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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 (CONASEM)”, took place during June 11 to 14, 2012. The aim was describe the views of participants at the CONASEM event regarding technological 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.
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 (REBRAHAT) 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 increase 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 benefit exists 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. Priorities for the governmental benefit assessment procedures 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 required: 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 demonstrate 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 lack of 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 – Prescription 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 a median of 45±5.3. The goal of the intervention was 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. The intervention will be evaluated against the control arm to assess the feasibility and acceptability of the intervention.
RESULTS: Twenty-one GP practices (response rate 82.3%) 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 one-off review of their current prescriptions with their GP, only 37.4% (196) agreed to participate. Preliminary results indicate medicine review identified 41% of patients. 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 suggested that older patients were satisfied with the medicines review, 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, cardiology, 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 1362 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, 207 (15.2%) applied 5 to 9, 283 (20.9%) applied 10 to 19, and 36 (2.7%) applied ≥20. Usage differed according to age group, specialty, and workplace. After multivariate adjustment, the mean probability (95% confidence interval) of a high usage of CPGs when providing explanations to patients was 65% (58.9%-71.3%) and 40% (30.0%-50%) for those aged <40 y vs. ≥60 y; y 40-49 y, 44% (38% - 50%) for general internists, 65% (59% - 71%) for surgeons, and 51% (46% - 57%) and 65% (58%-72%) for those working in university and hospitals, respectively. Attitudes towards the trustworthiness and convenience of CPGs were associated with age, specialty, and workplace. GPs placed a higher value on the latest CPGs than surgeons. 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...