

Developing an AI Governance Framework for Safe and Responsible AI in Healthcare Organisations: A Protocol for a Multimethod Study

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Abstract

Background: Artificial intelligence (AI) has significant potential for improving healthcare delivery through enhanced diagnostics, streamlined operations, and predictive analytics. However, healthcare organisations face substantial challenges in implementing AI safely and responsibly. This is due to regulatory complexity, ethical considerations, and a lack of practical governance frameworks. While many theoretical frameworks exist, few have been tested or adapted for real-world application in healthcare settings.

Objective: This study aims to develop and validate a practical AI governance framework to support the safe and responsible use of AI in healthcare organisations. The specific objectives are to: (1) identify governance requirements for AI in healthcare; (2) examine existing AI governance processes and best practices; (3) co-develop an AI governance framework to meet the needs of healthcare organisations; and (4) test and refine the framework through real-world application.

Methods: A multimethod research design will be used, comprising four key stages (1) a scoping review and document analysis to identify governance needs and current processes; (2) in-depth interviews with healthcare stakeholders as well as national and international AI governance experts; (3) development of a draft AI governance framework through synthesis of findings; and (4) validation and refinement of the framework through stakeholder workshops and application to case studies of AI tools. Data will be analysed using qualitative methods informed by grounded theory.

Results: The project received funding in October 2023. Ethics approval was obtained from the Alfred Health Human Research Ethics Committee (HREC) (Project ID: 171/24) and the Macquarie University HREC (Project ID: 16508). Data collection commenced in April 2024, with the scoping review and document analysis being finalised. As of March 2025, 43 interviews have been completed. The final AI governance framework is expected to be completed and ready for dissemination by June 2025.

Conclusions: This study will deliver a comprehensive AI governance framework co-designed with healthcare stakeholders to address real-world challenges in AI oversight. The framework will offer practical guidance to support healthcare organisations in adopting AI technologies safely, ethically, and in alignment with regulatory requirements. Outcomes from this study will inform local and international discussions on AI governance and promote the responsible integration of AI in health systems.

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Original Manuscript

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Keywords: Artificial Intelligence, governance, healthcare, oversight, patient safety, ethics, framework.

Introduction

Artificial Intelligence (AI) technologies have the potential to transform health care by improving standards of care and addressing global challenges such as rising costs, staff shortages, and increasing patient complexity. [1-4] AI applications span both clinical and non-clinical tasks, including predicting patient care needs, assisting with diagnosis, and optimising administrative processes. [5] Despite these benefits and technological advancements, adoption within healthcare organisations remains slow. [6] Compared to some other industries, health care is subject to significant regulation to ensure patient safety [7] and ethical considerations such as data privacy, transparency, and equity, which may limit adoption. [8]

Governance at the organisational level is critical to ensure AI is implemented safely and responsibly. However, there is little practical guidance for governing AI development, implementation, and use in healthcare. [9,10] While numerous theoretical frameworks exist, these often focus on broad ethical principles such as fairness, transparency, and accountability but lack actionable strategies for healthcare organisations to adopt. This gap leaves organisations without clear mechanisms to assess AI risks, ensure compliance with regulatory standards, or integrate AI into clinical and operational workflows safely. [8] Most existing frameworks have not been designed for real-world application within complex healthcare environments. Few have been systematically tested or implemented, meaning there is limited evidence on their effectiveness in practice. Additionally, little is known about how key stakeholders such as healthcare professionals, patients, administrators, and AI developers perceive AI governance challenges or what governance mechanisms would best support responsible AI adoption. [11] Without a structured and adaptable governance framework, AI technologies may be deployed without sufficient oversight, leading to potential safety, ethical, and legal concerns.

The evolution of AI further necessitates a governance approach that can accommodate emerging technologies such as generative AI, AI-enabled clinical decision support systems, and automated administrative processes. [12] With the likelihood that AI capabilities continue to progress, it is foreseeable that so do the potential risks, which will require governance approaches that are dynamic, iterative, and responsive to these technological and regulatory changes. [13]

Health care must also consider organisational factors not addressed in broad conceptual frameworks, such as financial constraints, organisational culture, and commercialisation. [14] Ongoing technological advancements and growing public awareness further necessitate governance strategies that adapt to emerging challenges. For example, the proliferation of generative AI, including AI

scribes, has led to the development of new guidelines to address associated risks. [15-17] This study seeks to bridge these gaps by developing an AI governance framework tailored to the needs of healthcare delivery organisations, ensuring that AI innovations can be integrated safely and responsibly while maximising their benefits for patient care and system efficiency. [18]

Aim

This study aims to develop and test an AI governance framework to enhance organisational oversight of AI applications in healthcare delivery.

