the results did not cause an added value of the drug in this respective application. In several cases, the improved comparison was a dramatic improvement 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 approach accurately assessed adjusted indirect comparisons. The approach is consistent and 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 results 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.


Controlled Health Technologies (CONASEMS), took place during June 11 to 14, 2012. The aim was to describe the views of participants at the CONASEMS event regarding methodological 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 and Adoption for 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% (244/4328) of all conference participants, being 70.8% policy makers, 16.0% health professionals and 12.8% 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 nine was: relationship between benefits and costs, health 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.

PHP190 ORPHAN DRUGS IN THE GERMAN EARLY BENEFIT ASSESSMENT – REAL WORLD VERSUS G-BA BUREAUCRACY Leibda A, Hülsebeck M, Plankton S

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OBJECTIVES: Early benefit assessment pursuant to AMNOG was introduced to cut costs and ensured 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 products have been submitted and assessed. Only one product has been admitted an important additional benefit. Five applications had a minor additional benefit and the other five products 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-orphans 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 II trials and demonstration of an additional benefit other than a comparable 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 G-BA’s 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 – Prescribing Behavior & Treatment Guidelines

PHP192 FEASIBILITY OF MEDICINES REVIEW TO REDUCE POTENTIALLY INAPPROPRIATE MEDICINES IN THE ELDERLY: THE OPTI-SCRIPT CLUSTER RANDOMIZED CONTROLLED TRIAL Chyne B, Hughes C, Smith SM*, Fahey T

Objective: To assess the feasibility of reducing medicines review to reduce FIMs in older patients in Clusters. METHODS: OPTI-SCRIPT C (Cluster Randomized controlled trial) (CCT), 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 FIMs. A qualitative evaluation is being conducted to determine the feasibility and acceptability of the intervention. RESULTS: Twenty-one GP practices (response rate 22.3%) participated. Identifying patients with a FIM required considerable time and expertise. Practice screened all patients aged ≥ 70 years to identify those suitable to participate. A pharmacist reviewed their repeat medications, identifying patients with a FIM 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 qualitative findings indicate that healthcare professionals 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 FIM is challenging. However, participating GPs and older patients saw the benefits. The medicines review reviews, but formal resourcing of such services would need to be considered.

PHP193 USE OF CLINICAL PRACTICE GUIDELINES BY PHYSICIANS IN JAPAN Shimo T1, Suzuki T1, Takahashi O2, Tanaka Y1

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 CGPs in practice, education, and research, as well as their attitudes toward CGPs. 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 CGPs in several practice settings, such as when providing explanations to patients based on CGPs, ranged from 27.7% to 54.6%. Among them, 822 respondents (61.3%) applied 1 to 4 CGPs, and (28.4%) applied 5 to 9. Usage differed according to age group, subspecialty, and workplace. At multivariate adjustment, the mean probability (95% confidence interval) of a high usage of CGPs when providing explanations to patients was 65% (62.3% - 67.4%) and 40% (35.0% - 45.2%) for young age (<40 y) and ≥ 60 y, respectively. Furthermore, 44% (38% - 50%) for general internists, 65% (59% - 71%) for surgeons, and 51% (46% - 57%) and 65% (58% - 72%) for those working in inpatient and university hospitals, respectively. Attitudes towards the trustworthiness and convenience of CGPs were associated with usage of CGPs. This study explained all differences in usage of CGPs between subgroups. CONCLUSIONS: A substantial proportion of Japanese physicians use CGPs in clinical practice. Age, subspecialty, and workplace were independently associated with CGP usage. This should be considered during the process of CGP implementation.

PHP194 VARIATIONS IN THE HEALTH STATUS OF IRISH REGIONS Kenneally M, Lynch B

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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 Department of Health’s National Survey of Patients (NSP), 1996 (22,747 respondents), which details on all health care stakeholders, including clinical experts. In the past, clinical