

the results did not cause an added value of the drug in this respective application. In seven cases the indirect comparison was declined due to a different comparator as determined by the G-BA. Three indirect comparisons were declined because of methodological deficiencies and another three indirect comparisons were declined because non-adjusted indirect comparisons were performed. **CONCLUSIONS:** The IQWiG only accepts adjusted indirect comparisons. The application of the correct methodology is necessary to gain valid results and shall not be questioned. The IQWiG approach is accurate with regard to contents and correct in a legal sense. However the procedure shows, that the external preconditions and methodological requirements are demanding and almost impossible to fulfill. Main reason for denial is the divergence from the prespecified appropriate comparator set by the G-BA. To get back to the original aim of the early benefit assessment, a more realistic and reasonable determination of the appropriate comparator would be desirable.

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THE ADOPTION OF HEALTH TECHNOLOGIES: A SURVEY OF BRAZILIAN POLICY MAKERS

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OBJECTIVES: Policy makers of municipalities decided to adopt health technology into the Brazilian Public Health System (SUS). This group met during national conferences. The last conference, "The XXVIII National Congress of Municipal Health Secretariats (CONASEMS)", took place during June 11 to 14, 2012. The aim was describe the views of participants at the CONASEMS event regarding technology assessment criteria for the Brazilian Public Health System (SUS). **METHODS:** A survey applied at the Ministry of Health's exhibition booth, June 11 to 14, 2012. Three variables were studied for the survey: "Participant Profile", "Knowledge of Health Technology Assessment for Adoption by the SUS" and pre-selected criteria for assessing health technologies (where 1=most important and up to 9=least important). **RESULTS:** The survey encompassed 5.6% (244/4.328) of all conference participants. Of these, 43% represented policy makers; 35% health professionals and 22% others. Of the total amount of participants, 67% have little or average knowledge of HTA and 14% declared having no knowledge of the area. The values in the adoption of health technologies were ranked by delegates. The score of one was: evidence on patient safety, improved quality of life and patient survival, impact on the population's health. The score nine was: relationship between benefits and costs, health system costs and patient costs. **CONCLUSIONS:** Considering the results, the value related to criteria regarding quality of life and survival were the most important in detriment to cost criteria. It is important to involve the Brazilian Network for Health Technology Assessment (REBRATS) as an additional contribution to the application of the new Brazilian law regarding the incorporation of health technologies.

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ORPHAN DRUGS IN THE GERMAN EARLY BENEFIT ASSESSMENT- REAL WORLD VERSUS G-BA BUREAUCRACY

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OBJECTIVES: Early benefit assessment pursuant to AMNOG was introduced to cut costs and illustrate the additional benefit of new pharmaceuticals including orphan drugs at launch in Germany. In this process orphan drugs have a special status. The EMA orphan drug designation implies the assumption that at least a not-quantifiable additional benefit is set by law. However the extent of the additional benefit still has to be demonstrated by the manufacturer. **METHODS:** By June 2013 seven orphan drug dossiers have been submitted and assessed. Only one product has been admitted an important additional benefit. Four substances had a minor additional benefit and two substances had a not-quantifiable additional benefit. **RESULTS:** An additional benefit needs to be proven against a comparator. But the G-BA will not define an appropriate comparator as for non-orphan drugs. Instead, the assessment of orphan drugs is based on the pivotal trial; the comparator will be derived from this trial. Due to the early phase of pivotal trials in rare diseases, using a comparator is not common. Furthermore, phase II trials often do not meet requirements in terms of evidence level requested: randomized controlled trials with large patient populations are unusual in orphan diseases as well as investigation of valid patient relevant endpoints or validated surrogate endpoints. **CONCLUSIONS:** The G-BA requirements for HTA assessments are drawn from phase III trials and demonstration of an additional benefit over an appropriate comparator, which also serves as price benchmark. The requirements derived for all newly launched products do not reflect orphan drug reality, which is indication and not agent based. In summary the EMA declaration of early admission of orphan drugs in phase II conflicts with the G-BA's methodological requirements for the quantification of an additional benefit. In fact, manufacturers of orphan drugs face an additional barrier before launch in Germany.

HEALTH CARE USE & POLICY STUDIES - Population Health

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VARIATIONS IN THE HEALTH STATUS OF IRISH REGIONS

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OBJECTIVES: This paper constructs a composite index that is sufficiently comprehensive to rank the overall health status of Irish regions and sufficiently detailed to identify the principal sources of varying regional health status. **METHODS:** We draw on the CSO (Central Statistics Office), PCRS (Primary Care Reimbursement Service) and IPH (Institute of Public Health) health and medicines databases to construct a composite index of the health status of the 8 HSE regions in Ireland in 2010. Our composite health index (CHI) has 6 component indices. Each maps the regional prevalence of major health conditions for which an ATC (Anatomical Therapeutic

