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

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