additional information in early assessment of innovation. The studied approach to early assessment showed potential in enhancing decision support and reducing risk from a concept stage of innovation.

OP143 Assessment Of mHealth Apps: Is Current Regulation Policy Adequate?

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Introduction. Australians are adjusting to mobile health (mHealth) applications (apps) being used in clinical care. The nature of apps presents unique challenges (e.g. rapid lifecycle) to mHealth regulation. The risks they pose are mainly through the information they provide and how it is used in clinical decision-making. This study explores the international regulation of mHealth apps. It assesses whether the approach used in Australia to regulate apps is consistent with international standards and suitable to address the unique challenges presented by the technology.

Methods. A policy analysis was conducted of all nine member jurisdictions of the International Medical Device Regulator's Forum (IMDRF), to determine if their regulatory agencies addressed the IMDRF recommendations relevant to the clinical evaluation of mHealth apps. Case-studies (submission to regulatory agencies) were also selected on varying types of regulated apps (standalone, active implantable, etc.) and assessed relative to the principles in the IMDRF's software as a medical device (SaMD): Clinical evaluation (2017) guidance document.

Results. All included jurisdictions evaluated the effectiveness of mHealth apps, assessing the majority of the key sub-categories recommended by SaMD: Clinical evaluation. The submissions and jurisdictional regulatory bodies did not address the IMDRF safety principles in terms of the apps' information security (cybersecurity). Furthermore, by failing to use the method recommended by the IMDRF (risk-classification), none of the submissions or jurisdictions recognized the potential dangers of misinformation on patient safety.

Conclusions. None of the approaches used by global regulatory bodies adequately address the unique challenges posed by apps. Australia's approach is consistent with app regulatory procedures used internationally. We recommend that mHealth apps are evaluated for cybersecurity and are also classified using the IMDRF risk-categories so as to fully protect the public.

OP144 mHealth App Evaluation Framework For Reimbursement Decision-making

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Introduction. Mobile health (mHealth) applications (app) are being integrated into healthcare by patients and practitioners in Australia. However, there are currently no policies or frameworks available that can be used to conduct a health technology assessment (HTA) on mHealth apps for reimbursement purposes. The aim of the study was to determine what policy changes and assessment criteria are needed to facilitate the development of a system that evaluates mobile medical apps for regulatory and reimbursement purposes in Australia.

Methods. To obtain the information to determine what policy changes are needed and create an evidence-based framework that can evaluate mHealth apps for reimbursement decision-making, four studies were conducted. This research included (i) a policy analysis on international mHealth app regulation; (ii) a case study on American and Australian app regulation; (iii) a methodological systematic review on the suitability of current mHealth evaluation frameworks for reimbursement purposes; and (iv) the identification of HTA pathways and impediments to app reimbursement through stakeholder interviews. An evaluation framework for apps was created by combining and synthesizing the results.

Results. Software changes, connectivity, and cybersecurity need to be considered when evaluating mHealth apps for reimbursement purposes. Additionally, the potential dangers of apps providing misinformation, and poor software reliability in current regulation must be considered. Stakeholders indicated that they trust how traditional medical devices are currently appraised for reimbursement in Australia. They expressed caution around the lack of clarity regarding who is responsible for app quality as well as concerns about the digital literacy of medical practitioners and their patients.

Conclusions. Since stakeholder trust in the current HTA process for medical devices in Australia is high, the process was adapted to create an evaluation framework for mHealth apps. The adaptations included making provisions for cybersecurity, software updates, and compatibility issues. Provisions to address concerns around practitioner responsibility and misinformation were incorporated into the framework.

OP147 Educational Costs And Benefits Of Mental Health Interventions

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Introduction. The burden of mental health disorders has a wide societal impact affecting primarily individuals and their significant others. Mental health interventions produce costs and benefits in the health care sector but can also lead to costs and benefits in non-healthcare sectors, also known as inter-sectoral costs and benefits (ICBs). The aim of this study was to develop an internationally applicable list of ICBs in the educational sector resulting from mental health interventions and to facilitate the inclusion of ICBs in economic evaluations across the European Union (EU) by prioritizing important ICBs.

Methods. Some ICBs of mental health interventions were identified in earlier research, which were used as a basis for this study. Additional data was collected via a systematic literature search of PubMed and a grey literature search carried out in six EU countries. In order to validate the international applicability of the list

https://doi.org/10.1017/S0266462319001715 Published online by Cambridge University Press

and prioritize the ICBs, a survey was conducted with the international group of experts from the educational sector. The outcomes of the expert survey were used to create the condensed list containing the most important ICBs.

