Introduction. Within early benefit assessment of pharmaceuticals in Germany, addenda can be commissioned by the Federal Joint Committee (FJC) to the health technology assessment (HTA) agency, mainly as a result of a hearing. Our aim was to analyze the issues for and impact of commissioned addenda, as well as the agreement between HTA agency recommendations and FJC decisions.

Methods. All available relevant documents on addenda commissioned up to the end of 2017 were screened and their essential content extracted. Differences between the HTA agency and FJC recommendations were tested, and concordance was analyzed using agreement statistics (Cohen's kappa and Fleiss' kappa).

Results. Most of the 90 addenda commissioned up to the end of 2017 concerned oncological products. In all contingent comparisons, positive changes in added benefit or evidence level on a subpopulation basis (n = 124) were more common than negative changes. Agreement of assessments, addenda, and appraisals reached a moderate strength for added benefit (Fleiss' kappa 0.47, range 0.41 - 0.54). Overall agreement between addenda and appraisals on a binary nominal basis was poor for added benefit (Cohen's kappa 0.18, range 0.01 - 0.36) and fair for evidence quality (Cohen's kappa 0.35, 0.19–0.52). Cohen's kappa ranged from "less than by chance" (respiratory diseases) to "perfect" (neurological diseases), but was only statistically significant for neurological and other diseases. Three addenda are presented in detail as examples.

Conclusions. Addenda have a high impact on decision-makers' appraisals, offering additional analyses of supplementary evidence submitted by the manufacturers. Nevertheless, the agreement between addenda and appraisals varies, highlighting different methodological approaches and decision-making factors between the HTA agency and the FJC.

PP86 Reimbursement of Combination Oncology Products: Can Two (Companies) Tango?

Erika Turkstra (erika.turkstra@PAREXEL.com), Lok Wan Liu, Andrea Berardi and Richard Macaulay

Introduction. A range of innovative, targeted anti-cancer therapies have been developed over the past 20 years. More recently, companies have been developing combinations of these drugs. While this promises substantial efficacy benefits, dual-brand oncology therapy combinations may potentially create substantial economic burden. Obtaining a positive health technology assessment (HTA) recommendation and public reimbursement can be a major challenge, and may be more difficult when each constituent monotherapy is marketed by a different company. We evaluated whether dual-brand oncology therapies developed by a single manufacturer had faster or better outcomes than those developed by two separate manufacturers.

Methods. Recent combination oncology drug products were screened in November 2018 to identify whether one or two manufacturers were involved. The websites of various HTA organizations were screened and the relevant data extracted.

Results. A total of 78 recommendations for dual-brand oncology treatments were identified across the HTA agencies screened: 26 of these were for combinations by the same manufacturer and 52 were for combinations with two manufacturers. Dual-brand therapies developed by a single manufacturer were more likely to receive full or optimized/conditional recommendations (58% "recommended" and 12% "optimized/conditional") than those marketed by two separate manufacturers (42% "recommended" and 8% "optimized/conditional"). Dual-brand therapies with two manufacturers were more likely to receive negative HTA recommendations than those marketed by a single manufacturer (50% versus 31%). However, the median time from marketing authorization to recommendation in European countries was the same (6 months), regardless of whether each constituent monotherapy was marketed by one or two manufacturers.

Conclusions. HTA agencies were more likely to issue negative recommendations for dual-brand oncology treatments marketed by two separate companies, compared with those marketed by a single company. A single company may have more flexibility in price setting, which may facilitate more positive HTA recommendations.

PP87 Inpatient Drug Reimbursement: Approaches For A Democratic Process

Sarah Wolf (Sarah.Wolf@hta.lbg.ac.at) and Claudia Wild

Introduction. In the context of limited healthcare resources and high healthcare expenditures, the introduction of new, cost-intensive medicines forces decision-makers to prioritize drug funding, especially in the areas of orphan diseases and oncology. In democratic societies, health policy decisions need to be evidence-based, transparent, fair, and efficient. Therefore, in some countries standardized (transparent) processes exist. In Austria, decisions on the reimbursement of new medicines have not been made for a long time. The aim of the present study was to develop different scenarios for a standardized, centralized reimbursement process for expensive hospital drugs in Austria that favors democratic decisions.

Methods. A multi-stage approach was undertaken. Firstly, the reimbursement processes (only for original preparations) in Austria and other selected countries were investigated. Secondly, the strengths and weaknesses of these processes were analyzed based on predefined criteria, following the concepts of "accountability for reasonableness" (A4R) and "deliberative decision making". Thirdly, scenarios for an Austria-wide uniform reimbursement process for hospital drugs were developed.

Results. Three scenarios were identified: (i) a reimbursement process for hospital drugs that follows the existing reimbursement process in the outpatient sector in Austria; (ii) a cooperative of decentralized Pharmaceutical and Therapeutics Committees for procurement, use, and reimbursement decisions for hospital drugs; and (iii) an adaptation of the existing reimbursement process of non-drug, highly specialized technologies to pharmaceutical interventions.

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Conclusions. According to the concepts of A4R and deliberative decision making, a transparent, evidence-based, fair, and efficient allocation of limited healthcare resources is indispensable for justifying decisions on health funding priorities in democracies. However, these criteria can be diametrically opposed. For example, methods, processes, and decisions can be evidence based, transparent, and fair, but also significantly more time consuming. Thus, a balance between the individual options for action is necessary, and priorities must be set.

