocardial infarction and cardiac death; n=50) in 933 men aged 45 to 64 years of the MONICA project of Augsburg, Germany. The incidence rate was 7.23 per 1000 person-years (95% confidence interval [CI], 5.37 to 9.53), and the subjects were followed up for 8 years. All suspected cases of an incident CHD event were classified according to the MONICA protocol. There was a positive and statistically significant unadjusted relationship between plasma viscosity and the incidence of CHD. The relative risk of CHD events associated with a 1-SD increase in plasma viscosity (0.070 mPa x s) was 1.60 (95% CI, 1.25 to 2.03). After adjustment for age, total cholesterol, high density lipoprotein cholesterol, smoking, blood pressure, and body mass index, the relative risk was reduced only moderately (1.42; 95% CI, 1.09 to 1.86). The relative risk of CHD events for men in the highest quintile of the plasma viscosity distribution in comparison with the lowest quintile was 3.31 (95% CI, 1.19 to 9.25) after adjustment for the aforementioned variables. A large proportion of events (40%) occurred among men in the highest quintile. These findings suggest that plasma viscosity may have considerable potential to identify subjects at risk for CHD events.
Arteriosclerosis, Thrombosis, and Vascular Biology

Krebs, O.; Schäfer, B.; Wolff, T.; Oesterle, D.; Deml, E.; Sund, M.; Favor, J.
The DNA damaging drug cyproterone acetate causes gene mutations and induces glutathione-S-transferase P in the liver of female Big Blue™ transgenic F344 rats.
Carcinogenesis 19, 241-245 (1998)

The gestagenic and antiandrogenic drug cyproterone acetate (CPA) is mitogenic, tumorigenic and induces DNA-adducts and DNA-repair synthesis in rat liver. Thus CPA is expected to be mutagenic. However in vitro mutagenicity test systems were negative. To examine whether CPA induces mutations in rat liver, the in vivo mutation assay based on Big Blue transgenic F344 rats was employed. Single oral doses of 25, 50, 75, 100 and 200 mg CPA/kg b.w. respectively were administered to female Big Blue rats. Six weeks after treatment, liver DNA was assayed for mutations. At the highest dose, 200 mg CPA/kg b.w., the frequency of (17 +/- 4) x 10(-6) spontaneous mutations was increased to a maximum of (80 +/- 8) x 10(-6) mutations. One-hundred and 75 mg CPA/kg b.w. resulted in mutation frequencies of (35 +/- 5) and (27 +/- 5) x 10(-6), respectively. The mutation frequency at doses of 50 and 25 mg CPA/kg b.w. was similar to that of vehicle treated controls. Statistical analysis of the dose-effect relationship revealed that it was not possible to decide whether a threshold dose exists or not. DNA adducts were analyzed by the 32P-postlabelling technique. The total level of the major and the two minor adducts observed in the autoradiograms increased between doses of 25 to 75 mg CPA/kg b.w. to a maximum of approximately 12,000 +/- 3000 adducts per 10(9) nucleotides. The level did not further increase significantly with 100 and 200 mg CPA/kg b.w. After CPA treatment no preneoplastic liver foci were observed. However, single glutathione-S-transferase placental form (GST-P) positive hepatocytes were observed and the frequency was dependent on the dose. These cells are not supposed to represent initiated cells, since they occurred only transiently after 6 weeks and disappeared thereafter completely. In conclusion, our results demonstrate that CPA is mutagenic in vivo. The mutation frequency increased at high CPA doses, when the increase of the DNA adduct formation had already ceased. This suggests that the mitogenic activity of CPA is required to express the mutations.
Carcinogenesis

Muehlberger, N.; Jelinek, T.; Schlipkoeter, U.; von Sonnenburg, F.; Nothdurft, H.D.
Effectiveness of chemoprophylaxis and other determinants of malaria in travellers to Kenya.
Trop. Med. Int. Health 3, 357-363 (1998)
OBJECTIVE: To investigate the effectiveness of chemoprophylaxis and the determinants of malaria importation from Kenya. METHOD: In a population-based case-control study, 51 travellers from Bavaria diagnosed with falciparum malaria imported from Kenya (cases) and a sample of 383 healthy Bavarian travellers returning from Kenya (controls) were interviewed. Data were analysed by multiple logistic regression. RESULTS: Mefloquine (OR = 0.055; 95% CI 0.019-0.16) and chloroquine combined with proguanil (OR = 0.128; 95% CI 0.039-0.419) were highly protective against P. falciparum malaria, whereas other drugs were ineffective (OR = 1.225; 95% CI 0.536-2.803). Ineffective prophylaxis (10.4%) and non-prophylaxis (11.2%) were the main reasons for malaria importation. Travelling alone or with friends, male sex, and travel duration over 4 weeks could be identified as additional risk factors. The main reason for inadequate chemoprophylaxis was inappropriate medical advice (87.5%). Prophylaxis refusal occurred frequently despite correct advice (58.1%). Diagnosis was often delayed unnecessarily (27.5%). CONCLUSION: Malaria importation from Kenya could be reduced substantially (34%) by eliminating inappropriate medical advice.
Tropical Medicine and International Health

