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Artificial Intelligence Implementation in Healthcare: Protocol for a Scoping Review using Qualitative Comparative Analysis

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ADMINISTRATIVE INFORMATION

Support - None.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 March 2026 and was last updated on 01 April 2026.

INTRODUCTION

Review question / Objective The primary aim of this scoping review is to quantify qualitatively reported implementation process activities in the literature to determine necessary and sufficient conditions for these activities to successfully achieve the desired implementation outcomes.

The primary research question for this scoping review therefore is: What implementation process activity conditions and condition combinations are reported in the literature pertaining to AI implementation in healthcare?
Specifically, data will be extracted and analysed to answer:
1. What reported conditions are necessary across different AI healthcare contexts for the implementation process outcomes of pre- or pilot implementation, implementation, or implementation with sustainment?
2. What combinations of reported conditions (equifinality or multifinality pathways) are sufficient to lead to these implementation process outcomes?
3. What condition combinations are reported by conceptual studies (Implementation framework/roadmap/model development) in the literature?
4. Are there evident gaps in reported conditions and combinations of conditions between empirical studies implementing AI and recommended activities in conceptual studies developing AI focused implementation roadmaps/frameworks/process models?

Background Artificial Intelligence and Healthcare
Artificial Intelligence (AI) is rapidly transforming the healthcare landscape. It has moved from an emerging technology with the potential to revolutionise healthcare and patient outcomes (Bajwa et al., 2021) to being highly present in healthcare research (Senthil et al., 2024). AI's real-time data predictions and insights are being utilised to enhance diagnostic accuracy, improve

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healthcare service delivery, and support patients' disease self-management as well as healthcare professionals' knowledge (Hirani et al., 2024; Periáñez et al., 2024). Recent years have witnessed rapid and significant growth in AI investment and AI healthcare research (Senthil et al., 2024; Silicon Valley Bank, 2024); however, in practice, the translation and integration of AI into routine clinical healthcare settings remain limited (Sharma et al., 2022b). It has been argued that understanding AI implementation in healthcare is still in its early stages, and current frameworks do not fully address the complexity and unique requirements of AI implementation (Gama et al., 2022). The challenges in translating AI research into healthcare settings stem from the intricacy of both healthcare and AI systems–that is, the adaptive technical nature of AI, and the diverse interactive contextual and geographic factors involving patients, healthcare professionals, organisations, and technology (Plsek & Greenhalgh, 2001).

Artificial Intelligence and Sociotechnical Systems

Effective translation and integration of AI require considering how the technology fits within broader social systems. A sociotechnical systems perspective shifts the focus of AI from just the technology to the wider system it is part of, including its components (Kudina & van de Poel, 2024). Viewing AI from this perspective involves looking at the technologies (both AI and others in the system), end-user characteristics—such as patients, caregivers, and healthcare professionals–and the organisation and broader environment, with interactions between these elements over time, forming system workflows (Salwei & Carayon, 2022; Sittig & Singh, 2010). Each component is considered not in isolation but in relation to the connections between factors as part of an interactive and evolving system.

Guidance on AI implementation processes in healthcare is still evolving, and the literature remains scattered across disciplines. Emerging research has developed AI-specific frameworks to assist with integrating AI-driven interventions into healthcare settings. Many of these frameworks have concentrated solely on regulatory aspects and governance, with limited exploration of how to effectively integrate and evaluate implementation within healthcare systems (Reddy et al., 2021; Sharma et al., 2022a). Recently, frameworks for assessing and monitoring AI models in healthcare have been introduced (Jacob et al., 2025; Wells et al., 2025). However, there is a scarcity of practical guidance on how to embed AI into healthcare practice. Most regulatory and institutional guidelines adopt a narrow approach focused on evaluation of AI models for translation. Importantly, while studies have identified barriers and facilitators influencing AI implementation in healthcare, it remains unclear what evidence supports successful implementation through documented causal mechanisms and pathways that ultimately lead to the final outcome of integration in healthcare.

Understanding the implementation process for AI from a sociotechnical systems perspective is crucial for several reasons. Firstly, gaining knowledge can lead to better planning and more efficient future AI implementation efforts in healthcare. There is also potential for an AI-specific implementation process to promote more sustainable and effective outcomes for AI integration. Secondly, robust implementation processes are vital in reaching key implementation milestones (Alley et al., 2023). Lastly, analysing activity patterns and relationships between activities may offer insights into critical tasks, helping identify activities that could form a standardised process adaptable across different AI implementation contexts in healthcare.