PP88 Economic Impact Of New Diagnostic Tools In Severe Sepsis

Kurt Neeser (K.Neeser@analytica-laser.com), Ilse-Barbara Oelze and Elvira Müller

Introduction. Constantly rising healthcare costs and the increasing incidence of antimicrobial resistance represent a growing burden on public health, affecting patients, physicians, payers, and health authorities. This analysis assessed the economic impact of improved diagnostic accuracy among septic patients.

Methods. A cost-consequence model was developed to evaluate two different scenarios for the treatment of severe sepsis: scenario one represents the current status of diagnostic performance used for an antimicrobial treatment; scenario two is based on the assumption that a more accelerated diagnostic process results in 15 percent more patients being treated with an efficient antimicrobial drug early in their therapy. Data for the average patient-related cost for diagnostics (EUR 1,182) and overall cost (EUR 12,090), length of hospital stay (average 18.7 days), and number of patients affected annually (n = 771) were derived from the German Diagnosis-Related Group Catalog for 2017. Further, the impact of optimal versus inadequate therapeutic approaches on length of hospital stay (38% decrease), hospitalization cost (40% decrease), and mortality rate (28% decrease) were derived from published sources.

Results. By using more efficient tests to enable earlier detection of sepsis in patients who otherwise would not receive appropriate treatment, 36 additional patients were appropriately treated. The overall annual length of hospital stay can be shortened by 319 days and the number of sepsis-related deaths reduced by three. The overall annual costs in scenarios 1 and 2 amounted to EUR 11.4 and EUR 11.2 million, respectively. The main savings resulted from reduced expenses for hospital stay, drugs, readmissions, and progression to septic shock.

Conclusions. Increasing cost pressure and the rise in multiresistant germs are a burden, which will increase over the next decade. The present analysis showed that a willingness to intervene early and stop detrimental developments, and to invest in effective technologies, can promote affordable health care.

PP89 Cost Effectiveness Of Hepatitis A Vaccination In India

Yogesh Gurav (gurav.yk@gmail.com), Bhavani Shankara Bagepally, Montarat Thavorncharoensap and Usa Chaikledkaew

Introduction. Due to epidemiological transition, a rise in hepatitis A outbreaks among adults in the state of Kerala, India has been noted. This has intensified the need for hepatitis A vaccination (HAV), but evidence regarding the cost effectiveness of HAV, which is essential to guide policy decisions, is lacking. This study was undertaken to evaluate the cost effectiveness of HAV among adults in Kerala state.

Methods. To determine the cost effectiveness of HAV from a societal and a payer perspective, a Markov model was constructed with a cycle length of two months. The lifetime costs and outcomes for HAV and no vaccination were compared using a discount rate of 3 percent. Data for the model input parameters of cost, coverage, and effectiveness were derived from the published literatures. One-way and probabilistic sensitivity analyses were applied. A threshold based on the per capita gross domestic product (GDP) was used (1 GDP = INR 127,702.48 [USD 1,886.03]).

Results. The incremental cost-effectiveness ratios for both societal and payer perspectives were negative, indicating that HAV was dominant, being less costly and more effective than no vaccination. The discount rates and utility values for adults with HAV were the most sensitive parameters.

Conclusions. A HAV strategy would be cost-saving, compared with no vaccination, in the Kerala state of India.

PP93 Efficacy Of Pharmacological Treatments For Type 2 Diabetes In China

Shuyan Gu (gushuyan@zju.edu.cn), Hai Yu, Yuanyuan Li, Yi Shen, Xuemei Zhen, Yuxuan Gu, Jingming Wei, Lizheng Shi and Hengjin Dong

Introduction. There are multiple antidiabetic drugs available in China, which vary in their efficacy and safety. However, no study exists that compares all the classes of antidiabetic drugs simultaneously. This study aimed to estimate and compare the efficacy of alternative classes of antidiabetic drugs for Chinese patients with type 2 diabetes, either in a monotherapy regimen or combined with metformin.

Methods. A systematic literature review was conducted by searching various literature databases to identify relevant randomized controlled trials published from 1990 to 2016. A meta-analysis was conducted to compare the efficacy of antidiabetic drug monotherapy and placebo or lifestyle interventions (i.e., diet and exercise), and antidiabetic drug plus metformin versus metformin alone, in Chinese patients with type 2 diabetes. An indirect comparison was used to estimate the efficacy of antidiabetic drug plus metformin versus placebo or lifestyle-intervention using metformin as the common comparator.

Results. The database search identified 354 relevant studies. Compared with placebo or lifestyle interventions, combination therapies achieved greater reductions in hemoglobin A1c (HbA1c) level (1.9% versus 0.9%), body mass index (BMI) (2.66 versus 0.98 kg/m2), and total cholesterol level (1.07 versus 0.35 mmol/L) than monotherapies. For monotherapies, the top three treatments for reducing HbA1c level were insulin, sulfonylurea, and glucagon-like peptide-1 (GLP-1) receptor agonist. The top three monotherapies for reducing BMI level were metformin,

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