

OP114 Health Technology Assessment Of Digital Technologies: Results From Two Past Examples And Thoughts For The Future

Jamie Erskine (jamie.erskine@alirahealth.com)

Introduction: Digital health care is a rapidly growing and increasingly diverse area of medicine and social care. Health technology assessment (HTA) agencies around the world are engaging with digital health technologies and developing methods for appropriately assessing their value. Given our experience in HTA for pharmaceuticals and how methodologies must differ when assessing medical devices and diagnostics, we must be proactive in rapidly developing useful methods for assessing a variety of digital health technologies.

Methods: We will first present the results of two completed HTAs from the UK and contrast their methods and results, while looking at the UK approach to assessing digital health care in general. Next, we will present preliminary results from an ongoing consensus conference study of HTA's for integrated digital technologies. This study will use a modified Delphi methodology to develop statements for discussion at a consensus conference. The primary research question is "how digital technologies can help build resilient healthcare systems and how HTAs can assess their value".

Results: An HTA conducted in the UK of an artificial intelligence-enabled ambulatory electrocardiogram device resulted in a recommendation for further real-world evidence generation. Another HTA of a digital therapeutic app for insomnia, which was also conducted in the UK, resulted in a positive recommendation but the process was lengthy and needed to be flexible. The preliminary results of an upcoming consensus conference study will also be presented. The consensus panel will consist of a range of stakeholders from digital experts, HTA practitioners, clinicians, health economists, industry representatives, and policy makers.

Conclusions: Digital technology is now a broad field with a wide range of very different technologies included in its definition. Questions remain as to whether digital technologies should be assessed using a traditional pharma-based framework for HTA, a MedTech model, or something else entirely. Given our past experience of developing flexible methods for HTA, we have an opportunity to develop useful recommendations and best practices from the ground up.

OP115 Scoping Meta-Review On Methods Used To Assess Artificial Intelligence-Based Medical Devices For Heart Failure

Rossella Di Bidino (rossella.dibidino@policlinicogemelli.it), Davide Piaggio, Ernesto Iadanza, Leandro Pecchia, Martina Andellini, Raza Zeeshan, Beatriz Merino-Barbancho, Laura López Pérez, Giuseppe Fico, Melody Ni, Simone Borsci and Tianhui Zhu

Introduction: The International Federation of Medical and Biological Engineering created a multidisciplinary working group to discuss assessments of artificial intelligence and machine learning (AI/ML) applications in health care. Engineers, clinicians, and economists identified evidence generation as a critical topic. Heart failure (HF) was selected to investigate the available evidence on the clinical effectiveness and safety of AI/ML applications. Attention was paid to transparency of AI/ML methods and their data sources.

Methods: A scoping review was conducted on AI/ML algorithms developed for the management of HF. A search for systematic reviews, scoping reviews, and meta-analyses published from 1976 to October 2022 was conducted in Embase, MEDLINE, and Scopus.

Results: Of 456 relevant publications, 21 papers were included in the final analysis. Most papers (10 systematic reviews, five meta-analyses, and six non-systematic or scoping reviews) included studies conducted in North America. No study was conducted in Africa. The healthcare setting was not clearly stated in approximately half of the studies. A lack of agreement was noticed regarding the quality assessment tools used among the reviews. The most common data source for AI/ML algorithms was electronic health records, but in some cases data sources were not reported. While deep learning emerged as the most common adopted methodology, covariates were not always included in the algorithm development. The review demonstrated that comparative assessment of algorithms requires further investigation, given the high variability in the comparator used (e.g., clinical gold standard, other AI/ML algorithms, or other statistical methods). The main investigated endpoints were the incidence of HF and the number of hospital admissions.

Conclusions: When assessing innovative health technologies such as AI/ML applications in health care, evidence is among the main challenges. Our scoping review, focusing on algorithms developed to manage HF, showed that the biggest challenges relate to the quality of the studies, the adoption of a comparative approach, and transparency of methods.