Conclusions. The outcome of an evaluation framework should be to enable healthcare professionals and patients to select and use safe and effective mHealth apps with greater confidence. A preliminary taxonomy and method of routing apps towards appropriate assessment are presented. Both need larger scale discussion, iterative testing and refining. This research faced significant challenges, including a high volume of heterogeneous apps with poorly standardized app definitions and associated nomenclature.

OP60 Challenges In Evaluating Smart Medical Devices

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Introduction. Smart medical devices can empower elderly to live independently in their familiar surroundings. To enhance their dissemination, they have to be shown to be cost-effective. Economic studies evaluating such technologies are missing or are criticized for their low quality. There are several challenges in the evaluation of smart medical devices, including their complex nature and innovative character. The question arises: how can evaluations elicit the benefits and cost-effectiveness of smart medical devices. This research has the aim of outlining challenges and demands on the evaluation of smart medical devices.

Methods. The embedding of the technology in existing structures can influence the effectiveness of the technology. By comparing such a technology with a regular intervention, learning effects have to be considered. Regular modifications and further developments of these technologies can complicate the traceability of the effects. Complex cause-effect relationships with possible interactions arise that are difficult to quantify and express in standardized endpoints, utilities or monetary values. Demands on the evaluation of smart medical devices have been explored with literature reviews and scenario techniques using the example of intelligent rollators.

Results. It is important to apply mixed-method approaches not only in the clinical but also practical setting and conduct observational as well as qualitative studies. Potential users, their relatives and care personnel should be involved in the evaluation of intelligent rollators and attention should be payed to subjects with disabilities. Prospective studies should be conducted at different stages along the lifecycle of the technology. A conceptual model should be developed and evaluated as well as adapted on a regular basis.

Conclusions. The research shows the need to adapt common methods used in economic evaluation to the characteristics of smart medical devices. As a next step, a framework for the economic evaluation of such technologies within the scope of Health Technology Assessment is developed based on these demands.

OP62 Let's Co-design A Tool To Assess Overweight And Obesity Health Apps

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Introduction. There are more than 320,000 accessible health apps, with the most downloaded of those related to physical exercise and weight control. However the initiatives for their validation address only partial aspects of the evaluation. The EVALAPPS project aims to develop an assessment tool for overweight and obesity management apps, based on the evaluation of efficacy, effectiveness and safety. In the present phase of the project, the team is co-creating the assessment tool considering both the evidence and the expertise of professionals (co-creation process).

Methods. Proposed co-creation methodology includes: 1) a modified Delphi process for selecting the assessment criteria. Criteria were identified through a) an exhaustive review of the criteria used by several mHealth assessment tools and b) a systematic review of efficacy, safety and effectiveness criteria used in mHealth interventions that assess overweight and obesity management. 2) a co-creation session using "Design Thinking" techniques for defining the final content and appearance of the tool (November 2018).

Results. Ten dimensions and 133 criteria were identified, both in relation to the outputs (Usability, Clinical Effectiveness, Security, Development, etc.) and the outcomes (such as weight loss, number of steps). Of those, 114 were included in the modified Delphi, in which 31 professionals participated. A set of 63 criteria were selected as candidates for being part of the tool. Criteria mainly belonged to Security (22%) and Usability dimensions (14%), followed by Quality (11%), and outcomes related to Activity (11%) and Physical status (11%). Once the co-creation session has been performed, the final tool will be developed.

Conclusions. Relevant criteria to evaluate the efficacy and safety of mHealth interventions in the management of overweight and obesity have been identified. Once the tool is developed it will be user tested and piloted on users of overweight and obesity management apps.

OP63 Clinical Videoconferencing - Critical-realist Review As Evidence?

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Introduction. It is not clear yet whether new digital health interventions can and should be assessed by using 'conventional' health technology assessment (HTA) methodology. In response to the question about how much and which type of evidence is needed for decisions on new digital health interventions, this presentation discusses complimentary evidence as generated through a critical-realist review and a qualitative meta-synthesis. This work follows from earlier work by AG Ekeland, AH Hansen and TS Bergmo.

Methods. A realist review addresses complex social interventions investigated in real life settings. The review was conducted with the purpose of generating knowledge on what works, for whom and under which circumstances. The aim was to enable

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decision-makers to reach a deeper understanding of how the intervention can be made to work most effectively. A critical review goes beyond mere description of identified articles and includes analysis and conceptual innovation. An effective critical review synthesizes material from diverse sources, provides an opportunity to 'take stock' and evaluate what is of value related to a previous body of work.