Wachinger, M.; Kleinschmidt, A.; Winder, D.; von Pechmann, N.; Ludvigsen, A.; Neumann, M.; Holle, R.; Salmons, B.; Erfle, V.; Brack-Werner, R.
Antimicrobial peptides melittin and cecropin inhibit replication of human immunodeficiency virus 1 by suppressing viral gene expression.
J. Gen. Virol. 79, 731-740 (1998)
Antimicrobial peptides are effectors of innate immunity, providing their hosts with rapid non-specific defence against parasitic invaders. In this report, the effects are assessed of two well-characterized antimicrobial amphipathic peptides (melittin and cecropin) on human immunodeficiency virus 1 (HIV-1) replication and gene expression in acutely infected cells at subtoxic concentrations. Production of infectious, cell-free virus was inhibited in a dose-dependent manner, with ID50 values in the range 0.9-1.5 microM for melittin and 2-3 microM for cecropin. Analysis of the effect of melittin on cell-associated virus production revealed decreased levels of Gag antigen and HIV-1 mRNAs. Transient transfection assays with HIV long terminal repeat (LTR)-driven reporter gene plasmids indicated that melittin has a direct suppressive effect on activity of the HIV LTR. HIV LTR activity was also reduced in human cells stably transfected with retroviral expression plasmids for the melittin or cecropin gene. It is concluded that antimicrobial peptides such as melittin and cecropin are capable of inhibiting cell-associated production of HIV-1 by suppressing HIV-1 gene expression.
Journal of General Virology

1997
Buchkremer, G.; Klingberg, S.; Holle, R.; Schulze Mönking, H.; Hornung, W.P.
Psychoeducational psychotherapy for schizophrenic patients and their key relatives or care-givers: Results of a 2-year follow-up.
Acta Psychiatr. Scand. 96, 483-491 (1997)
Psychoeducational medication management training (PMT), cognitive psychotherapy (CP) and key-person counselling (KC) were carried out in various combinations in this randomized, controlled intervention study of schizophrenic out-patients (according to DSM-III-R). Special design characteristics of the study were a control group consisting of non-specifically treated patients and a 2-year follow-up after completion of treatment in order to evaluate medium-term effects. A total of 132 patients underwent a follow-up examination 2 years after completion of treatment and were evaluated with an intention-to-treat approach. In the second follow-up year, all treatment groups had lower but not significantly different relapse rates compared to the control group. The most intensive treatment (PMT+CP+KC) produces a clinically relevant reduction in rehospitalization rate (a 26% reduction compared to the control group). In comparison with the non-specifically treated control group, whose original effect decreased, at least a medium-term therapeutic effect was recorded in the treatment groups.
Acta Psychiatrica Scandinavica

van Doorslaer, E.; Wagstaff, A.; Bleichrodt, H.; Calonge, S.; Gerdtham, U.G.; Gerfin, M.; Geurts, J.; Gross, L.; Häkkinen, U.; Leu, R.E.; O'Donnell, O.; Propper, C.; Puffer, F.; Rodríguez, M.; Sundberg, G.; Winkelhake, O.

Income-related inequalities in health: Some international comparisons.
J. Health Econ. 16, 93-112 (1997)
This paper presents evidence on income-related inequalities in self-assessed health in nine industrialized countries. Health interview survey data were used to construct concentration curves of self-assessed health, measured as a latent variable. Inequalities in health favoured the higher income groups and were statistically significant in all countries. Inequalities were particularly high in the United States and the United Kingdom. Amongst other European countries, Sweden, Finland and the former East Germany had the lowest inequality. Across countries, a strong association was found between inequalities in health and inequalities in income.
Journal of Health Economics

Favor, J.; Neuhäuser-Klaus, A.; Ehling, U.H.; Wulff, A.; van Zeeland, A.A.
The effect of the interval between dose applications on the observed specific-locus mutation rate in the mouse following fractionated treatments of spermatogonia with ethylnitrosourea.
Mutat. Res. -Fund. Mol. Mech. Mutag. 374, 193-199 (1997)
Our earlier analyses have suggested an apparent threshold dose-response for ethylnitrosourea-induced specific-locus mutations in treated spermatogonia of the mouse to be due to a saturable repair process. In the current study a series of fractionated-treatment experiments was carried out in which male (102 x C3H)F1 mice were exposed to 4 x 10, 2 x 40. 4 x 20 or 4 x 40 mg ethylnitrosourea per kg body weight with 24 h between applications; 4 x 40 mg ethylnitrosourea per kg body weight with 72 h between dose applications; and 2 x 40, 4 x 20 and 4 x 40 mg ethylnitrosourea per kg body weight with 168 h between dose applications. For all experiments with 24-h intervals between dose applications, there was no effect due to dose fractionation on the observed mutation rates, indicating the time interval between dose applications to be shorter than the recovery time of the repair processes acting on ethylnitrosourea-induced DNA adducts. In contrast, a fractionation interval of 168 h was associated with a significant reduction in the observed mutation rate due to recovery of the repair process. However, although reduced, the observed mutation rates for fractionation intervals of 168 h were higher than the spontaneous specific-locus mutation rate. These observations contradict the expectation for a true threshold dose response. We interpret this discrepancy to be due to the differences in the predictions of a mathematical abstraction of experimental data and the complexities of the biological system being studied. Biologically plausible explanations of the discrepancy are presented.
Mutation Research / Fundamental and Molecular Mechanisms of Mutagenesis