Results. The literature search allowed identifying additional ICBs and creating a comprehensive list of items. In order to improve its usability, a multi-dimensional list was constructed distinguishing between tangible (i.e. special education) and intangible items (i.e. cognitive deficits). Based on the expert survey, the international applicability of the list was validated and the most important ICBs from the economic perspective were determined.

Conclusions. Mental health interventions can affect a large number of educational facilities. The list of ICBs developed in this study could be used to select relevant educational facilities for economic evaluations of specific mental health disorders. Further research is needed to define, measure, and valuate the identified ICBs in order to facilitate the practical application of the list in economic evaluations.

OP151 Cost-Utility Of Gender-Neutral HPV Vaccination In Ireland

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Introduction. A number of economic evaluations of gender-neutral human papillomavirus (HPV) vaccination have been published, generally finding that the cost-effectiveness is sensitive to the uptake rate in girls. In Ireland there is a girls-only program in place, but the initial high uptake rate (>85 percent) was substantially impacted by high profile negative publicity concerning perceived vaccine safety issues. Efforts to address perceived safety concerns have recently yielded a partial recovery in uptake rates. The aim of this study was to estimate the cost-utility of extending the program to include boys and explore the impact of fluctuating uptake rates.

Methods. A previously published cost-utility model used in the United States of America and Norway was adapted to the Irish setting and populated with Irish epidemiological and cost data. Comparators included no vaccination, and girls-only and gender-neutral vaccination, both with either a 4-valent or 9-valent vaccine. Vaccination is at age 12 years and oropharyngeal and penile cancers were excluded in the base case analysis. Additional analyses were used to incorporate fluctuating uptake rates into the model.

Results. A 9-valent girls-only program dominated the existing girls-only 4-valent program. The incremental cost-effectiveness ratio (ICER) for a gender-neutral 9-valent program was EUR 50,823/quality-adjusted life year (QALY). Gender-neutral vaccination would be cost-effective at a willingness-to-pay threshold of EUR 45,000/QALY when the uptake rate is below 78 percent. The ICER decreased to between EUR 41,000 and EUR 42,000/QALY when the uptake rate was allowed to fluctuate across six to 12 yearly cycles.

Conclusions. The cost-effectiveness of gender-neutral HPV vaccination is highly sensitive to the assumed uptake rate in girls. Large fluctuations in HPV vaccine uptake rates have been observed in a number of countries in the last decade. Incorporating fluctuating uptake rates in the model shows that a gender-neutral program may be more cost-effective than when a stable uptake is assumed.

OP152 Pharmacoeconomic Assessment And Drug Expenditure Reduction In Ireland

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Introduction. All new products to be reimbursed from the Irish health budget are subject to a rigorous assessment by the National Centre for Pharmacoeconomics (NCPE). Following assessment, a recommendation is made regarding its cost-effectiveness at the submitted price. This may lead a reduction in the drug price. This study aimed to determine the reduction in expenditure due to the pharmacoeconomic assessment process in Ireland.

Methods. Product details, submitted price and gross budget impact were recorded for each NCPE submission from 2012 to 2015. The latter was chosen as reimbursement data are currently available until 2016. A product was included if its assessment suggested price reduction was required and the product was reimbursed under the High-Tech Drug Scheme (HTDS), a scheme for high cost drugs in a primary care setting. The utilization and actual expenditure of each product was extracted from national reimbursement data for the year after approval. The expected expenditure, calculated using the submitted price, was then compared to the actual expenditure.

Results. A total of 162 products were assessed during the study period. There was a potential price reduction for 65 products based on the assessment outcome. Of these, 15 were reimbursed under the HTDS. A reduction in expenditure was evident for eight of the 15 products (53 percent). The average reduction was eight percent of the expected expenditure. All products showed an actual expenditure greater the predicted budget impact submitted by the applicant.

Conclusions. To the authors' knowledge, this is the first report of expenditure reduction due to a pharmaco-economic assessment process. With the ever-increasing utilization of high cost drugs, the study demonstrates the importance of a process to assess and negotiate cost-effective drug prices. However, the study underestimates reductions, as it is yet to include commercial rebates returned to a central budget. Future research will aim to capture these reductions.

OP157 Carbon Ion Radiotherapy: A Systematic Review

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Introduction. Due to the promising physical dose distribution of carbon ion radiation therapy (CIRT), CIRT can be regarded as a novel tumor irradiation technique and is sometimes considered as a breakthrough therapy for various tumor types. However, it is unclear whether superiority or inferiority can be claimed when

https://doi.org/10.1017/S0266462319001715 Published online by Cambridge University Press