Implementation Processes

Implementation process activities (referred to here as implementation activities or activities) are the actions undertaken by those facilitating the integration of an intervention into a system that make up the implementation process. This can be understood through Implementation Process Models, which are intended to inform the translation of research into practice through the mapping of specific practical activities, thereby offering practical guidance on how to implement (Nilsen & Moore, 2024). Typically, process models are represented in a graphical format, which outlines implementation process activities across temporal phases (or stages, steps) - from pre-implementation through to implementation, and post-implementation or sustainment. The phases/stages/steps are commonly depicted as sequential and may be linear or cyclical. Process models are utilised in the planning of implementation, and to retrospectively analyse the success of an implementation.

Implementation process activities may crossover with implementation strategies in implementation strategy taxonomies, however process models themselves are distinct from such taxonomies. Implementation strategy taxonomies align with the definition of frameworks rather than process models (Nilsen, 2024). There is much debate about distinguishing terms in the cross-disciplinary field

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of implementation science, which can be attributed to the overlap in how terminology is used in everyday language, research language, and across research disciplines (semantic ambiguity), as well as the difficulty of defining broad concepts using language that has multiple meanings (Kennedy, 2019; Moore & Khan, 2024; Rapport et al., 2018; Sterner, 2022).

The updated Consolidated Framework for Implementation Research (CFIR; Damschroder et al., 2022) and a widely used implementation strategy classification taxonomy (Leeman et al., 2017; Leeman et al., 2024) separately classify strategies related to implementation processes as activities that are specifically geared towards "planning, selecting, implementing, and sustaining an EBI [Evidence-based Intervention]". Process activities are not strategies designed to be tailored to overcome impeding factors to implementation or specifically aimed at integration of the evidence-based intervention, but rather are agnostic to the intervention, involving the planning and execution of intervention implementation across all research-to-practise phases or stages.

Qualitative Comparative Analysis

Fuzzy-set Qualitative Comparative Analysis (fsQCA, QCA; Mello et al., 2021; Ragin, 2008, 2014) stemming from set theory, is the analytical methodology utilised in this study to examine the necessary and sufficient conditions and relationships between those conditions to achieve the reported implementation outcomes. QCA examines the complexity of causation, drawing from Boolean algebra operators AND, OR and NOT to examine condition-outcomes set relations and membership, rather than independent effects as found in more traditional statistical modelling approaches. The use of Boolean logic operators aligns with the recognised complexity of AI implementation in healthcare settings, and the intricacies of both AI and healthcare systems from a sociotechnical perspective. The assumption of symmetrical causation in traditional independent effect approaches (i.e. XY) is rejected in fsQCA, where causal asymmetry posits that the outcome of X on Y does not also equate to non-outcome and may be independently or jointly sufficient, or necessary, thus are treated as separate analysis (i.e. sufficiency= X→Y; ~X→~Y; necessity= ~Y→~X) (Greckhamer et al., 2018; Mello et al., 2021; Schneider & Wagemann, 2012). There are two other causal complexity assumptions that QCA methodology follows: conjunctural causation, and equifinality. Conjunctural causation assumes that there is no singular sufficient condition to produce a specified outcome, rather that multiple condition relationships (a conjunction) combine to equate an outcome (i.e. (A*B*c)→Y), whereas equifinality assumes multiple different combinations of conditions (multiple conjunctions) add together to produce an outcome (i.e. (A*B*c)+(~A*D*Z)→Y).

Set theory, the underlying principle of QCA, defines a 'set' as a collection of phenomena and develops a theory around understanding the memberships and relationships that exist or do not exist between and within these sets (Mello et al., 2021). Membership in a set can be either binary ('crisp' set analysis in QCA), where phenomena either belong or do not belong to a set, or non-binary ('fuzzy' set analysis or fsQCA), where membership can be partial and are considered in terms of degrees of membership. Relationships within and between sets in QCA may be examined from the underlying causal complexity assumptions as subsets (sufficient relationship conditions for an outcome), supersets (necessary relationship conditions for an outcome), and set intersections, which combine conditions that are either necessary or sufficient for an outcome.

QCA will be used to understand the complexity of the implementation process as reported in both empirical and conceptual implementation literature pertaining to AI in healthcare, as the method considers the ambiguous boundaries inherent in qualitative data (Ragin, 2008), making it ideal in analysis of qualitatively reported implementation activities described in the literature.

Rationale Artificial Intelligence is increasingly present in healthcare research, yet translation into clinical practice remains limited. Current frameworks for implementation of Artificial Intelligence do not fully address the complexity and unique requirements of Artificial Intelligence within healthcare systems. Understanding the implementation process activities which lead to specific integration outcomes is critical for advancing and improving success of Artificial Intelligence integration in healthcare settings.

The activities identified in the scoping review, and analysed using fsQCA, will support further studies in the development of an evidence-based Implementation Process model for AI integration in healthcare, that is grounded in sociotechnical systems theory, co-designed, and validated through expert consensus. The secondary aim is to highlight potential gaps in implementation process guidance for AI in healthcare settings and emphasise the need for a sociotechnical perspective on the implementation of AI.