Fröhlich, M.; Sund, M.; Russ, S.; Hoffmeister, A.; Fischer, H.G.; Hombach, V.; Koenig, W.
Seasonal variations of rheological and hemostatic parameters and acute-phase reactants in young, healthy subjects.
Arterioscler. Thromb. Vasc. Biol. 17, 2692-2697 (1997)
The incidence of cardiovascular diseases is increased in winter months. Recent studies have shown seasonal changes in plasma viscosity, fibrinogen, and factor VII activity with elevated levels during winter. An increase in these factors generates a "hypercoagulable state," which may lead to a rise in cardiovascular morbidity and mortality. It has been suggested that an increase in upper respiratory infections might be the underlying cause for the raised acute-phase reactants, in particular fibrinogen, during the winter season. We investigated seasonal variations of 26 parameters, determining blood rheology and hemostasis in 16 healthy volunteers (8 men and 8 women) aged 20 to 41 years. They were seen at monthly intervals over a period of 1 year. Seasonal variation with peak fitted values in the winter months was found for plasma viscosity ($P < .001$ for the seasonal difference), red blood cell deformability ($P < .001$), whole blood viscosity ($P < .001$), hemoglobin ($P < .001$), hematocrit ($P < .001$), mean corpuscular volume ($P = .001$), platelet count ($P = .01$), alpha 1-glycoprotein ($P < .001$), fibrinogen (measured by immunonephelometry; $P < .001$), plasminogen activator inhibitor-1 ($P = .002$), LDL cholesterol ($P = .003$), and triglyceride levels ($P < .001$). HDL cholesterol ($P < .001$) and cortisol ($P = .001$) showed inverse seasonal patterns, with a maximum during summertime. No statistically significant seasonal variations were seen for red blood cell aggregation, complement factor C4, total cholesterol, ceruloplasmin, haptoglobin, white blood cell count, and plasminogen. These data do not support the hypothesis that increased morbidity and mortality from cardiovascular diseases during winter may be mainly attributable to increased synthesis of acute-phase proteins due to infections. The cause for the seasonal variations in rheological and hemostatic parameters remains unclear and should be studied in more detail.
Arteriosclerosis, Thrombosis, and Vascular Biology

[Eds.]
Medical guidelines: a valid and reliable management tool?
Int. J. Health Plann. Manage. 12, 51-62 (1997)
Medical practice guidelines are one instrument to improve either quality care or to encourage efficient health care production. To achieve these goals they have to be valid, reliable, clinically applicable, clear, and timely revised. This article checks whether current efforts to develop and establish guidelines meet these criteria. Unfortunately, it turns out that especially the compliance of the first two criteria is problematic. It is concluded that medical guidelines are, as yet, neither a scientifically sound way to improve quality care nor a ready means to improve efficient care production. Approaches to complement these efforts are therefore discussed.
International Journal of Health Planning and Management, The

Helmert, U.; Mielck, A.; Shea, S.
Poverty and health in West Germany.
Soz. Präventivmed. 42, 276-285 (1997)
The relationship between poverty and several health-related characteristics in West Germany was investigated. Data were derived from the National and Regional Health Surveys conducted in West Germany from 1984 to 1992. 25,544 males and 25,719 females with German nationality aged 25-69 years were examined. Poverty was defined as a household income of 50% less than the mean for West Germany. Multiple logistic regression analysis was used to analyze the relationship between poverty and four health variables: individual health behavior, subjective assessment of health status, cardiovascular disease risk factors, and self-reported prevalence of lifetime chronic diseases. 10.2% of males and 12.8% of females were classified as being below the poverty line. For most but not all health parameters, less favourable results were found for the segment of the population with a household income below the

poverty line. The most striking poverty-related differences were observed for lack of regular sport activities, subjective health satisfaction, obesity and myocardial infarction/stroke. Significantly lower prevalence rates for study subjects below the poverty line were observed for hypercholesterolemia in females only. Allergic disorders were the only chronic diseases reported significantly less often in males and females below the poverty line. Poverty has strong effects on individual health status and the prevalence of chronic diseases. Due to the rising unemployment rates in Germany in the last years it is very likely that the strong negative consequences of poverty for health are increasing.
Sozial- und Präventivmedizin

Holle, R.; Windeler, J.
Is there a gain from "chance-corrected" measures of diagnostic validity?
J. Clin. Epidemiol. 50, 117-120 (1997)
Several authors have proposed alternatives to sensitivity and specificity which they recommend as so-called "chance-corrected" versions of these parameters of diagnostic validity. We argue that these new measures have some undesirable properties in comparison with the established measures and no substantial advantages. In particular, the extension of this concept to chance-corrected ROC curves is shown to be less useful than classical ROC analysis.
Journal of Clinical Epidemiology

