What Policies and Guidelines should Health Technology Appraisals (HTA) bodies in the UK and Ireland implement to govern the use of Artificial Intelligence (AI) in HTA

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01. Introduction

This research aims to understand the current use of artificial intelligence (AI) in health technology appraisals (HTA), and available policies governing AI use in the UK and Ireland. The primary research includes exploring the current perspectives of HTA bodies, specifically the National Institute for Health and Care Excellence (NICE) in the UK and the National Centre for Pharmacoeconomics (NCPE) in Ireland, on the use of AI in HTA processes.

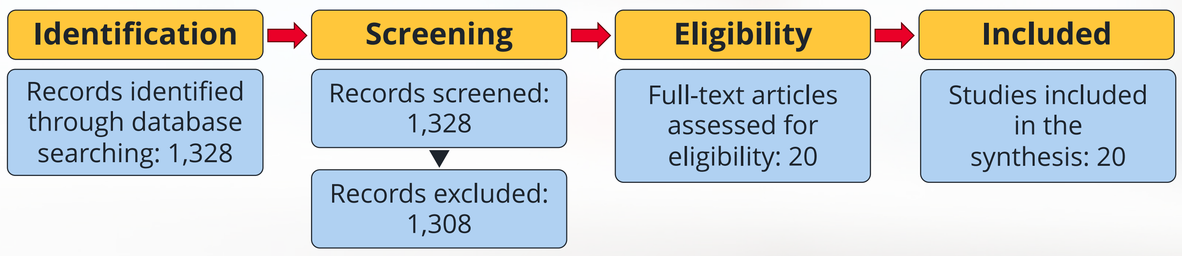
AI has the potential to enhance the efficiency and accuracy of HTA processes, but its implementation raises critical challenges, including ethical concerns, data governance, and the need for updated regulatory frameworks. The primary goal of this research is to identify the status of AI adoption in HTA and determine the necessity for updated policies and guidelines that address these emerging challenges.

To achieve this, qualitative semi-structured interviews were conducted with stakeholders across Ireland and the UK. The findings will provide insights into the opportunities and risks associated with AI in HTA and discuss main points derived along with outlining key recommendations for the development of future policies governing its use.

The aims of this research are:

- Understand the current use of AI in HTA submissions
- Explore the current policies in place surrounding the use of AI in HTA processes
- Gain key insights into the attitudes and experiences of key stakeholders
- Form recommendations for future policy makers to build on to create an equitable efficient use of AI in HTA

02. Literature Review



Finding 1: 'The need for Policy'

- A strong need for continuous collaboration with regulatory groups at national and international levels – this is crucial to adapt to AI's rapid evolution (WHO, 2023)
- Concerns about the ethical implications of AI tools, including disparities in healthcare access, and the need for clinician training on AI processes (Russell et al., 2023).

Finding 2: 'Barriers in the usage of AI'

- Lack of AI awareness, regulatory gaps, and biases in data. Traditional HTA might not be set up to robustly utilise/integrate AI methods (Zemplenyi et al., 2023).
- Need for new legal frameworks, emphasising human rights, accountability, and liability, to ensure ethical AI use (Cath, 2018)

Finding 3: 'Governance of AI'

- Clear and transparent processes are critical. Traceability and accountability should be emphasised (WHO, 2023).
- Implementing a risk-based approach, including external validation and adherence to privacy and data protection laws, is essential for AI governance.
- AI in healthcare should meet pre-specified criteria in areas such as transparency ethics, safety and effectiveness.
- Need for codes of practice on AI and copyright, working to address barriers related to data mining and licensing for healthcare bodies (GOV.UK, 2022).

Search Strategy

Key Words:
Health technology assessment, Health technology appraisal, HTA, Artificial intelligence, AI, Machine learning, ML, Policies, Guidelines, Ireland, United Kingdom, NICE.

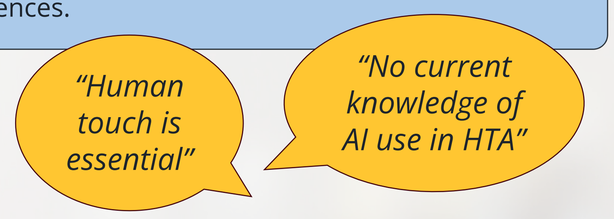
Data sources:
English language articles were identified in PubMed using phrases related to Health technology assessment, Health technology appraisal, Artificial intelligence, Machine learning, Policies, Guidelines, Ireland, United Kingdom, NICE.

