OP26 Artificial Intelligence For Literature Screening And Selection: Does The Evidence Support Its Use In Systematic Literature Reviews?

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Introduction: The past decade has seen an exponential increase in peer-reviewed clinical research literature. Consequently, preparing and updating systematic literature reviews (SLRs) is more resource intensive and costly. Artificial intelligence (AI) could potentially accelerate SLR preparation. This study presents a review of evidence evaluating the accuracy of AI methods in SLR preparation and results of a case study using DistillerSR's AI functionality.
Methods: The review was based on a search of MEDLINE, Embase, and Embase Preprints databases using title/abstract keywords and subject heading synonyms for AI, machine learning, natural language processing (NLP), and publication screening and selection. The protocol is published on PROSPERO (CRD42023452391). To supplement this review, we conducted a case study with DistillerSR's AI tools. We applied the AI classifiers, which use NLP to learn patterns from multiple SLRs across several indications, which encompassed over 15,000 references' titles and abstracts. We then compared those patterns with the human responses to build an AI model that can be applied to other references.
Results: The search identified 2,209 records. After deduplication, the titles/abstracts of 2,200 records were screened; of these, 79 full-text records were assessed. A total of 42 records met the eligibility criteria for inclusion. The majority were case studies. The most frequently reported tools were DistillerSR AI (n=9), Abstrackr (n=6), ASReview (n=2), and LiveSTART (n=2). The evidence showed efficiency gains, but accuracy varied across studies and AI tools. Results of the case study using DistillerSR's AI tools indicated efficiency gains with adequate accuracy but with variability across different SLRs. Inclusion and exclusion of articles were consistent with the human decisions.
Conclusions: The findings of our review and case study indicated that AI can be used reliably in the screening of articles for SLRs and could improve efficiency. However, the evidence is still evolving, and additional studies are needed. There is a need for clear guidelines on the role of AI in study screening and selection for health technology assessments SLRs and submissions.

OP27 Artificial Intelligence Use In Health Technology Assessment In Low- And Middle-Income Countries

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Introduction: Health technology assessment (HTA), by investigating clinical, economic, and social consequences of technologies in a country, enhances health system equity and sustainability. In low- and middle-income countries (LMICs), economic constraints and inadequate access to specialized human resources present challenges. Therefore, strategies to optimize resource allocation in the health sector are necessary.
Methods: A literature review was carried out, with studies that directly identified barriers or facilitators for the use of artificial intelligence (AI) in HTA being considered eligible. The texts were analyzed from the perspective of LMIC. The searches were carried out on 8 August 2023 using the following databases: MEDLINE via PubMed, Web of Science, and Google Scholar. The selection was performed in two stages: (i) screening by title and abstract and (ii) evaluation of the eligibility criteria in full text.
Results: After conducting the search, five studies were selected for narrative synthesis. Evidence of the potential benefits of using AI in HTA in low- and middle-income countries includes rationalization of resources; reduction of the burden on health systems and minimization of human workload; efficiency in data analysis, including clinical data; prediction of economic impact; and support for managerial decision-making. However, important challenges were also raised, such as the deficiency of local infrastructure; the training and education of professionals; the lack of ethical regulation; and the organizational and political considerations of these countries.
Conclusions: There are few studies in the literature that provide scientific support on the use of AI in HTA decision-making in LMIC. The evidence points to increasing the efficiency and rationality of resources, enhancing the results arising from HTA. With this, it is expected to expand access to health technologies and enable more sustainable health systems.

OP28 Digi-HTA: The Assessment Method For Digital Health Technologies In Finland

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Introduction: The ever-increasing number of new and innovative digital health technologies (DHTs) also sets new demands on health

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technology assessment (HTA) methods in addition to traditional HTA domains. In 2018, the Finnish Ministry of Social Affairs and Health recognized the need for new HTA methods for DHTs in Finland and commissioned method development.
Methods: The development work of the new HTA method for DHTs and the findings related to it were based on three substudies:
(i) The new HTA method was developed through a literature review, expert interviews, and four multiprofessional workshops.
(ii) Feedback about new HTA recommendations was collected from healthcare decision-makers through a web-based survey (n=24). Feedback on the developed HTA framework was collected through a web-based survey for companies offering DHT products (n=8).
(iii) Initial experiences about the state of data security and protection of assessed products were gathered through the assessment process.
Results: A new Digi-HTA method that supports a wide range of DHTs, such as health apps, AgeTech, artificial intelligence, and robotic solutions, was published in 2019. According to the healthcare decision-makers participating in the study, although the Digi-HTA recommendations included clear and beneficial information, their integration into healthcare decision-making processes should be improved. Responses from companies offering different DHTs indicated that the Digi-HTA framework would be an appropriate tool for performing assessments for their products. During the assessments, deficiencies in compliance with the best practices of data security and protection as well as data security problems were found.
Conclusions: The rapid development of DHTs requires that the HTA methods also adapt to the development so that no new and innovative products are excluded from the assessments. In addition to the value of DHTs, their quality, such as data security and protection, should be assessed so that decision-makers can be supported in the best possible ways.

OP29 Determinants Of The Financial Impact Of Rare Disease Drugs In Italy: Differences Between Expected And Observed Pharmaceutical Expenditure

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Introduction: In Italy, a fixed proportion of health spending is allocated to pharmaceutical expenditure. While the main objective of setting a budget for pharmaceuticals is to control spending, the effectiveness of this ceiling is questionable. This study aims to investigate the determinants of pharmaceutical expenditure for orphan drugs and gather information for effective planning and programming of pharmaceutical spending.
Methods: Data analysis relied on pharmaceutical companies' pricing and reimbursement (P&R) dossiers submitted to the Italian Medicines Agency (AIFA) for drug-reimbursement approval, along with AIFA's internal procedural documents. The study encompassed all rare disease drugs reimbursed from January 2013 to January 2019. For each drug, a comparison was made between the expected post-negotiation expenditure and the actual spending observed over the three years following reimbursement approval. Potential determinants of the normalized ratio between observed and expected spending were identified using univariate and multivariate beta regression models. The same methodology was replicated to identify potential determinants of the difference between expected spending before and after negotiation.
Results: Fifty-two rare disease drugs admitted for reimbursement during the study period were analyzed. The median expenditure in the first three commercialization years was 7.6 percent lower than the expected post-negotiation spending. Beta regression analysis indicated a significantly lower reduction for innovative drugs (β 0.736, p-value 0.011 univariate, β 0.585, p-value 0.045 multivariate). Similar effects were observed for P&R procedures (β 0.902, p-value 0.007) and the number of indications presented (β 0.754, p-value 0.021), but only in univariate model. Beta regression analysis for the expected expenditure ratio before/after negotiation revealed a significant effect only for the payment-by-result variable (β 1.485, p-value 0.001).
Conclusions: Observed expenditure for orphan drugs aligns with the expected spending post-negotiation. However, in the subgroup of innovative orphan drugs, the observed pharmaceutical spending was higher than estimated. This could be attributed to prescriber preferences and to a prevalent patient pool awaiting innovative treatment. It appears that the recognition of innovativeness favors orphan drugs that are rewarded with faster market access.

OP31 Monitoring Of The Budget Impact Determinants Of Incorporated Technologies For Rare Diseases In The Brazilian Health System

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Introduction: Budget impact analyses for the treatment of rare diseases are especially important for the sustainability of health systems due to high treatment costs and uncertainties in target population estimates. The objective of this work is to analyze the elements that influence discrepancies between predicted and observed budget impacts for enzyme replacement therapies for rare diseases in Brazil's public health system.

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