Koenig, W.; Sund, M.; Döring, A.; Ernst, E.
Leisure-time physical activity but not work-related physical activity is associated with decreased plasma viscosity. Results from a large population sample.
Circulation 95, 335-341 (1997)
BACKGROUND: Regular leisure-time physical activity (LTPA) is inversely associated with coronary heart disease (CHD). This has been mainly explained by its impact on traditional CHD risk factors, but more recently it was also shown to lower fibrinogen, which largely determines plasma viscosity. No data on the effect of work activity (WA) on plasma viscosity have been published. METHODS AND RESULTS: We studied the relationship between self-reported LTPA or WA and plasma viscosity as well as other CHD risk factors in 3522 men and women age 25 to 64 years. Physical activity was assessed by questionnaire. LTPA was inversely associated with plasma viscosity in both sexes. The unadjusted mean differences in plasma viscosity in men between no activity and the highest activity were 0.024 mPa.s (95% confidence interval [CI], 0.016 to 0.032 mPa.s, $P < .001$) during winter and 0.024 mPa.s (95% CI, 0.016 to 0.031 mPa.s, $P < .001$) during summer. After adjustment for age, cholesterol, smoking, blood pressure, body mass index, and years of education, mean differences decreased but still remained substantial and statistically significant (0.010 mPa.s; 95% CI, 0.003 to 0.018 mPa.s [$P = .009$] for winter activity; and 0.010 mPa.s; 95% CI, 0.002 to 0.017 mPa.s [$P = .011$] for summer activity). Similar results were found in women. WA showed no appreciable association with plasma viscosity after controlling for the covariates. CONCLUSIONS: LTPA is inversely associated with plasma viscosity, independent of other risk factors, whereas WA shows no material effect in men and women. Decreased plasma viscosity may represent one mechanism through which LTPA confers a decrease of CHD risk.
Circulation

von Kummer, R.; Allen, K.L.; Holle, R.; Bozzao, L.; Bastianello, S.; Manelfe, C.; Bluhmki, E.; Ringleb, P.; Meier, D.H.; Hacke, W.
Acute stroke: Usefulness of early CT findings before thrombolytic therapy.
Radiology 205, 327-333 (1997)
PURPOSE: To determine whether the extent of subtle parenchymal hypoattenuation detected on computed tomographic (CT) scans obtained within 6 hours of ischemic stroke is a factor in predicting patients' response to thrombolytic treatment. MATERIALS AND METHODS: The baseline CT scans of 620 patients, who received either recombinant tissue plasminogen activator (rt-PA) or a placebo, in a double-blind, randomized multicenter trial were prospectively evaluated and assigned to one of three categories according to the extent of parenchymal hypoattenuation: none, 33% or less (small), or more than 33% (large) of the middle cerebral artery territory. The association between the extent of hypoattenuation on the baseline CT scans and the clinical outcome in the placebo-treated and the rt-PA-treated groups after 3 months was analyzed. RESULTS: In 215 patients with a small hypoattenuating area, treatment increased the chance of good outcome. In 336 patients with a normal CT scan and in 52 patients with a large hypoattenuating area, rt-PA had no beneficial effect but increased the risk for fatal brain hemorrhage. CONCLUSION: The response to rt-PA in patients with ischemic stroke can be predicted on the basis of initial CT findings of the extent of parenchymal hypoattenuation in the territory of the middle cerebral artery.
Radiology

Mackenbach, J.P.; Kunst, A.E.; Cavelaars, A.E.; Groenhof, F.; Geurts, J.J.
Socioeconomic inequalities in morbidity and mortality in western Europe. The EU Working Group on Socioeconomic Inequalities in Health.
Lancet 349, 1655-1659 (1997)
BACKGROUND: Previous studies of variation in the magnitude of socioeconomic inequalities in health between countries have methodological drawbacks. We tried to overcome these difficulties in a large study that compared inequalities in morbidity and mortality between different countries in western Europe. METHODS: Data on four indicators of self-reported morbidity by level of education, occupational class, and/or level of income were obtained for 11 countries, and years ranging from 1985 to 1992. Data on total mortality by level of education and/or occupational class were obtained for nine countries for about 1980 to about 1990. We calculated odds ratios or rate ratios to compare a broad lower with a broad upper socioeconomic group. We also calculated an absolute measure for inequalities in mortality, a risk difference, which takes into account differences between countries in average rates of illhealth. FINDINGS: Inequalities in health were found in all countries. Odds ratios for morbidity ranged between about 1.5 and 2.5, and rate ratios for mortality between about 1.3 and 1.7. For men's perceived general health, for instance, inequalities by level of education in Norway were larger than in Switzerland or Spain (odds ratios [95% CI]: 2.57 [2.07-3.18], 1.60 [1.30-1.96], 1.65 [1.44-1.88], respectively). For mortality by occupational class, in men aged 30-44, the rate ratio was highest in Finland (1.76 [1.69-1.83]), although there was no large difference in the size of the inequality in those countries with data. For men aged 45-59, for

whom France did have data, this country had the largest inequality (1.71 [1.66-1.77]). In the age-group 45-64, the absolute risk difference ranked Finland second after France (9.8% [9.1-10.4], 11.5% [10.7-12.4]), with Sweden and Norway coming out more favourably than on the basis of rate ratios. In a scatter-plot of average rank scores for morbidity versus mortality. Sweden and Norway had larger relative inequalities in health than most other countries for both measures; France fared badly for mortality but was average for morbidity. INTERPRETATION: Our results challenge conventional views on the between-country pattern of inequalities in health in western European countries.
Lancet, The