Results. User patterns of clinical videoconferencing turned out to be dependent on contextual factors like clinical condition, motivation, technological skills, professional and organizational arrangements, trust and the perceived value they add compared with "services as usual". The pattern of what works, for whom and under which circumstances was heterogeneous and dynamic. The review types helped identify and conceptualize new user categories, and understand the complex patterns of use.

Conclusions. The in-depth accounts of different clinical use resulting from such a review provide decision makers with a highly practical understanding of complex social interventions which is likely to be of use when planning and implementing programs at a national, regional or local level. A critical-realist review of digital services can complement controlled studies and evidence summaries in HTA.

OP64 Implementation Of Whole Exome Sequencing For Rare Diseases

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Introduction. The Victorian Department of Health and Human Services provided AUD 25 million (i.e. USD 17.3 million) over four years to determine the place of whole exome sequencing (WES) for patients attending public genetics clinics. Comparative analysis of WES and 'usual care' determined that WES increased diagnosis rate (from 14 to 58 percent), changed clinical management in one third of patients and identified relatives and couples at high risk of recurrence in future pregnancies. Translating this into routine care requires co-design with clinical and laboratory stakeholders.

Methods. Victoria's clinical and laboratory genetics service system uses a 'hub and spoke' model. Representatives from these were invited to join a 'Clinical Adoption Group' (CAG) to oversight implementation of new government funding (AUD 2 million (i.e. USD 1.4 million) per year) to ensure statewide access to, and funding of, WES for children with rare undiagnosed genetic conditions. The CAG developed terms of reference, 'traffic light' evidence-based eligibility criteria, a pricing model and reporting mechanism, and recommended funding for sequencing, curation, curator training and multidisciplinary team (MDT) meetings to support implementation.

Results. Funding was distributed across hub and spoke sites reflecting clinical and laboratory demand and workforce requirements. All cases demonstrated clinical utility and were reviewed at MDT meetings. To date, 37 percent of patients have received a diagnosis changing management, with equity of access between metropolitan and regional areas demonstrated. Eligibility criteria are reviewed as new evidence is published to ensure new evidence is incorporated, although curation capacity limits turn-around-times.

Conclusions. Co-designing a statewide and evidence-based clinical model has resulted in sector (i.e. clinician and laboratory) buy-in and supported broad access to funded WES. In addition, the sector has developed a better understanding of how evidence informs policy and funding decisions, which has resulted in delivering equitable WES that provides early diagnosis leading to changed clinical management and cessation of unnecessary interventions.

OP65 Pharmacoeconomic Evaluation Of Orphan Drugs: Impact Of Extra Criteria?

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Introduction. There is ongoing debate as to whether conventional pharmacoeconomic evaluation (PE) methods are appropriate for orphan medicinal products (OMPs). The National Centre for Pharmacoeconomics (NCPE) in Ireland has a well-defined process for conducting pharmacoeconomic evaluations of pharmaceuticals, which is the same for OMPs and non-OMPs. The objective of this study was to identify whether supplementary criteria considered in the pharmacoeconomic evaluation of OMPs would affect final reimbursement recommendations.

Methods. A literature search was conducted to identify criteria. Orphan drug pharmacoeconomic evaluations completed by the NCPE between January 2015 and December 2017 were identified and supplementary criteria, where feasible, were applied.

Results. Fourteen pharmacoeconomic evaluations were included in the study. Three criteria that could feasibly be applied to the NCPE evaluation process were identified, all three of which essentially broadened the economic perspective of the pharmacoeconomic evaluation. Higher cost-effectiveness threshold: Despite being arbitrarily raised from EUR 45,000/QALY to EUR 100,000/QALY, only one orphan drug demonstrated cost-effectiveness at this higher threshold. Weighted QALY gain: here, a weighted gain of between one and three is applied to drugs demonstrating QALY gains between 10 and 30, respectively. No OMPs included in the study showed a QALY gain of more than 10. Thirteen demonstrated QALY gains less than 10 and one could not be evaluated. Societal perspective: six submissions incorporated societal perspective as a scenario analysis. Despite incremental cost-effectiveness ratios (ICERs) being reduced between 4 percent and 58 percent, only two OMPs demonstrated cost-effectiveness at the higher threshold (EUR 100,000/QALY).

Conclusions. Application of supplementary criteria to the pharmacoeconomic evaluation of OMPs had a minor effect on three products assessed. However, for the majority, the final cost-effectiveness outcomes remained the same. The study highlights that other criteria are being considered in the decision to reimburse.

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