

AI-based tools applied in HTA processes, regarding human supervision and “open-sourceness” aspects.

Methods: A search strategy using the terms “AI,” “HTA,” and correlated terms was performed in nine specialized databases (health and informatics) in February 2022. Inclusion criteria were publications testing AI models applied in HTA. Selection of studies was performed by two independent researchers. No filter was applied. Variables of interest included a subset of AI models (e.g., machine learning [ML], neural network), learning methods (e.g., supervised, unsupervised, or semi-supervised learning), and code availability (e.g., open source, closed source). Data were analyzed exploratorily as frequency statistics.

Results: ML with one layer of hidden nodes was applied in 48 (78.6 %) studies, while deep learning (DL) (two-plus layers) were applied in eight (13.1 %). ML models that used supervised learning accounted only for half of the reported models, while half used unsupervised learning. Considering supervision methods in DL models, seven used unsupervised learning, and one used supervision. Four studies did not report the AI model, and 14 studies did not report the supervision paradigm. It was not possible to assess “open-sourceness” in 31 studies. Among the identified software, seven models were not open source, and 13 were open source.

Conclusions: Transparency and accountability are of utmost importance to HTA. Complexity of AI models may introduce trustworthiness issues in HTA. Transparency provided by open-source code becomes essential in building trust in the automation of HTA processes, as does quality of report. Although progress has been observed in transparency and quality, the lack of a methodological framework still poses challenges in the field.

OP68 Adaptation Of Processes For HTA Of Digital Health Technologies Based On Artificial Intelligence

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Introduction: The advent of artificial intelligence (AI) in digital health technologies (DHT) requires a comprehensive health technology assessment (HTA) to ensure safety and effectiveness and to demonstrate the value of these technologies in healthcare systems. Recognizing the unique requirements posed by AI-based DHT, our agency has undertaken several initiatives to tailor and adapt our processes for effective HTA.

Methods: We started by identifying the processes that were not working optimally and planned a list of actions needed to improve them. These actions were: (i) to develop a new evaluation framework for the assessment of DHT, including those based on AI; (ii) to increase our activity on early HTA; (iii) to seek collaboration with an organization for technical assessment of AI, with a particular emphasis on trustworthy AI requirements; (iv) to adapt our HTA report templates; (v) to create new forms to request information from

the technology developers; and (vi) to set up a working group on HTA of AI-based DHT.

Results: We have now an evaluation framework that informs on the relevant aspects for HTA of AI-based DHT and the evidence that developers need to generate in order to prove the value of their technology. We designed a circuit to identify promising technologies and increased our early HTA work for timely advice. The evaluation team now involves an additional partner for the technical assessment domain. In addition, we have new templates for early HTA reports, which explain those AI-specific elements to be addressed, as well as industry information request forms that enable collecting specific information like algorithm type and population used for clinical validation.

Conclusions: Tailoring HTA processes to AI-based DHT is crucial in today's fast-paced health technology landscape. Our new evaluation framework, the involvement of new partners in the assessment team, the creation of new templates, and enhanced early HTA work helps to evaluate these technologies optimally. We are also setting up a working group to ensure homogeneous evaluation within Spain.

OP69 Are Artificial-Intelligence-Based Literature Reviews Accepted By Health Technology Assessment Bodies?

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Introduction: Literature reviews (LR) play a crucial role in all health technology assessment (HTA) dossiers, presenting evidence-based value of interventions. There is global exploration of artificial intelligence (AI) to expedite and enhance the efficiency of literature reviews. Our research aimed to identify any existing guidance from HTA bodies regarding the use of AI for conducting literature reviews.

Methods: We conducted a comprehensive search and review of any published guidance from prominent HTA bodies, including the National Institute for Health and Care Excellence (NICE, England), Scottish Medicines Consortium (SMC, Scotland), National Centre for Pharmacoeconomics (NCPE, Ireland), National Authority for Health (HAS, France), Federal Joint Committee (G-BA, Germany), Institute for Quality and Efficiency in Health Care (IQWiG, Germany), Canadian Agency for Drugs and Technologies in Health (CADTH, Canada), and Pharmaceutical Benefits Advisory Committee (PBAC, Australia). This was done to gain insights into their views regarding the utilization of AI in literature reviews. Additionally, we engaged with HTA representatives, such as NICE, to gain a deeper understanding of their perspectives.

Results: We found a lack of clear guidance on the use of AI for conducting LRs. NICE has recommended a priority screening technique using machine learning (ML) for identification of a higher proportion of relevant papers at an earlier stage. NICE is currently in the process of developing guidance and is updating its manual in this area. SMC refers readers to NICE methodologies. In its HRB-CICER report, NCPE only acknowledges the potential of ML algorithms for