PP21 Are We Ready For It? Developing Criteria To Include Artificial Intelligence Medical Devices (AI-MDs) For Health Technology Assessment

Rachel See-Toh (rachel_see-toh@moh.gov.sg), Lydia Ooi, Zhen Long Ng, Swee Sung Soon, Hong Ju and Kwong Ng

Introduction: The increasing pace at which artificial intelligence medical devices (AI-MDs) or digital health technologies (DHTs) have been introduced and integrated in healthcare has not been matched with appropriate selection criteria for health technology assessment (HTA) to inform funding decision-making. To align with international best practice and local regulatory guidance, the Agency for Care Effectiveness (ACE) developed criteria to include AI-MDs as part of its 2022 topic prioritization process for medical technologies. This abstract describes ACE's approach to develop the inclusion criteria.

Methods: To develop key principles for including AI-MDs in ACE's topic prioritization process, relevant information from overseas HTA agencies, local regulatory guidelines, and ACE's existing topic selection criteria were reviewed. A search of international HTA agency websites was conducted in September 2022 to identify relevant information on inclusion of AI-MDs in healthcare for reimbursement recommendations.

Additionally, local regulatory guidelines for AI-MDs in healthcare were also identified. The inclusion criteria were then piloted with AI-MDs identified from ACE's horizon scanning workstream to examine their feasibility for HTA topic selection.

Results: One overseas framework on DHTs from the National Institute for Health and Care Excellence (NICE) and two local regulatory guidelines were identified. Based on the key finding that the purpose of AI-MD use in guiding clinical management and its associated risks were important considerations, the following criteria were developed: (i) full registration with the regulatory body; (ii) device characteristics should be interventional, have direct impact on patient safety, or support accurate diagnosis or treatment which is critical to avoid death and serious health deterioration; and (iii) the AI algorithm should be fixed as opposed to adaptable as per regulatory requirements. Using this inclusion criteria, eight AI-MDs surfaced from horizon scanning were screened with the above criteria and deemed suitable for HTA topic selection.

Conclusions: As AI technologies are increasingly used to replace or supplement current clinical practice, continuous adaptation of HTA method is needed to ensure appropriate topic selection.

PP23 A Health Technology Assessment Of Computerized Clinical Decision Support Systems: Challenges And Lessons Learnt

Carolina Moltó-Puigmartí (cmolto@gencat.cat), Edurne Gallastegui-Calvache, Davide Cirillo and Rosa Maria Vivanco-Hidalgo

Introduction: Computerized Clinical Decision Support Systems (cCDSS) are promising digital health tools whose development and use are increasing. The Agency for Health Quality and Assessment of Catalonia (AQuAS) received a request from the Spanish Ministry of Health, through the Spanish Network of Health Technology Assessment (HTA) Agencies (RedETS), to perform an HTA of cCDSS for cancer. We present the challenges that arose during the evaluation process.

Methods: We evaluated the safety, effectiveness and cost-effectiveness through a systematic literature review. We involved two clinicians and a technology expert to gain insight into the pathology and technology, respectively. To identify cCDSS used in Spain, we consulted with the Spanish regulatory agency (AEMPS) and the Spanish Federation of Healthcare Technology Companies (FENIN), plus did a survey among Spanish hospitals. To understand applicable regulations, we reviewed the European regulation (MDR) and consulted the Medical Device Coordination Group from the European Commission, AEMPS, and a regional regulatory expert.

Results: The scientific literature revealed large heterogeneity in the definition of cCDSS (e.g., from simple online prognostic calculators to complex commercial software using machine learning), making the literature search and screening arduous. Many articles dealt with cCDSS that do not qualify as medical devices, are not in the market anymore, are currently used as newer versions or are developed in-house. Next, we faced the difficulty to attain a comprehensive overview of the tools in use in the country. In terms of legislation, we observed that similar tools might receive different classifications in different jurisdictions, and the complexity of the MDR might lead to the need for a case-by-case discussion at a National level.

Conclusions: We identified many challenges in the HTA of cCDSS. The first step for proper assessment is a clear definition of the device and version to be evaluated. Multiple stakeholders must be involved, and alignment between regulatory and HTA agencies is key. We expect that the European Database on Medical Devices (EUDAMED) will help in the identification of existing cCDSS and hence ease their assessment.

https://doi.org/10.1017/S0266462323001794 Published online by Cambridge University Press