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METHODS

Strategy of data synthesis The search strategy is developed using Population, Concept, Context (PCC). The initial search developed for Scopus will be adjusted to fit the syntax and filters of the other listed search databases. Systematic searches will be conducted in Medline (Ovid), CINAHL, PsycINFO, and Scopus, as these databases encompass published literature in AI, implementation, and healthcare research.

To align with the methodology and support analysis in this study, reported implementation activities can be understood as conditions. Conditions will be aligned to the Sittig and Singh (2010) sociotechnical systems model and may be necessary or sufficient to produce an implementation outcome. We define implementation outcomes (here referred to as implementation process outcomes) as the stage in the research-to-practice process the activities are reported against in the literature, aligned with the stages of the Exploration, Preparation, Implementation, Sustainment framework (EPIS; Aarons et al., 2011), with an additional pre-Exploration stage included for activities outside of the standard EPIS definitions. Additionally, fuzzy-set membership scores have been applied in this study to reflect the level of detail for implementation activities reported in the literature, as a proxy for the presence or intensity of the implementation activity in real-world evaluation. Fuzzy weightings therefore capture visible evidence from the literature, rather than the strength of causation. Whilst potentially confounding, the intention of fsQCA calibration is for the researcher to reflect their substantive knowledge on the topic and guide set calibration (Mello et al., 2021; Ragin, 2008, 2014). However, reporting quality may limit calibration of QCA set membership, and as such there is the potential for implementation process activities to be poorly reported and thus under-weighted. Whilst this constitutes a study limitation, mitigation will be undertaken through completion of sensitivity analysis using binary QCA coding (absent/present), in addition to dual researcher data extraction and weightings. Where the total number of individual implementation activities extracted across all included cases do not fit the formula for ideal number of conditions in QCA (2^k=ideal number of individual phenomena for truth table construction and analysis, where 'k' represents the number of conditions), variations of QCA analysis may be employed (Mello et al., 2021).

Heterogeneous reporting quality is expected in empirical studies, as the quality of implementation reporting is a known challenge. Many studies will likely provide limited details on implementation processes, particularly individual activities, and focus more heavily on the surfacing of barriers and facilitators. Moreover, it is anticipated that there will be limited reporting on implementation failure.

Eligibility criteria Inclusion criteria

Peer-reviewed publications will be eligible if published in English after 2017, following the release of several key studies on the use of Deep Learning Algorithms (a subset of Artificial Intelligence) in healthcare to enhance disease classification and diagnostics (Esteva et al., 2017; Gulshan et al., 2016; Hirani et al., 2024; Rajpurkar et al., 2022). Inclusion will cover all studies addressing AI (including machine learning) implementation in healthcare settings that describe or synthesise implementation processes (including activities and phases). Studies may include primary empirical of any method that reports on AI implementation, studies of framework or model development that are derived from empirical evidence (such as case studies, or expert consensus or experience surfaced from focus groups, working groups. workshops or Delphi), reviews that synthesis implementation activities. Implementation studies of barriers and facilitators will only be included where they detail implementation processes (i.e. synthesise implementation activities for facilitating implementation in the process domain of the CFIR, or similar).

Exclusion criteria

Exclusion will apply to studies focused solely on the design of AI-driven or general health interventions, or the design and development of AI models, and not on implementation itself. During full-text screening, studies will be excluded if they focus on AI implementation but do not report specific implementation activities (i.e., they only mention barriers and facilitators without detailing implementation processes). Studies which detail implementation strategies without describing the implementation process will be excluded, as will studies which focus on patient and healthcare practitioner perspectives of AI use in healthcare that do not describe implementation process activities. Additionally, protocols are excluded and reviews (of any kind) that focus on AI in healthcare without synthesising implementation process activities.

Source of evidence screening and selection Extracted papers will be imported into Covidence

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software for de-duplication, screening and data extraction. Titles and abstracts will be independently screened for inclusion by two members of the research team. Disagreements on any inclusions will be discussed between the two researchers, and a third team member's opinion will be sought if no consensus is reached on a paper's inclusion. Inter-rater reliability will be automatically calculated within Covidence.

Data management A data charting tool will be developed and tested on 10 studies within Covidence, refined as needed, and then employed for full data extraction. Following a modified approach from the JBI Manual for Evidence Synthesis - Scoping review methodology (Peters et al., 2022), data extraction will be completed by two independent researchers. Completion of data extraction by two researchers independently will ensure robust data for analysis. Agreement between items that are not aligned will be discussed for consensus between the two researchers once all data extraction has been completed.