Classification) group of drugs was prescribed. Our composite health index, CHI, is a coverage-weighted average of the separate indices we construct for persons covered by each community drug scheme in each region. **RESULTS:** Respiratory health status varies most across Irish regions but Cardiovascular, Central Nervous System and 'Other' health conditions have higher CHI weights and contribute more to overall regional health disparities. The Midlands region had the poorest health status in 2010 (8% below the national average); the Eastern region had the best (6% above average), followed closely by the Mid-West. The Mid-West has a better health status than the Midlands despite having lower income and a larger elderly population share. The health status of the Eastern region is just 2% higher than the Mid-West even though its income is 6% higher and the percentage of its population aged over 65 is 1.8 percentage points lower. Simple economic and demographic variables - mean income and the elderly population share - correlate well with health status. **CONCLUSIONS:** Our index maps significant regional disparities and paves the way for complementary epidemiological studies to trace their underlying lifestyle and medical causes and inform regional health policy.

HEALTH CARE USE & POLICY STUDIES - Prescribing Behavior & Treatment Guidelines

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FEASIBILITY OF MEDICINES REVIEW TO REDUCE POTENTIALLY INAPPROPRIATE MEDICINES IN THE ELDERLY: THE OPTI-SCRIPT CLUSTER RANDOMIZED CONTROLLED TRIAL

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OBJECTIVES: Potentially inappropriate medicines (PIMs) can result in increased morbidity, adverse drug events and hospitalizations. Polypharmacy is the strongest predictor of PIMs, the prevalence of which was 36% in 2007 in those aged ≥ 70 years, with an associated expenditure of over €45 million. Medicines review may have the potential to improve patient outcomes and reduce prescribing costs. This study aims to assess the feasibility of introducing medicines review to reduce PIMs in older patients. **METHODS:** OPTI-SCRIPT is a cluster randomized controlled trial (RCT), that aims to assess the effectiveness of a complex intervention incorporating academic detailing, a medicines review with web-based pharmaceutical treatment algorithms that provide recommended alternative treatments, and tailored patient information leaflets in reducing PIMs. A qualitative evaluation is being conducted to determine the feasibility and acceptability of the intervention. **RESULTS:** Twenty-one GP practices (response rate 32.3%) participated. Identifying patients with a PIM required considerable time and expertise. Practices screened all patients aged ≥ 70 years to identify those suitable to participate. A pharmacist reviewed their repeat medications, identifying patients with a PIM who were then invited to participate. Despite being offered a once off review of their current prescriptions with their GP, only 37.4% (196) agreed to participate. Preliminary qualitative findings indicate that intervention group GPs valued the review process as an opportunity to reflect on their prescribing practice. Some GPs highlighted that conducting routine structured reviews with older patients wouldn't be feasible due to the time, resources and funding available to them currently in primary care. Participating patients placed a high value on their medicines review. **CONCLUSIONS:** Preliminary findings illustrate that implementing a system of structured reviews for older patients with a PIM is challenging. However, participating GPs and older patients saw the value of conducting medicines reviews, but formal resourcing of such services would need to be considered.

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USE OF CLINICAL PRACTICE GUIDELINES BY PHYSICIANS IN JAPAN

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OBJECTIVES: The present study aimed to determine the proportion of physicians in Japan who use clinical practice guidelines, as well as factors influencing this choice. **METHODS:** We conducted an on-line cross-sectional survey throughout Japan on general internists, gastroenterologists, cardiologists, endocrinologists and general surgeons, including gastrointestinal or breast surgeons, who registered for marketing research. Questions addressed their usage of CPGs in practice, education, and research, as well as their attitudes toward CPGs. We then investigated associations between usage and characteristics of the respondents. **RESULTS:** We received responses from 1342 physicians, 1222 (91.1%) of whom were male (mean age (SD), 46.5 (9.6) years). The proportion of respondents who always or often use CPGs in several practice settings, such as when providing explanations to patients based on CPGs, ranged from 27.7% to 54.6%. Among them, 822 respondents (61.3%) applied 1 to 4 CPGs, and 381 (28.4%) applied 5 to 9. Usage differed according to age group, subspecialty, and workplace. After multivariate adjustment, the mean probability (95% confidence interval) of a high usage of CPGs when providing explanations to patients was 65% (60% - 71%) and 40% (30% - 50%) for those aged < 40 y and ≥ 60 y, respectively, 44% (38% - 50%) for general internists, 65% (59% - 71%) for surgeons, and 51% (46% - 57%) and 65% (58% - 72%) for those working in clinics and university hospitals, respectively. Attitudes towards the trustworthiness and convenience of CPGs were associated with usage, although this was unable to explain all differences in usage among subgroups. **CONCLUSIONS:** A substantial proportion of Japanese physicians use CPGs in clinical practice. Age, subspecialty, and workplace were independently associated with CPG usage. This should be considered during the process of CPG implementation.

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SYSTEMATIC REVIEW ON USE OF ECONOMIC EVIDENCE BY CLINICAL GUIDELINES

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OBJECTIVES: The recent reforms and policy changes have increased the cost pressures on all health care stakeholders, including clinical experts. In the past, clinical