Study selection:
Original research, articles, and grey literature were considered.

Data extraction:
Data from relevant literature were identified, reviewed, and integrated into a concise narrative review.

03. Stakeholder Interviews

Qualitative research methods were employed to gain in-depth insights into the current use of AI in HTA. Semi-structured interviews were conducted with key stakeholders to explore their personal perspectives, experiences, and expectations regarding AI integration in HTA processes. Participants were selected from the UK and Ireland to understand if there were any key differences in perspectives. Efforts were made to ensure complete transparency during interviews, detailed notes were taken during the interviews by a second party to capture key points and observations. These interviews allowed for the open-ended exploration of participants views and experiences.



Findings

- No current knowledge of AI use in HTA – companies are not required to disclose whether they have used AI in their submissions.
- Strong emphasis on the need for internal policies to be created to outline specific criteria for the use of AI in HTA.
- Potential ground rules to be put in place to avoid the inflation of the data by AI systems.
- Gradual approach should be obtained when using AI – along with transparency to ensure ethical uptake of AI.
- HTA bodies should set a criterion of recommendations to ensure that AI systems are providing accurate and reliable information.
- The need for HTA professionals and healthcare bodies to partake in mandatory education sessions to keep up with progressing AI.
- Can see the potential advantages of using AI in submissions but highlight that human touch is essential and must be incorporated throughout the process.

04. Discussion & Recommendations

Potential

The potential for AI in HTA is expansive and promising.

As AI technologies continue to evolve, their applications in HTA are likely to broaden significantly. Future AI tools could offer more advanced capabilities, such as clinical decision making.

Stakeholders in Ireland and the UK foresee AI being able to streamline tasks to ensure an efficient approach to daily duties. This advancement leaves space and time for more nuanced tasks which require active thinking, thereby accelerating the overall deliverable completion.

These AI tools can assist researchers in creating a more efficient timeline to the HTA process, which in turn will accelerate the route of drug reimbursement, leading to patients getting access to drugs quicker.

Risks

However, the integration of AI tools into the HTA process presents several challenges.

Stakeholders have voiced a need to be cautious with the implementation of AI, stressing the need for rigorous policy to be implemented before use. This presents itself as a key challenge as ethical consideration must be at the forefront of these policies. These concerns require collaboration to ensure that values of integrity and transparency are achieved through these standards. Regulatory barriers are seen as one of the most pressing challenges associated with the uptake of these tools.

The benefits associated with AI-assisted health policy making initiative can help encourage policy makers to start creating regulations and policies necessary to welcome the integration of AI tools in an effective and ethical way.

Recommendations

Data Governance and Privacy

- Implement robust data protection measures and clear guidelines for AI use to safeguard patient confidentiality while facilitating effective HTA.

Ethical Frameworks and Bias Mitigation

- Develop policies that enforce regular bias audits, ensure diverse and representative data is used to train AI models, and mandate the involvement of ethical review boards to assess the impact of healthcare equality, patient groups, and access to care.

Training and Capacity Building

- Provide ongoing education for HTA professionals to enhance their understanding of AI technologies and their responsible use in healthcare.

Continuous Monitoring and Evaluation

- Establish frameworks to ensure AI systems are regularly assessed and updated to keep pace with evolving technologies, addressing new challenges as they arise.

05. Conclusion

The integration of AI into Health Technology Assessment (HTA) offers transformative potential for improving efficiency in drug reimbursement and healthcare decision-making. This review highlights AI's capacity to automate routine tasks and enhance data analysis while highlighting significant challenges such as ethical considerations, data governance, and the need for standardisation.

Although stakeholders are optimistic about AI's future in HTA, they emphasise the importance of a cautious and collaborative approach. A critical gap exists in current regulations, necessitating input from academic institutions, government bodies, and healthcare professionals.

Prioritising ethics and addressing these regulatory gaps will be key to ensuring that AI enhances HTA processes without compromising patient rights or introducing biases.

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