Introduction. Following marketing authorization in Spain, new medicines are assessed by the Inter-Ministerial Pricing Commission for Pharmaceuticals (CIPM), which provides reimbursement recommendations with a maximum ex-factory price. However, there are 17 autonomous regions, which can make distinct reimbursement decisions. To drive consistency, the Spanish Agency for Medicines and Health Products has issued national Therapeutic Positioning Reports (TPRs) for new medicines since 2012. Since November 2017, CIPM recommendations have been published monthly, giving the opportunity to analyze the impact of TPRs on the speed and outcome of CIPM decisions, which this research evaluates.

Methods. Publicly-available CIPM and TRP decisions were identified from www.msssi.gob.es and www.aemps.gob.es, respectively. Marketing authorization dates were identified from www.ema.europa.eu or www.aemps.gob.es (10 March 2007-11 February 2018). Pearson's chi-squared and Mann-Whitney U statistical tests were performed using R.

Results. One hundred and ninety-three drug-indication pairings with an associated TPR were identified. The majority (62% [120/193]) were recommended as alternative treatment options with only 19 percent (36/193) deemed to be superior and 19 percent (37/193) not recommended. One hundred and eight CIPM recommendations were identified across seven monthly reports, issued a mean of 12.2 months after market approval, 59 percent (64/108) were positive and 41 percent (44/108) were negative recommendations. There were 34 drug-indication pairings with both CIPM and TPR recommendations available. Of these, 24 percent, 56 percent and 21 percent had TPR outcomes of 'superior', 'alternative' and 'not recommended', respectively and 71 percent and 29 percent had positive and negative CIPM outcomes. Drug-indication pairings with 'negative' TPRs were significantly more likely to have negative CIPMs than those with either 'alternative' or 'superior' TPRs (71% vs. 19%, respectively, $\chi 2 = 5.16$, $p = 0.02$) and were more likely to experience significantly longer delays to CIPM recommendation (23.9 vs. 13.5 months, respectively, $U = 50$, $p = 0.03$).

Conclusions. Drug-indication pairings with 'positive' and 'alterative' TPR outcomes are associated with significantly better and faster CIPM recommendations than those with 'not recommended' TPR outcomes

OP57 Threats And Opportunities To Digital Health In Primary Care

Marie-Pierre Gagnon (Marie-Pierre.Gagnon@fsi.ulaval.ca), Geneviève Rouleau, Hassane Alami and Jean-Paul Fortin

Introduction. The use of digital technologies in healthcare systems (digital health)– such as electronic health records and telehealth – can improve primary care (PC). However, integration of digital health can be constrained/impaired and/or facilitated due to several factors. We propose an integrative framework for classifying the factors that could favour or limit digital health integration in PC in order to guide the identification of strategies that could be helpful for technology promoters, managers, clinicians and researchers.

Methods. Based on a systematic review, our framework includes seven categories to classify the main opportunities and threats to digital health integration in PC: technological; individual/interpersonal; professional; organisational/institutional; ethical/legal; sociopolitical; economical. We consulted a panel of researchers, managers, clinicians, and citizens/patients in a scientific meeting regarding the main opportunities and threats to the integration of digital health in PC. We performed a content analysis of the reported factors according to the framework.

Results. Technological factors such as maturity, interoperability and ease of use were often mentioned as key conditions for digital health integration. Individual and interpersonal factors such as depersonalisation and digital literacy were seen as threats. The impact on workload and shared responsibility were threats at the professional level, whereas silos and change management were noted as organisational threats. Current policies and social trends favored digital health. Threats regarding privacy and confidentiality were mentioned at the legal/ethical level. The possibility to reduce costs and sharing of benefits were noted as opportunities at the economic level.

Conclusions. Knowing these multidimensional conditions, perceived as either threats or opportunities depending on the context of each PC setting, is essential to inform decisions, from strategic planning to evaluation. Our integrative framework allows a simple classification of opportunities and threats that can guide the development and implementation of tailored strategies favouring the integration of digital health in PC.

OP58 Developing An Evaluation Based Taxonomy For mHealth Apps

Kate Goddard (kate.goddard@kcl.ac.uk) and Jamie Erskine

Introduction. Mobile Health (mHealth) apps offer potential to promote greater public engagement in health, improve efficiency and open up new care pathways and models of care. However, the volume and heterogeneity of apps has led to uncertainty and lack of standardization around app definitions. Some mobile apps carry minimal risks to consumers, but others can carry significant risks. Work has been carried out to develop a framework for assessment (for example, for the NHS app library [beta version]). We discuss work helping to inform a preliminary framework of categorizing mHealth apps for proportionate assessment and validation, and the challenges involved.

Methods. A literature review was carried out to identify different types of categorizations used to define health apps and the most important dimensions for their assessment. A taxonomy of apps and a process for routing them towards appropriate methods of evaluation was developed through iterative review, discussion and refinement.

Results. Fourteen types of mHealth apps were established which were categorized by app function and by the potential risk involved with use. Subsequently, this research suggested a method of routing apps towards the most appropriate and proportionate method of evaluation, by using four example dimensions of impact (population size, disease burden, priority of clinical condition, and innovation), and four levels of risk.

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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

Mareike Mähs (mareike.maehs@uni-vechta.de)

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

Elisa Puigdomenech Puig (epuigdomenech@gencat.cat), Noemí Robles, Corpus Gomez, Francesc Saigí-Rubió, Alberto Zamora, Montse Moharra, Guillem Paluzié, Mariona Balfegó, Guillem Cuatrecasas and Carme Carrion i Ribas

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?

Anne Ekeland (anne.granstrom.ekeland@ehealthresearch.no)

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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