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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.

Review Stage at time of this submission - Formal screening of search results against eligibility criteria.

Conflicts of interest - None declared.

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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 12 March 2026.

INTRODUCTION

Review question / Objective Objective: 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.

Primary research question: 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?

Rationale 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 socio-technical systems theory, co-designed, and validated through expert consensus. 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.

Condition being studied The implementation of Artificial Intelligence in healthcare settings, specifically focusing on empirically and conceptually reported implementation process activities.

METHODS

Participant or population Studies of Artificial Intelligence (AI) implementation in healthcare settings (this may involve Organisations, implementation teams or clinician researchers).

Intervention Concept: Implementation process activities and processes reported in empirical or conceptual framework studies, including combinations of activities, and Implementation phase/stage.

Comparator Context: Any country and healthcare setting (primary, tertiary, community, etc.).

Study designs to be included Studies may include primary empirical of any method that reports on AI implementation, or conceptual 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), and reviews that synthesise implementation activities.

Eligibility criteria 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 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.

Information sources Systematic searches will be conducted in Medline (Ovid), CINAHL, PsycINFO, and Scopus, as these databases encompass published literature in AI, implementation, and healthcare research.

Main outcome(s) It is anticipated that the necessary implementation activities specific to 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.

Quality assessment / Risk of bias analysis None (scoping review).

Strategy of data synthesis Data Analysis 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. Alignment of each research questions to fsQCA and comparative analysis is demonstrated in Table 1.

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.

Subgroup analysis None.

Sensitivity analysis Mitigation will be undertaken through completion of sensitivity analysis using binary QCA coding (absent/present), in addition to dual researcher data extraction and weightings.

Country(ies) involved Australia, England.

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

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