Objectives

To achieve the aim of the study, there are four specific objectives:

1. Identify governance requirements for AI applications in healthcare delivery organisations.
2. Examine existing AI governance processes and current best practice for AI governance.
3. Co-develop an AI governance framework to meet the needs of healthcare organisations.
4. Test and refine the AI governance framework by applying it to exemplar AI tools.

Output

Comprehensive AI governance framework for a healthcare delivery organisation.

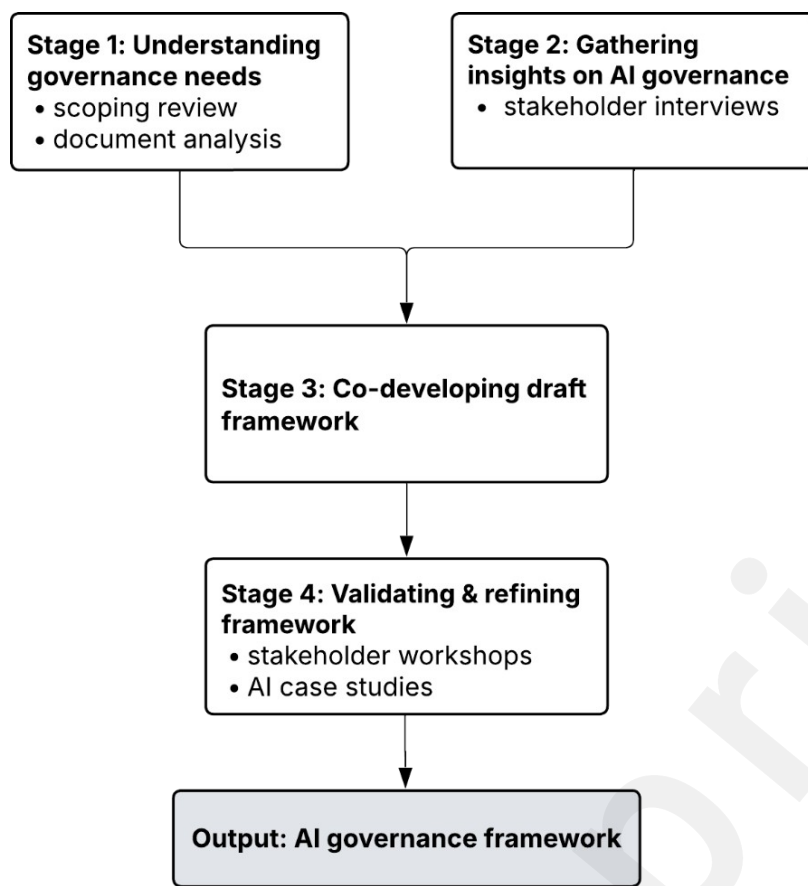
Methods

Study setting

This study will be conducted within a major Australian public healthcare organisation that delivers care to a catchment of over 770,000 residents in Melbourne's inner-south. The organisation operates across three hospital campuses, including a major tertiary and quaternary referral hospital that provides specialised care for critically ill patients. The other campuses focus on community-based healthcare, offering services in rehabilitation, geriatric medicine, general medicine, and aged mental health. Additionally, the organisation delivers statewide and national healthcare services to patients across Victoria and Australia. As a large and diverse healthcare provider, this setting offers a robust environment for developing and testing an AI governance framework for real-world application in healthcare. While the organisation already has established AI-driven initiatives and governance structures supporting patient safety and digital health, there is currently no standardised AI governance framework tailored to its varied operational needs.

Study design

This study will adopt an exploratory multimethod approach [19] to develop and test an AI governance framework for the safe and responsible use of AI in healthcare delivery organisations. The structure of the study will comprise four stages that are directly linked to the study objectives: (1) understanding governance needs through a scoping review and document analysis, (2) gathering stakeholder insights on AI governance via in-depth interviews, (3) co-developing the AI governance framework through synthesis of findings, and (4) validating and refining the framework through stakeholder workshops and AI case studies (Figure 1).

Figure 1. Study process diagram

Given the evolving nature of AI governance within healthcare organisations, we have developed a comprehensive research strategy that draws on existing methodologies for investigating emerging technologies, [20,21] evaluating complex systems, [22] and ensuring stakeholder engagement in governance development. [23] This qualitative study will be designed in accordance with the consolidated criteria for reporting qualitative research (COREQ). [24] The final output of the study is to produce a practical and actionable AI governance framework that addresses key challenges in AI oversight at the organisational level. The research will run concurrently to enable insights from one stage to inform other stages iteratively. In detail, the four research stages will comprise:

Stage 1: Understanding governance needs

Scoping review

Published literature about approaches to AI governance at an organisational level will be reviewed. Given the extent published in this domain, only frameworks that are specific to healthcare will be reviewed [25]. The search strategy will be designed to address study site requirements including

governance approaches for AI tools with a clear intended purpose (e.g. AI-enabled medical devices). The following electronic databases will be searched: (1) MEDLINE, (2) Embase, and (3) Scopus. These databases were selected based on consultation with a Macquarie University research librarian. A search will also be conducted on Google Scholar and Google search, where the first 200 results will be included for review. This is based on guidance around the use of Google for grey literature searching [26]. Reference lists of key papers will be hand searched for additional peer-reviewed and grey literature. Appropriate search strings will be developed by linking concept clusters relating to each component of the question (artificial intelligence, governance and implementation, and a healthcare setting) with Boolean operators “AND” and “OR”. Search results will be imported into Covidence where a two-stage review process (title and abstract screening, followed by full-text review) will be conducted by two independent reviewers. Data will be extracted into Excel.

Document analysis

To ensure the AI governance framework aligns with the current state of governance processes at the study sites, a document analysis will be conducted to map current processes. This will involve a systematic review of relevant internal policies, governance documents, and procedural guidelines. This is to help establish a baseline of governance structures to ensure that the AI framework does not replicate existing or previously established governance processes and to identify strengths and gaps in current governance approaches.

Stage 2: Gathering stakeholder insights on AI governance

In depth semi-structured interviews will be conducted with two key groups, healthcare staff and national and international experts in AI governance, policy, healthcare, AI and patient safety. A purposive sampling technique will be used to identify key informants from both groups. A snowballing technique will also be used, allowing participants to refer other relevant informants for involvement in the study. Semi-structured interview guides will be developed based on a review of the existing literature and input from the multidisciplinary project team. Members of the project team have recognised experience in healthcare, qualitative research and AI safety and governance. 25-30 interviews (total 50-60) from both groups are expected to provide thematic saturation (where no new themes are identified). Key informants who agree to participate will be interviewed via online videoconferencing or in person, with audio recording. Audio files will be de-identified and professionally transcribed by a secure transcription service. Two investigators will independently analyse and code the interviews using open coding techniques based on grounded theory. A grounded theory approach will be applied as it provides a methodology and procedure for collecting and

analysing data and conceptualising the results [27].

Healthcare stakeholder interviews

We will recruit a diverse range of healthcare stakeholders to gain their perceptions on how to effectively govern the safe and responsible use of AI. The interviews will initially include informants from the board and executive, clinicians undertaking AI projects, clinical trial managers, and representatives from ethics and research governance offices, clinical governance, risk, research, clinical operations, medical services, hospital liaison, legal, and consumer representatives. During the interviews, participants will be asked about current approaches to governance and processes to manage the safe and responsible application of AI in healthcare and barriers to adoption.

National and international expert interviews

We will examine current practices for governing AI in healthcare. Experts will include participants from academia (ethics, governance, digital health, technology, AI), government, healthcare administration, clinical settings, and professional healthcare associations. Participants will be asked about current approaches to AI governance in healthcare and will be invited to share any documentation about governing AI as well as tools or templates used to support AI governance processes.

Stage 3: Co-developing a draft AI governance framework

Findings from the scoping review, document analysis, and stakeholder interviews will be synthesised to develop a draft AI governance framework tailored to the needs of healthcare organisations. This process will incorporate regulatory requirements, best practices, and stakeholder insights to ensure the framework is practical and adaptable for real-world implementation. A structured approach will be used to define key governance components, including oversight mechanisms, compliance processes, accountability structures, and ethical considerations. The framework will also outline pathways for integrating AI governance within existing clinical and operational workflows. The draft AI governance framework developed in this stage will be tested and validated in Stage 4 through stakeholder workshops and AI case studies.

Stage 4: Validating and refining the draft AI governance framework

Stakeholder workshops

Stakeholder workshops will be conducted to refine and validate the AI governance framework with key stakeholders from the healthcare organisation. Key stakeholders will be identified in consultation

with the study site. Workshops will follow a structured facilitation approach, incorporating guided discussions and scenario-based evaluations to assess the framework's feasibility and applicability. Real-world cases about the implementation of AI tools will be used to explore governance challenges and ensure alignment with organisational priorities. Feedback from these workshops will be thematically analysed and incorporated iteratively to enhance the framework's practicality and adaptability.

Testing the draft framework on case studies

The draft governance framework will be applied to exemplar AI tools from the study site to determine whether it provides adequate oversight. In consultation with the study site we will identify 3-5 tools that are representative of the different pathways by which healthcare organisations acquire and utilise AI tools, such as: (1) developing AI tools in-house; (2) co-developing AI tools in partnership with technology companies, universities, etc.; and (3) procuring AI tools from commercial or external vendors (including AI tools subject to medical device regulations). We will also assess the extent to which the AI framework will continue to be fit for purpose for current and next generation AI technologies. Findings from these case studies and Stages 1-3 will help identify gaps to refine the AI governance framework.