Muehlberger, N.; Schneeweiss, S.; Hasford, J.
Adverse drug reaction monitoring--cost and benefit considerations. Part I: frequency of adverse drug reactions causing hospital admissions.
Pharmacoepidemiol. Drug Saf. 6 Suppl 3, S71-S77 (1997)
In an era of health care cost containment it is of particular interest to identify measures that reduce costs and at the same time improve health care quality. One of these cost cutting measures might be the reduction of the frequency of Adverse Drug Reactions (ADR). The objective of this paper is to summarize all original work on ADR frequencies at hospital admission and to come up with a valid estimate for the actual frequency of ADR-related hospital admissions. Additionally, we compared established concepts of ADR monitoring with respect to their utility for drug safety monitoring and pharmacoepidemiologic research. We reviewed 25 studies from the past 25 years. Analysing the effect of methodological characteristics showed that variation of reported ADR frequency mainly depends on differing study bases and the concepts of ADR monitoring. Investigations that thoroughly screened all members of the study population for the presence of adverse drug reactions (comprehensive ADR monitoring) generally yielded highest ADR proportions. Studies that concentrated screening on selected high-risk patients (preselective ADR monitoring) and those applying spontaneous or intensified spontaneous reporting detected lower ADR proportions (2.9% and 2.5%). The ADR proportion among admissions to departments of internal medicine was higher than among mixed hospital populations including surgical patients. In conclusion 4.2-6.0% (lower and upper quartile) and in median 5.8% of all admissions to medical departments are caused by adverse drug reactions. A two-step preselective ADR monitoring appears to be appropriate and efficient for both signal generation and signal validation as compared to spontaneous reporting and comprehensive monitoring. In conclusion, adverse drug reactions are a common cause of hospital admissions. As hospital care is expensive, attempts to prevent ADR and thus hospital admission need active encouragement.
Pharmacoepidemiology and Drug Safety

Schmid, R.G.; Tirsch, W.S.; Reitmeir, P.
Correlation of developmental neurological findings with spectral analytical EEG evaluations in pre-school age children.
Electroencephalogr. Clin. Neurophysiol. 103, 516-527 (1997)
For the differentiation of developmental neurological disorders in pre-school age children, the relationship between automatically derived EEG parameters and developmental neurological findings was investigated. Within the scope of the Munich Pediatric Longitudinal Study, the sample sets of 4- and 5-year-old children (according to the frontal and parieto-occipital EEG derivations) with selected abnormal findings categorized by special items were compared with the corresponding control groups. This was carried out by means of one-sided t tests and relative frequency band-related as well as single-step spectral power parameters in the alpha range of the EEG. Automatic analysis using single-step power values was superior to that using band-related parameters. This led to the conclusion that use of age-specific single-step parameters for a quantitative EEG analysis and ignoring the classical frequency bands will yield statistically greatly improved results. For 4- and 5-year-old children, the best separation of the neurologically abnormal groups from the normal control groups was obtained using relative spectral values in the frequency range of 9.0-9.8 Hz with a maximum at 9.4 Hz. At the same time, the topographical conditions of brain immaturation should be taken into account. The results for the children examined in this study differ in a stronger distinction over the frontocentral brain region of 4- and 5-year-olds ($P < 0.01$) and through an additional distinction over the parietooccipital region of the 5-year-olds ($P < 0.001$). It still must be tested whether the spectral parameter at 9.4 Hz is age-specific for 4- and 5-year-old children or whether in other age groups different spectral parameters are of use. As an examiner-independent method, the automatic EEG analysis should become an integral component of developmental neurological diagnostics.
Electroencephalography and Clinical Neurophysiology

Wassmer, G.; Jörres, R.A.; Heinrich, J.; Wjst, M.; Reitmeir, P.; Wichmann, H.-E.
The association between baseline lung function and bronchial responsiveness to methacholine.
Eur. J. Med. Res. 2, 47-54 (1997)
It has been reported that females show an increased frequency of bronchial hyperresponsiveness (BHR) compared to males and that this difference is abolished after taking into account differences in baseline FEV1. The aim of our study was to analyse how the distribution of BHR in males and females depends on the definition of BHR. Special emphasis was paid to the question whether the prevalence rates of BHR according to different definitions were related to baseline characteristics of the subjects and baseline lung function in the same manner. We analysed the data obtained within the European Community Respiratory Health Survey (ECRHS) in the Eastern German population sample of Erfurt aged 20-65 years ($n = 931$). In logistic regression analyses of different definitions of BHR, we used as parameters age, height, gender, smoking habits, baseline forced expiratory volume in one second (FEV1), forced vital capacity (FVC), and FEV1 as a percent of FVC (FEV1% FVC). Symptoms and reported diagnosis of asthma did not significantly depend on gender or age. When BHR was defined as the provocative dose causing a 20% fall in FEV1, BHR was more prevalent in females than in males (27.6% vs. 13.2%). Similar gender differences were found when defining BHR via a 10% fall in FEV1 or by using corresponding cut-off values of the linear dose-response slopes of the percent decline in FEV1 (DRS). Multiple linear regression analyses of various transformations of the DRS also indicated a higher degree of BHR in females. Independently of the definition chosen, however, the gender difference in the prevalence of BHR disappeared when height and FEV1 or FEV1% FVC or

appropriate combinations were included in the model. The reciprocally transformed DRS showed the best resolution of the spectrum of bronchial responsiveness. These data are compatible with the hypotheses that (1) estimates of the distribution of BHR are distorted by differences in the methacholine dosage per lung size and that (2) airway geometry affects the measurement of BHR. It appears that these factors and not intrinsic differences in BHR between males and females contribute to the gender differences in the prevalence of BHR. Furthermore, our data support the superiority of the dose response slope for the analysis of bronchial responsiveness in epidemiologic surveys.
European Journal of Medical Research

