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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