Study characteristics
Title, Author(s), Publication Year, Study design, Country, Health field, Healthcare system or setting and verbatim extractions of the described AI application, Implementation Phases, framework(s) used, and key stakeholders.

Implementation activity data
To align with fsQCA methodology, each study included in data extraction will be considered a 'case' (Mello et al., 2021). For each case the implementation activities will be extracted verbatim and mapped to the relevant corresponding Sittig and Singh (2010) Sociotechnical Systems Model for Health Information Technology domain (Hardware/Software, Clinical Content, Human-Computer Interface, People, Workflow/Communication, Internal Organizational Features, External Rules/Regulations, System Measurement/Monitoring), and Exploration, Preparation, Implementation, Sustainment framework (EPIS; Aarons et al., 2011), phase of implementation. An activity detail score will be given to each activity within the case (see section 'Coding for fsQCA'), which will then be aggregated to produce a domain level score based on the median, per case for truth table construction and data analysis. Range will be reported alongside median.

Coding for fsQCA
During extraction, implementation activity data will be coded for fuzzy QCA analysis based on whether the activity was absent (0), mentioned or fully described in the study (1=mentioned; 2=described; 3=detailed). Implementation process outcomes will be coded for comparative analysis using a weighted scale from 0 to 1, where 0 indicates the lower outcome of pre-implementation or pilot, and 1 indicates the higher outcome of full AI deployment in a healthcare setting, with evidence of sustained use; EPIS framework mappings of reported phases within the cases will provide consistency in coding of the outcomes. For conceptual studies where a framework/roadmap or other such implementation tool has been developed, a separate implementation process outcome table will be utilised that reflects the level of validation from 0 to 1, where 0 is no validation reported and 1 is the use of the framework/roadmap or tool in a real-world implementation. This ensures that all research questions can be answered through the comparison of empirically established pathways versus conceptual recommended pathways.

Reporting results / Analysis of the evidence Both descriptive analysis and fsQCA (Mello et al., 2021; Ragin, 2008, 2014) will be utilised to examine the implementation activities leading to different outcomes and the various combinations of activities that produce those outcomes. Comparative analysis will be undertaken to investigate gaps in what is reported in empirical based implementation studies to the recommended activities reported in conceptual frameworks and roadmaps.

Descriptive statistics
Frequency will be calculated for reported implementation activities, as well as for activities categorised by Sittig and Singh (2010) sociotechnical model components. The implementation frameworks used and study characteristics will also be reported.

fsQCA analysis
Necessity and sufficiency analysis will be conducted using tools such as R, or fsQCA (https://sites.socsci.uci.edu/~cragin/fsQCA/) to identify which activities are necessary, where the condition must be present for the outcome to be true, and which different combinations of activities lead to the outcome being true (sufficient). The analysis may reveal patterns of context-dependent activities (for example a necessary condition in certain AI intervention types or healthcare settings) versus those that are intervention or setting agnostic.

Presentation of the results It is anticipated that the necessary implementation activities specific to

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AI implementation in healthcare will be identified, and the key activities (i.e., those that appear to be universally important from QCA analysis) will be specified. The following hypothesis will be tested through necessary and sufficient condition analysis in fsQCA, and comparative analysis between empirical and conceptual studies:

H1: It is hypothesised that there will be no singular activity identified as important for implementation process outcomes, but rather, consistent with AI and healthcare implementation's complexity and contextuality, varying distinct specific combinations of activities will be seen as sufficient pathways for AI implementation and vary by healthcare setting and the type of application of AI.

H2: There will be a distribution of activities across all implementation phases with a higher concentration in pre-implementation phases and under-reporting in sustainment/maintenance phases.

H3: There will be evident gaps in the activities and sufficient pathways between empirical and conceptual studies (what has been reported as 'what works' versus what has been 'recommended').

H4: It is anticipated that the empirical and conceptual literature on AI implementation will have a larger emphasis in the Hardware/Software and System Measurement/Monitoring categories of Sittig and Singh's sociotechnical model, rather than the People and Workflow categories, reflecting the technology-centric nature of AI implementation rather than a sociotechnical perspective. Consideration should be given for our exclusion criteria regarding studies evaluating AI technologies and development.

Language restriction English language.

Country(ies) involved Australia, England.

Keywords artificial intelligence, implementation, health services, sociotechnical systems, qualitative comparative analysis, scoping review.

Dissemination plans Findings will be disseminated through peer-reviewed journal publication and may be presented at relevant conferences in the fields of Implementation Science, Health Informatics and Digital Health. Findings will also support a wider programme of research, through the development of an evidence-based Implementation Process model for AI integration in healthcare, that is grounded in sociotechnical systems theory, co-designed, and validated through expert consensus.

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