Windstetter, D.; Schaefer, F.; Schärer, K.; Reiter, K.; Eife, R.; Harms, H.K.; Bertele-Harms, R.; Fiedler, F.; Tsui, L.C.; Reitmeir, P.; Horster, M.; Hadorn, H.B.
Renal function and renotropic effects of secretin in cystic fibrosis.
Eur. J. Med. Res. 2, 431-436 (1997)
In ten cystic fibrosis patients and nine age-matched controls, renal function was determined before and after infusion of secretin. Under baseline conditions creatinine excretion and clearance were significantly elevated, exclusively due to those patients who were homozygous for the DF508 mutation (153 vs 132 ml/min*1.73m2), whereas the glomerular filtration rate, measured by inulin clearance showed no difference. Renal plasma flow and the fractional reabsorption rates of electrolytes were similar in patients and controls. During secretin infusion renal plasma flow increased and the fractional reabsorption rates of electrolytes decreased in both groups. The patients had a increased metabolic clearance (2900 vs 1660 ml/min*m2) and endogenous production rate (9,9 vs 2,5 pmol/min*m2) of of secretin. In conclusion global renal function and electrolyte handling, in particular chloride permeability, are unchanged in cystic fibrosis. Individuals expressing the DF508 genotype showed a selective elevation of creatinine excretion and clearance. The secretion and metabolic clearance of secretin are increased in cystic fibrosis.
European Journal of Medical Research

1996
Altenstetter, C.
Regulating healthcare technologies and medical supplies in the European Economic Area.
Health Policy 35, 33-52 (1996)
A complex relationship exists among EU regulations, current national practices and rules, institutional capacities to implement regulatory adjustments and the legacy of past health and regulatory policy and traditions. However, there is little empirical information on medical devices policy, the medical devices industry, and the assurance of medical device safety and usage. Drawing on a review of the secondary literature and on-going field work, the evidence suggests that the current mix of state-centric and self-regulatory traditions will be as important in determining the implementation and final outcomes of EU-rules as the new rules themselves. EU directives redesign rules, but they do not necessarily lead to institutional change, create manpower, skills and institutional capacities, or alter governance and administrative practices in the short term. Neither EU directives nor national regulatory adjustments determine the 'man-machine/skills-experience' interface which is shaped and influenced by local medical traditions and the acceptance of these traditions by local publics.
Health Policy

Küchenhoff, H.; Thamerus, M.
Extreme value analysis of Munich air pollution data.
Environ. Ecol. Stat. 3, 127-141 (1996)
We present three different approaches to modelling extreme values of daily air pollution data. We fitted a generalized extreme value distribution to the monthly maxima of daily concentration measures. For the exceedances of a high threshold depending on the data, the parameters of the generalized Pareto distribution were estimated. Accounting for autocorrelation, clusters of exceedances were used. To obtain information about the relationship of the exceedance of the air quality standard and possible predictors we applied logistic regression. Results and their interpretation are given for daily average concentrations of ozone and nitrogen dioxide at two monitoring sites within the city of Munich.
Environmental and Ecological Statistics

Mielck, A.; John, J.
Kostendämpfung im Gesundheitswesen durch Rationierung - Was spricht dafür und was dagegen?
Gesundheitswesen 58, 1-9 (1996)
In Germany, the discussion on the pros and cons of rationing health care services in the statutory health insurance funds has just begun, but it will probably be of great importance in the years to come. Until now, it is mainly a political discussion with only very few researches participating. In order to enhance the matter-of-factness in this controversial debate, the experiences in the USA with rationing health care services are summarised, and in the second part a more general discussion is added on different forms and consequences of rationing. The present discussion in Germany is outlined in the third part of the paper. In our own evaluation two arguments are stressed: Firstly, the central argument that rationing of health care services is inevitable because health care costs are "exploding", has as yeb no firm empirical and theoretical basis. Secondly rationing by taking medically useful benefits from the schedule of benefits in the statutory health insurance funds is not compatible with the ethical principles governing these funds.
Gesundheitswesen, Das

