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

Carolina Moltó-Puigmartí (cmolto@gencat.cat), Joan Segur-Ferrer, Didier Domínguez Herrera, Susanna Aussó Trias and Rosa Maria Vivanco-Hidalgo

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 proof 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?

Gautamjeet Singh-Mangat, Sugandh Sharma and Rito Bergemann (rito.bergemann@parexel.com)

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

https://doi.org/10.1017/S0266462324001284

LRs, with no additional information. IQWiG, in its general methods, recommends the use of ML-validated classifiers for identifying randomized controlled trials (RCTs) within bibliographic searches.
Conclusions: Our research indicates that there is scarce guidance available for the use of AI in LRs for HTA submissions. However, considering the rapidly evolving nature of this field, it is anticipated that guidance documents and manuals will be updated in the near future.

OP70 Implementation Of An Online Consultation Hub To Facilitate Consumer Engagement In Health Technology Assessment Processes

Rebecca Trowman,
Jo Watson (HTAconsumerengagement@health.gov.au)
and Bella Beach-Mills

Introduction: In 2021, the Australian Government Department of Health and Aged Care's Consumer Evidence and Engagement Unit (CEEU) launched an online consultation hub to provide a centralized pathway for consumer engagement in health technology assessment (HTA) processes. The hub enables consumers (patients, carers, health professionals, and citizens) to provide commentary on items being considered by HTA committees for subsidization.
Methods: A survey was developed by the CEEU, committee members, and consumer representatives to facilitate consultation on applications assessed by the Pharmaceutical Benefits Advisory Committee (PBAC)—a principal Australian HTA committee. Questions were designed as simple and engaging, including guidance on the type of information required. Responses are summarized thematically by efficacy, safety, accessibility, and quality-of-life impacts of the proposed health technology. New surveys are launched to coincide with each PBAC meeting agenda publication and allow a ten-week consultation period. Awareness of consultations is supported by the CEEU's HTA Engage e-newsletter, which alerts the public and targeted stakeholders.
Results: The hub surveys have enabled streamlined consumer commentary to be provided for PBAC considerations. It has also allowed increased time for quality consultation with stakeholders. The success of the hub is further demonstrated in the current development of a similar survey for another principal committee, the Medical Services Advisory Committee (MSAC), to transition its consultation processes to the hub. Of note, while consumers' feedback on the hub is positive, there remains a desire for educational resources and face-to-face interactions to support consumer engagement in HTA processes. The CEEU are developing materials to address and further support this need.
Conclusions: In a time when technological communication can be optimized to complement face-to-face conversations, it is vital consumer engagement in HTA processes follows suit. To facilitate continued engagement that is sustainable for both present and future Australians, the CEEU continues to evolve a strategy regarding virtual consultations to increase consumer awareness and education and promote effective participation in Australian HTA.

OP71 Patient Disease Strategy: A New Operational Framework For Collecting And Applying Patient Experience Data Into Clinical Development Programs

Catherine Coulouvrat, Victoria DiBiaso,
Stephanie Bascle, Laurence Lucats,
Nathalie Largeron (nathalie.largeron@sanofi.com),
Sophie Van Tomme and Benoit Arnould

Introduction: Understanding patient experience and needs is crucial to develop high-value therapies. Patient experience data (PED) inform trial design and evidence generation plans. The U.S. Food and Drug Administration's roadmap to patient-focused outcome measurement advocates integrating PED into product development. We adapted this theoretical framework to include the health technology assessment (HTA) perspective and operationalized it as a patient disease strategy (PDS) framework.
Methods: The PDS framework is a methodology that systematically integrates patient-informed activities to reflect the patient health value of a new treatment. A PDS is developed per indication, initiated in the preclinical phase, applied in clinical development, and continuously adapted throughout the product development lifecycle. The three PDS phases include: (i) development of patient profile, including epidemiology, demographics, patient journey, disease, and treatment burden for patients and caregivers; (ii) PED gap analysis, focusing on identification of patient priorities, unmet needs, preferences, and expectations for new therapies; and (iii) translation into actions, such as diversity and inclusion (D&I) plans and outcomes strategy.
Results: Out of 58 indications, 31 percent have endorsed PDS and 67 percent are in progress. Patient-relevant label opportunities increased by over 50 percent. Each indication was informed on average by patients from three different countries. The PDS framework helped to identify factors that impacted health outcomes for integration into trial designs and D&I plans. Early understanding of heterogeneous patient populations, unmet needs, benefit/risk trade-offs, and patient experiences ensured development programs measured the most meaningful outcomes while also addressing evidence gaps. Early understanding of patient priorities and barriers to participation optimized the studies by reducing burden and identifying proactive support needed to complete the trial.
Conclusions: The PDS framework systematically identified health value opportunities for a target population and integrated the patient needs into the overall development plan. PED informs clinical trial design and endpoint strategy optimization, including factors that

https://doi.org/10.1017/S0266462324001284