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/S0266462319002241 Published online by Cambridge University Press