Mielck, A.; Reitmeir, P.; Wjst, M.
Severity of childhood asthma by socioeconomic status.
Int. J. Epidemiol. 25, 388-393 (1996)
BACKGROUND: A review of studies on the association between childhood asthma and socioeconomic status (SES) in industrialized countries leads to the conclusion that there does not seem to be a clear association. A study from Aberdeen published 25 years ago, however, shows that among children with asthma, severe asthma is most prevalent in the lower social class, but this distinction between grades of asthma severity has been largely ignored since. METHODS: We screened all fourth grade schoolchildren of German nationality in Munich (4434 children, response rate 87 percent), distinguishing three severity grades in the same way as the study in Aberdeen. RESULTS: Prevalences of childhood asthma are reported by severity grade and SES. Prevalence of severe asthma was found to be significantly higher in the low as compared with the high socioeconomic group (Odds ratio = 2.37; 95 percent confidence

interval: 1.28-4.41). This association could not be explained by established risk factors. CONCLUSIONS: More attention should be paid to the association between severe asthma and SES, with measures such as targeting early diagnosis and treatment towards low socioeconomic groups.
International Journal of Epidemiology

Reitmeir, P.; Wassmer, G.
One-sided multiple endpoint testing in two-sample comparisons.
Commun. Stat.-Simul. Comput. 25, 99-117 (1996)
This article reviews several methods for comparing two treatments with multiple endpoints that take into account the dependence structure among the endpoints and that are sensitive to the multivariate one-sided alternative. The methods are classified into procedures that adjust single endpoint P-values separately, into bootstrap procedures that adjust single endpoint P-values through resampling from the whole data, and into procedures that summarize the data into a global test statistic. In this context, we describe step-down procedures leading to conclusions about the single endpoints. Applying the closed test principle, James (1991, Statistics in Medicine 10, 1123-1135)-based, O'Brien (1984, Biometrics 40, 1079-1087)-based, Tang, Gnecco, and Gellar (1989, Biometrika 76, 577-583)-based, and Westfall and Young (1989, Journal of the American Statistical Association 84, 780-786)-based procedures are investigated and compared to standard techniques. Monte Carlo simulations for small to moderate sample sizes are performed to give some recommendations for practical use.
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Complications of combined intraoperative radiation (IORT) and external radiation (ERT) of the upper abdomen: An experimental model.
Radiother. Oncol. 38, 205-214 (1996)
An experimental model in the rabbit is presented which is suitable for analysis of clinically relevant, early side-effects of combined upper abdominal IORT and ERT. Fractionated ERT alone given through an upper abdominal a.-p. field including the entire stomach caused gastric ulcerations within < or = 58 days. Latent times decreased with increasing dose and the ED50 for occurrence of ulcers was 39 +/- 3.3 Gy. Single doses of IORT of 20-40 Gy alone administered through a 2-cm diameter field localized on the coeliac axis and carefully excluding any intestinal mucosa caused neither gastric ulcerations nor other clinical symptoms. When ERT with 40 Gy was preceded by IORT with 20-40 Gy or by sham IORT, 13 out of 15 animals developed ulcers after latent times which in a life-table analysis were shown to be significantly shorter than after ERT alone. However, a statistically significant IORT dose-dependence of latent time or incidence of ulcers could not be demonstrated in the present experiment. The most significant histological changes were observed in the areas of gastric ulcers. Already during ERT, the mucosal epithelium was depleted and regenerative activity was evident in spite of ongoing fractionated irradiation. However, profound irregularities in glandular structure and distribution, as well as number of proliferating epithelial cells were still present in healed ulcers at 80 days. In summary, IORT to the coeliac artery did precipitate the development of gastric ulcers induced by subsequent ERT. On the one hand, the data indicate that the surgical procedure of IORT did contribute to this effect. On the other hand, IORT to the coeliac artery could cause transient, functional alterations in blood supply to the depending organs, i.e. the stomach, and could thus precipitate the development of radiation-induced ulcers.
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Predictors of 10-year macrovascular and overall mortality in patients with NIDDM: The Munich General Practitioner Project.
Diabetologia 39, 1540-1545 (1996)
The 10-year follow-up of the Munich General Practitioner Project was designed as a long-term prospective study to evaluate factors predicting macrovascular and overall mortality in a random cohort of non-insulin-dependent diabetic (NIDDM) patients. Of the original 290 patients (103 males, 187 females, median age 65 years) 92.5% could be assessed, 103 subjects had died, 58 from macrovascular causes. In an univariate analysis of baseline data, deceased patients, and especially those who died from macrovascular causes had significantly higher fasting blood glucose, HbA1c, von Willebrand-factor protein, urine albumin excretion, and serum beta 2-microglobulin, were significantly older, exhibited significantly more ischaemic heart disease (abnormal ECG Minnesota codes), carotid artery and peripheral vascular disease (both determined by ultrasound-Doppler), and had significantly inferior knowledge about diabetes and its treatment. No significant differences were seen for gender, blood pressure, smoking, total cholesterol, triglycerides, HDL-cholesterol, or the use of antidiabetic, antihypertensive or coronary drugs. In a multiple logistic regression analysis, the risk factors for macrovascular death were age, HbA1c and von Willebrand-factor protein. When baseline macrovascular disease was taken into account, carotid artery disease was also a determinant. The main variables from the metabolic syndrome (blood pressure, dyslipidaemia, body mass index) did not enter a multiple logistic regression analysis. The data suggest that age and haemoglobin A1c are major determinants, and that in addition von Willebrand-factor associated endothelial damage is a risk factor for macrovascular mortality in NIDDM patients.
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Psychosocial characteristics of asthma.
J. Clin. Epidemiol. 49, 461-466 (1996)
The objective of this study was to compare psychosocial characteristics of children with asthma and children with bronchial hyperreactivity with those of normal children. A population-based study of 2634 children (mean age, 10 years) was carried out. Pulmonary function tests of children were performed in children before and after cold air hyperventilation challenge to determine bronchial hyperreactivity. Parental assessment of children's behavior was evaluated with 15 questions about school/learning habits, level of activity, communication/affection, and sleeping patterns. A factor analysis was performed and the factor loading adjusted for confounders compared in the different groups. Asthmatic children sleep less well than normal and hyperreactive children (p < 0.001). Unexpectedly, however, all other single items did not differ significantly. As a result of the factorial analysis we obtained two factors. On the first factor, measuring school behavior and

