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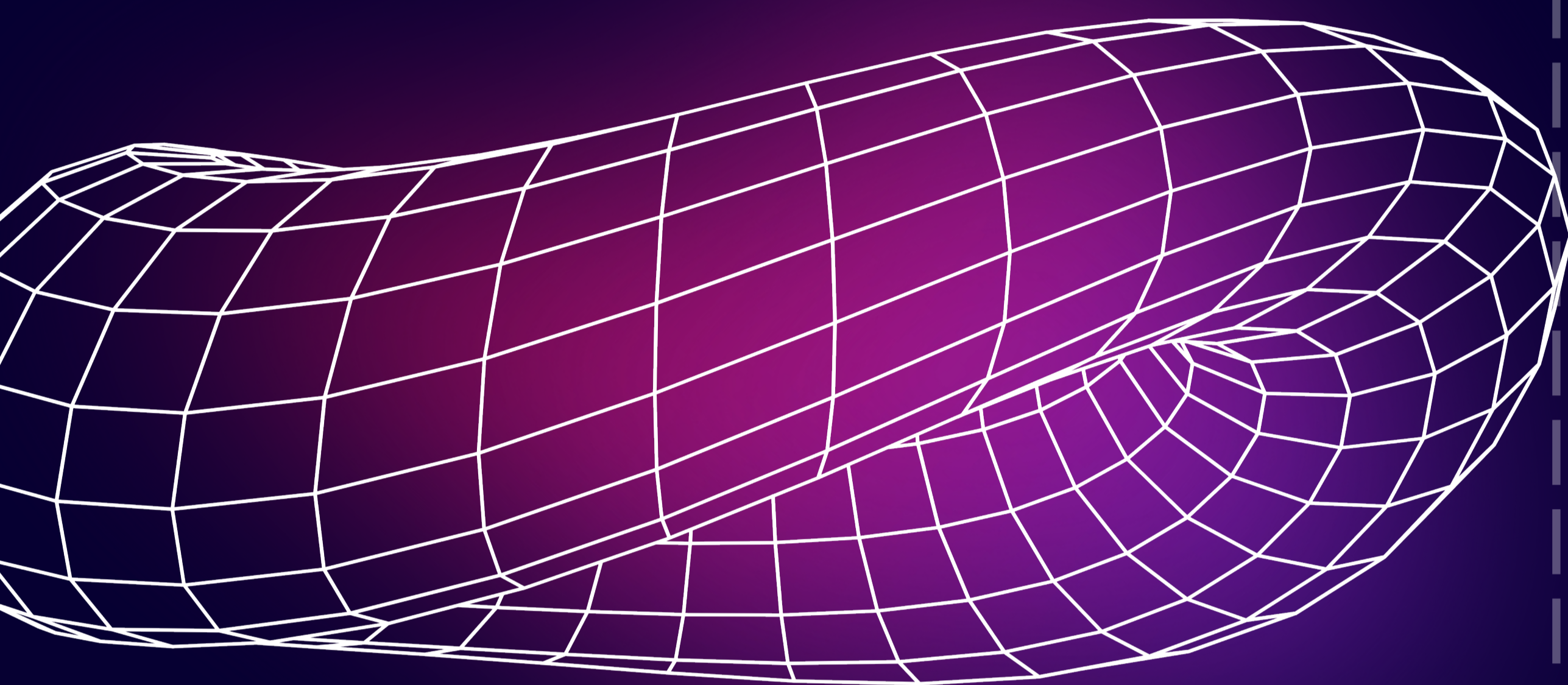
Background

Medical AI introduces various novel issues that should be incorporated into a health technology assessment.



Highlights

1. Analysis of the gaps in HTA for medical AI.
2. Identification of **key issues** in a full HTA of medical AI.
3. Illustration of various key AI-assessment issues through three **exemplary cases**.



Results

Key issue for HTA of medical AI	Elaboration
Performance & Evidence	
Training data	To what extent is the AI application trained on high quality and representative data that are adequately annotated?
Clinical validation	To what extent is the AI application validated in a clinical setting?
Clinical effectiveness	What is the clinical effectiveness of the AI application?
Cost-effectiveness	What is the cost-effectiveness of the AI application compared to the standard of care?
Budget impact	What is the impact on budget of adopting the AI?
Generalizability	To what extent does the AI application's performance generalize across institutions / countries etc.?
Continuous learning	To what extent is the continuous learning component of the AI application monitored?
Human & Organizational	
Workforce	To what extent are workforce alterations and re-education necessary to facilitate the AI application's implementation?
Clinical workflow	To what extent are changes in clinical workflow necessary to facilitate the AI application's implementation?
User bias	To what extent does the human-AI collaboration pose risks concerning automation bias, aversion bias, or alert fatigue?
Interoperability	To what extent is the AI application interoperable with other systems and data in place?
Equipment	To what extent are investments in equipment required?
Local governance	To what extent do institutions have a clear AI governance system in place?
Legal & Ethical	
Regulation	To what extent does the AI application comply with legislation and regulation?
Intellectual property	To what extent is it clear who holds ownership over the data, algorithm, and platform?
Fairness	To what extent might the AI application treat different subgroups unfairly?
Patient privacy	To what extent is patient privacy sufficiently addressed?
Informed consent	To what extent is patient consent with the use of AI ensured?
Accountability	To what extent is it clear who is held accountable in case of failure?
Cybersecurity	To what extent is cybersecurity ensured?
Environmental impact	To what extent is the environmental impact of the AI application clear?
Transparency & Usability	
Explainability	To what extent are the AI application's decisions explainable and should they be?
Access & availability	To what extent are data available and accessible to clinicians and researchers?
Communication	To what extent is it clearly explained what the AI application can (and cannot) do?
Usability	To what extent is it clearly explained how the AI application should be used?



Methods

1

Targeted review of policy documents

31 reports

2

Systematic review of academic literature on HTA & AI

9 articles

3

Systematic review of academic literature on cost-effectiveness of AI

69 articles

4

Case studies to validate the list of issues extracted from 1 to 3

3 case studies



Case study 1: Stroke

AI is leveraged in stroke care by using algorithms to analyse computed tomography (CT) images and find potential occlusions in patients with ischemic strokes. Radiologic reports are generated and immediately shared with stakeholders to facilitate fast triage.



Case study 2: Intensive care

AI is utilized to analyse (clinical) patient data to optimize discharge timing of patients on the intensive care unit (ICU), which helps to reduce negative patient consequences and optimizes efficient ICU bed utilisation.



Case study 3: Clinical data abstraction

AI and natural language processing are used to analyse structured and unstructured data housed in electronic health records (EHRs), unlocking a wealth of information from which insights can be drawn.



Case study 1 Stroke

The **clinical workflow** is strongly altered due to the AI, as it alters the collaboration between the various departments (emergency, neurology and radiology).

This has implications for the **workforce** that requires optimisation and training needed for this novel workflow.



Case study 2 Intensive care

Due to the usage of multiple data sources (including demographic data), **explainability** is crucial in identifying any biases in the AI discharge decision.

This helps to ensure **fairness** of the AI in allocating ICU beds, free of bias.



Case study 3 Clinical data abstraction

Interoperability of AI tools is vital due to the different electronic health record (EHR) formats that are analysed with the AI.

This has implications for **generalizability** of the AI results, depending on EHR format, language of the content, medical discipline, etc.



Key Take-Aways

1. An HTA of medical AI calls for an adapted evaluation framework, as various AI-specific issues are not adequately captured in current frameworks.
2. Different types of medical AI may require a tailored approach to evaluation.

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