Results

This study received funding in October 2023 from the Digital Health Cooperative Research Centre, Alfred Health, and Macquarie University. Ethics approval was granted by the Macquarie University Human Research Ethics Committee (HREC) (Project ID: 16508) in December 2023 and Alfred Health HREC (Project ID: 171/24) in February 2024. Data collection commenced in April 2024 and is progressing as planned.

As of March 2025, the scoping review and document analysis (Stage 1) are underway, with preliminary findings identifying key themes in existing AI governance frameworks and internal governance structures at the study site. Interviews with healthcare stakeholders and AI governance experts (Stage 2) are complete (n=43), with thematic analysis commenced. Case study selection for framework testing has been finalised in consultation with the study site. The final AI governance framework is anticipated to be finalised and disseminated by June 2025.

Discussion

Study significance and strengths

This study will generate critical insights into AI governance by developing and validating a framework for the safe and responsible integration of AI in healthcare. By addressing the gap in practical governance guidance at the healthcare organisational level, this study will provide actionable strategies for managing AI tools in both research and operations. The study's multimethod approach will ensure a comprehensive understanding of AI governance by integrating findings from a scoping review, stakeholder engagement, and case studies. This methodology will support the development of a governance framework that is both theoretically grounded and practically applicable.

A key strength of this study is the inclusion of diverse stakeholder perspectives ensuring that governance recommendations are aligned with real-world requirements. By systematically developing an AI governance framework, this study will provide evidence-based recommendations for improving oversight of AI tools in healthcare delivery. Findings will contribute to international discussions on AI governance and support the development of governance that balances adaptability with patient safety and ethical considerations.

Limitations

Despite the strengths of this study, its limitations should be acknowledged. The study is currently limited to one Australian healthcare organisation, which may limit the generalisability of the AI governance framework to other settings with different regulatory environments, organisational structures, or levels of technical maturity. While stakeholder interviews will include international participants, the findings may still reflect context-specific challenges rather than universal governance solutions.

Additionally, the study focuses on governance at the healthcare organisational level, which may not account for broader policy, legislative, or technological changes that might impact AI adoption in healthcare. The rapid progress of AI technologies such as generative AI presents challenges in ensuring the framework remains adaptable and relevant over time. While the iterative design of this study allows for ongoing updates, future research will be needed to assess the long-term sustainability and adaptability of the framework as AI capabilities are likely to continue to evolve.

Future directions

This study will provide an AI governance framework specifically designed for healthcare

organisations, however, further research will be needed to ensure its long-term applicability and scalability. Future studies should focus on implementing and evaluating the framework's effectiveness across a broader range of healthcare organisations, including regional and rural health services, to assess its adaptability in diverse settings. Expanding the research to include international case studies will also provide comparative insights into how different regulatory and healthcare systems approach AI governance. Further research will be critical to track the sustained impact of AI governance frameworks on patient safety, operational efficiency, and clinician trust over time. This includes researching how governance processes develop alongside emerging AI technologies and regulatory changes.

Conclusions

This study will develop and validate an AI governance framework to support the safe and responsible use of AI in healthcare. By integrating a multimethod approach, the study will provide practical guidance on AI oversight at the organisational level, addressing gaps in existing governance structures. Findings will contribute to international discussions on AI governance, ensuring that AI technologies are adopted in a way that prioritises patient safety, ethical considerations, and regulatory compliance. The iterative nature of this research will enable the framework to adapt to evolving AI capabilities and organisational needs, providing a foundation for robust governance strategies in healthcare.

Funding statement

The study was supported by Digital Health CRC Limited ("DHCRC"). DHCRC is funded under the Australian Commonwealth's Cooperative Research Centres (CRC) program, an Australian Government initiative for collaboration between university researchers and industry.

Data availability

The datasets generated during this study will not be made not publicly available for privacy reasons but requests to the corresponding author will be considered on a case-by-case basis.

Authors' contributions

FM and EC conceptualised the study. FM, SF and AW designed and are conducting the study, SF, AW and FM drafted the manuscript with input from all

authors. All authors provided revisions for intellectual content. All authors have approved the final manuscript.

Conflicts of interest

SS and EP are employees of Alfred Health and participated on the project steering committee, but were not involved in data collection, analysis, or interpretation. Their involvement in recruitment was limited to forwarding the study invitation to potential participants. SS participated in the Board and CEO interviews. SF, AW, FM and EC have no professional or personal affiliation with Alfred Health.

Abbreviations

AI: artificial intelligence

HREC: Human Research Ethics Committee

Ethics

The study received Alfred Health HREC approval (Project ID: 171/24) and Macquarie University HREC approval (Project ID: 16508). Informed consent was gained from all respondents participating in the study.

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