learning, there was a small difference between asthmatic and normal children, which could not be found on the second factor indicating activity and communication. We conclude that psychosocial differences of asthmatic children are less remarkable than expected. As a result of the examination of the hyperreactive children it is likely that asthmatic children are influenced more by secondary psychosocial factors than by any primary effect of asthmatic disease.
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Social Inequities in Cardiovascular Disease Risk Factors in East- and West-Germany.
Soc. Sci. Med. 35, 1283-1292 (1992)
Social class related differences in prevalence of cardiovascular disease risk factors in Germany were investigated with special emphasis on comparisons between East and West Germany and on time trends. Databases for West Germany are the first and second National Health Survey (survey 1: N = 4794, survey 2: N = 5315), carried out in the framework of the German Cardiovascular Prevention Study, and for East Germany the first GDR-MONICA project (N = 6125). Different social class indices were applied to evaluate social inequities for hypertension, hypercholesterolemia, cigarette smoking, obesity and predicted cardiovascular disease mortality. As a main result, it was found that very similar patterns in the relation between social class characteristics and cardiovascular disease risk factor prevalence occurred for both parts of Germany. Social class gradients were strongest for obesity and weakest for hypercholesterolemia. Analysis of time trends for the period from 1984 to 1988 (for West Germany only) revealed an increase in social inequalities for hypertension in males and cigarette smoking in females. These findings point to the need to focus more on social disadvantaged segments in the population when community based health promotion and disease prevention programs are brought into action.
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Einschränkungen des Rauchens am Arbeitsplatz und Rauchgewohnheiten: Ein Literaturreview.
Soz. Präventivmed. 37, 162-167 (1992)
Anhand eines kritischen Literaturreviews wird der Frage nachgegangen, wie sich Rauchbeschränkungen am Arbeitsplatz auf die Rauchgewohnheiten aktiver Raucher auswirken. Die vierzehn dazu bisher vorliegenden Studien (elf Studien aus den USA, je eine Studie aus Kanada, Australien und Westdeutschland) weisen in der Mehrzahl darauf hin, dass Beschränkungen des Rauchens am Arbeitsplatz die Reduktion des Zigarettenkonsums und die Aufgabe des Rauchens bei aktiven Rauchern spürbar fördern können. Allerdings sind diese Studien aufgrund methodischer Probleme nur bedingt aussagekräftig und sollten dringen durch wissenschaftlich stringentere Untersuchungen ergänzt werden. Analog dem Vorgehen in anderen Ländern erscheint eine weitergehende Implementation von Rauchbeschränkungen im Rahmen des Nichtraucherschutzes jedoch auch vor der endgültigen Abklärung der hier untersuchten Fragestellung sinnvoll. Eine solche Implementation sollte in jedem Falle aber ohne Diskriminierung der Raucher im Kontext umfassender betrieblicher Interventionsprogramme und unter strenger wissenschaftlicher Evaluation erfolgen.
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Procedures for two-sample comparisons with multiple endpoints controlling the experimentwise error rate.
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Clinical trials are often concerned with the comparison of two treatment groups with multiple endpoints. As alternatives to the commonly used methods, the T2 test and the Bonferroni method, O'Brien (1984, Biometrics 40, 1079-1087) proposes tests based on statistics that are simple or weighted sums of the single endpoints. This approach turns out to be powerful if all treatment differences are in the same direction [compare Pocock, Geller, and Tsiatis (1987, Biometrics 43, 487-498)]. The disadvantage of these multivariate methods is that they are suitable only for demonstrating a global difference, whereas the clinician is further interested in which specific endpoints or sets of endpoints actually caused this difference. It is shown here that all tests are suitable for the construction of a closed multiple test procedure where, after the rejection of the global hypothesis, all lower-dimensional marginal hypotheses and finally the single hypotheses are tested step by step. This procedure controls the experimentwise error rate. It is just as powerful as the multivariate test and, in addition, it is possible to detect significant differences between the endpoints or sets of endpoints.
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To determine whether an unbalanced redox state might accompany the development of particular inherited mouse cataracts, the lenticular content of oxidized glutathione (GSSG) and the activity of superoxide dismutase (SOD) were chosen as markers. For wild-type lenses, an enhanced GSSG content could be observed in females as compared to males. Such a sex effect could not be detected for the SOD activity. In the mutants, GSSG content in cataractous lenses was found to be enhanced in 2 of 7 cases; the increases in other mutants were not significant. Changes of the SOD activity were even less consistent and only a random correlation of GSSG content and SOD activity with cataractogenesis could be deduced.
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