Results. Of 297 unique studies identified, 219 were reviewed by two independent reviewers. Finally, eight articles were identified as being relevant for this study. With regard to validity, GUSS had a sensitivity ranging from 90 to 100 percent and a specificity of between 50 and 88 percent. In addition, GUSS results significantly correlated with the results of the videofluoroscopic swallow study and the fiberoptic endoscopic evaluation of swallowing. In terms of effectiveness, early systematic dysphagia screening with GUSS by nurses reduced the duration of screening and rate of pneumonia, compared with the control group ($p = 0.004$). The incidence of X-ray verified pneumonia in the GUSS group was also significantly lower than in the clinical screening group ($p < 0.01$), although there was no difference in the occurrence of pneumonia, compared with the 10 mL water swallowing test.

Conclusions. Results showed that GUSS is a reliable and sensitive tool for screening patients for dysphagia. This early and systematic assessment can reduce the occurrence of aspiration and pneumonia, although further research is needed to establish the effectiveness of GUSS.

PP81 Real World Data: The Early Access To Medicines Scheme Catches The Worm

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Introduction. The Early Access to Medicines Scheme (EAMS) aims to provide access to medicines prior to market authorization for patients with severe, life-threatening diseases who do not have adequate treatment options. An EAMS designation enables the potential collection of United Kingdom-specific real world evidence (RWE) prior to health technology assessment (HTA) by the National Institute for Health and Care Excellence (NICE). This research evaluates whether RWE is being gathered through the EAMS and utilized to support HTA submissions.

Methods. All EAMS designations as of 7 November 2018 were identified from the Medicines and Healthcare products Regulatory Agency website. For products with final NICE guidance, all publicly-available NICE documentation was reviewed.

Results. Sixteen product and indication pairings with an EAMS designation were identified, with 12 having received final NICE guidance (11 were recommended, 3 were recommended for temporary reimbursement via the Cancer Drugs Fund, and 2 were not recommended). Of the 11 recommended products, seven had references to the number of patients or sites with product access through the EAMS, but only one (dupilumab for atopic dermatitis) had detailed data collected during the EAMS period. The manufacturer of dupilumab reported baseline demographics and disease characteristics from a cohort of 35 patients treated under the EAMS to inform the generalizability of trial populations for clinical practice. Follow-up results from this cohort demonstrated that real-world data on dupilumab effectiveness was comparable with the clinical trial data, despite a higher proportion of patients in the real-world cohort receiving immunosuppressant therapy, which makes improvements in efficacy harder to achieve. The committee also noted that the RWE presented supported the understanding of dupilumab's long-term clinical effectiveness and informed assumptions for the economic model.

Conclusions. To date, the majority of products receiving an EAMS designation have not presented RWE at NICE reappraisal. The case of dupilumab illustrated how RWE collected through the EAMS can be used to reduce uncertainty around how clinical trial data can be translated into clinical practice. In the future, RWE may increasingly be used to help inform NICE decisions.

PP83 A Conceptual Decision-Making Framework For Pharmaceutical Innovations

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Introduction. The trend of growing healthcare expenditures is unsustainable in many countries. The increasing pressure on healthcare budgets due to, for example, population ageing, increasing numbers of patients with chronic diseases (including multimorbidity), and the introduction of new pharmaceutical innovations, leads to political and societal debate. In particular, the introduction of expensive pharmaceutical innovations causes a lot of discussion and uncovers various paradoxes and dilemmas. There is a societal demand for innovation focused on existing medical needs (e.g., oncological, immune-mediated inflammatory, and orphan diseases), but the price of pharmaceutical innovations is a barrier to patient access. As a consequence, systems try to introduce measures or incentivize market forces to improve access for patients, while also containing budget impact. This does not always lead to better access and affordability. The aim of this study was to develop and test a conceptual decision-making framework for pharmaceutical innovations.

Methods. A retrospective study was conducted to identify the successes and challenges of decision-making systems across Europe. A conceptual decision-making framework, including proposed procedures, criteria, and health technology assessment (HTA) requirements (including tools), was developed and tested based on specific case examples (e.g. oncology and hepatitis C).

Results. The conceptual decision-making framework comprised an algorithm for relevant decision-making criteria (e.g. clinical evidence, medical need, cost-effectiveness, and budget impact). The algorithm was developed hierarchically and ranked the criteria in order to optimally inform various types of investment decisions. This novel approach to conducting budget impact analyses resulted in more realistic predictions of the burden of pharmaceutical innovations on healthcare budgets, and can be used as part of horizon-scanning processes to inform healthcare decision making. Results from selected case examples are presented.

Conclusions. The conceptual decision-making framework and proposed method for budget impact predictions will allow for more balanced future healthcare investment decisions.

PP84 Different Interpretation Of Evidence By A Health Technology Assessment Body And A Decision Maker

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https://doi.org/10.1017/S0266462319002265 Published online by Cambridge University Press

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?

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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

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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.

https://doi.org/10.1017/S0266462319002265 Published online by Cambridge University Press