

PP24 Methodological Frameworks And Assessment Domains For Digital Health Technology Assessment: Scoping Review And Thematic Analysis

Joan Segur-Ferrer (joan.segu@gencat.cat),
Carolina Moltó-Puigmartí, Roland Pastells-Peiró and
Rosa Maria Vivanco-Hidalgo

Introduction: Experts highlight the need to reconsider the frameworks used in health technology assessment (HTA) in order to cover the particularities of digital health technologies (DHT). However, there is a large heterogeneity in the literature about terminologies and definitions. Our objective was to identify the methodological frameworks used worldwide for HTA of DHT and generate a proposal of domains to consider in the assessment through a thematic analysis, a qualitative data analysis method that consists of identifying, analysing and reporting patterns across the data.

Methods: Methodological frameworks were identified through a scoping review (ScR) in accordance with the PRISMA extension for ScR. We searched five different databases for peer-reviewed and grey literature published between 2011 and 2021. The retrieved references were screened using Rayyan by two authors in a single-blind manner. References included were analyzed thematically by three reviewers using ATLAS.ti.

Results: The systematic search retrieved 3,061 references (2,238 unique), of which 26 were included. These, in turn, synthesized 102 frameworks designed for the assessment of DHT. The included documents contained a wide variety of items to consider in HTA of DHT and often used different wording to refer to similar concepts. Through the thematic analysis, we reduced this heterogeneity. Specifically, in the first analysis phase we established 176 provisional codes related to different assessment domains. In the second one, these codes were grouped in 86 descriptive themes that, in turn, were clustered in the third phase in 61 analytical themes. The latter were organized through a vertical hierarchy of three levels: level 1 (13 domains), level 2 (38 dimensions), and level 3 (11 sub-dimensions).

Conclusions: There is a need to reconsider the frameworks and assessment domains used for HTA of DHT. Our thematic analysis of 26 references led to the definition of 13 domains, 38 dimensions and 11 sub-dimensions to consider in HTA of DHT. From our perspective, thematic analysis is the most appropriate method to identify assessment items for HTA of DHT from literature.

PP26 Critical Review Of The Reimbursement Process For Software As A Medical Device And Challenges In South Korea

Soontack Kwon (soontack@hira.or.kr),
Seung Jin Han and Kyung-Hoon Kim

Introduction: The global artificial intelligence (AI) healthcare market is predicted to grow rapidly. Various technologies for AI-based Software as Medical Device (SaMD) have been developed, and demand for their health insurance reimbursement coverage is increasing. Reimbursement policies for new medical technologies need to be thoroughly examined, despite their role in stimulating the market. The reason is that health insurance finance can have significant impact on the entire country, including patients, providers, and industry.

Methods: Based on guidelines for applying Korea's innovative medical technologies, especially AI-based imaging medical technology, to health insurance, we examined outcome factors such as procedures and benefits. After the guidelines' publication in 2019, we examined their impact on the medical device market through changes in the number of clinical trials and identified cases in which health insurance was listed.

Results: The process of registering SaMD's health insurance occurs in accordance with the existing medical technology evaluation system, and it can take up to 460 days from application to approval. If new technologies, including SaMDs demonstrate significant improvement in diagnostic capabilities and cost-effectiveness compared to existing practices, separate health insurance claims are available. Since the scheme's announcement in 2019, items approved for SaMD clinical trials have increased (2018: n=4; 2020: n=44; 2021: n=37). However, as of November 2022, only one was listed for health insurance benefits (VUNO Med-DeepBrain®), and one case was not listed on benefits but was recognized for its innovation and entered the market on the premise of suspending the health technology assessment process and accumulating real-world data (VUNO Med-DeepCARS®).™ DeepBrain® is a deep learning-based image reading technology costing about KRW80,000 (USD60) higher than conventional brain-magnetic resonance imaging and readings.

Conclusions: The number of SaMDs attempting clinical trials is increasing, but there is a low number of cases of reimbursement because most technologies are often classified as existing technologies and do not receive additional compensation. Since SaMD continuously is developed by accumulating data and feedback, a flexible system that can reflect this is required.