Introduction. Due to the specific characteristics and challenges of mobile health (mHealth) technologies there is a need to have assessment tools based on their particularities to be used by health technology assessment (HTA) agencies and evaluation experts. In the development of a comprehensive and practical evaluation tool for the evaluation of mHealth solutions we aimed to include the views and opinions of key stakeholders: health professionals, developers, hospital managers, HTA agencies, patients and general public.

Methods. Focus groups and an online modification of the Delphi technique are being used to discuss and agree on domains and criteria to be included in the mHealth assessment tool. Domains and criteria used for health apps evaluation were drawn from a literature review on the topic. The initial list includes 95 criteria grouped into the following domains: purpose of the app, privacy and security, clinical effectiveness, content of the intervention, user experience and usability, interoperability, expenses, impact on the organization, and legal and ethical aspects. Data coming from focus groups is currently being analyzed from a thematic and content analysis perspective.

Results. Focus groups with professionals have showed that the most important domains to be considered when evaluating health apps are those related with security, user experience, and clinical effectiveness. Some criteria were considered to be mandatory (mainly regarding safety issues), on which a first step assessment should indicate whether the app 'pass or fails' for the subsequent throughout assessment. Focus groups with patients will provide insight on critical aspects related to the choice, use and adherence to a health app.

Conclusions. Insights from main stakeholders on the design of the tool for mHealth assessment are relevant and complementary between them. Next steps include (i) the agreement of criteria by using an online modification of the Delphi Technique and (ii) piloting of the tool.

OP140 Adult Patient Access To Electronic Health Records

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Introduction. In order to facilitate patient information, patient involvement, and to support patient-centered care, healthcare organizations are increasingly offering access to patient data that are stored in the institution-specific electronic health record (EHR). Patients can access these data, read, and print them, or download and integrate them into any type of patient-held record. This EHR access is typically web-based and called "patient portal" allowing the independent access via the Internet from everywhere. A patient portal may also offer additional features such as prescription requests, appointment booking, messaging, personal health-related reminders, individual therapeutic recommendations, personal diaries, and social networking with other patients. In a Cochrane review, we assessed the effects of providing access to EHR for adult patients on patient empowerment and health-related outcomes compared to usual care.

Methods. According to the methods of evidence-based medicine, we developed a protocol for a Cochrane review, which is published in the Cochrane database.

Results. We identified ten randomized controlled trials (RCTs) including 6,668 randomized participants. Seven RCTs took place in the USA, two in Canada, and one in Japan. Additional functionalities of interventions and disease conditions were heterogeneous. Three studies (n = 601) reported on patient empowerment. The risk differences reported were neither statistically significant nor clinically relevant. Eight studies (n = 2,070) reported on nine different risk factors (blood pressure, blood glucose, poor asthma control, 10-year Framingham risk score, cholesterol, body mass index, composite score of eight variables, intraocular pressure, composite score of three variables). The results were heterogeneous. Mostly there were no statistically significant risk differences between study groups.

Conclusions. Overall, there is no evidence for a clear positive effect of patient portals on patient empowerment and health related outcomes (mainly risk factors). However, we identified only a small number of studies. The usage of portals was often low and several studies were older.

OP142 Reviewing Methods For Early Assessment

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Introduction. The project DigiHelse aims to support the municipality health in Norway by offering a digital communication platform to users of the home care service nationally. In a concept stage of innovation, an early assessment of the potential socioeconomic value of the project was carried out by means of stakeholder insight and scenario drafting. As the assessment showed favorable potential in providing decision support and reducing risk, the project received funding to move into the pilot phase. The objective of this study is to reassess the effect of stakeholder insight and scenario drafting by validating the results using empirical data from the first pilot of DigiHelse.

Methods. Through collecting empirical data on resource consumption and inquiries to the service from four intervention districts and one control district in Oslo, the socioeconomic value of DigiHelse was reassessed. In addition to survey and register data collected before and after the pilot, behavioral data was introduced as a new data source.

Results. The effect of early assessment by means of stakeholder insight and scenario drafting was successfully studied adding empirical data from the projects first pilot. The real-time data on user behavior registered in the DigiHelse server contributed to verify the assumptions from the first assessment of the project. Although the results from the analysis were less optimistic than the first assessment, the study revealed important improvement measures necessary to improve the innovation process.

Conclusions. The usefulness of early assessment is questioned, due to lack of precision of estimates caused by scarce available data. The present study presents a first step in evaluating the precision of employing stakeholder insight and scenario drafting as

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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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