BMJ Open Determinants of implementing artificial intelligence-based clinical decision support tools in healthcare: a scoping review protocol

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ABSTRACT

Introduction Artificial intelligence (Al), the simulation of human intelligence processes by machines, is being increasingly leveraged to facilitate clinical decisionmaking. Al-based clinical decision support (CDS) tools can improve the quality of care and appropriate use of healthcare resources, and decrease healthcare provider burnout. Understanding the determinants of implementing Al-based CDS tools in healthcare delivery is vital to reap the benefits of these tools. The objective of this scoping review is to map and synthesise determinants (barriers and facilitators) to implementing Al-based CDS tools in healthcare.

Methods and analysis This scoping review will follow the Joanna Briggs Institute methodology and the Preferred Reporting Items for Systematic reviews and Meta-Analysis extension for Scoping Reviews checklist. The search terms will be tailored to each database, which includes MEDLINE, Embase, CINAHL, APA PsycINFO and the Cochrane Library. Grey literature and references of included studies will also be searched. The search will include studies published from database inception until 10 May 2022. We will not limit searches by study design or language. Studies that either report determinants or describe the implementation of Al-based CDS tools in clinical practice or/and healthcare settings will be included. The identified determinants (barriers and facilitators) will be described by synthesising the themes using the Theoretical Domains Framework. The outcome variables measured will be mapped and the measures of effectiveness will be summarised using descriptive statistics.

Ethics and dissemination Ethics approval is not required because all data for this study have been previously published. The findings of this review will be published in a peer-reviewed journal and presented at academic conferences. Importantly, the findings of this scoping review will be widely presented to decision-makers, health system administrators, healthcare providers, and patients and family/caregivers as part of an implementation study of an Al-based CDS for the treatment of coronary artery disease.

INTRODUCTION

Artificial intelligence (AI) is the intelligence of perceiving, synthesising and inferring information demonstrated by machines, as

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Our scoping review will employ a comprehensive search strategy using several academic databases and grey literature sources. However, despite our broad search strategy, it is possible that some evidence may be missed.
- ⇒ Our review will adhere to the most rigorous methodological guidelines for scoping review to ensure a high-quality review of the evidence.
- ⇒ This scoping review will not limit studies based on study setting, study design, the language of publication and clinical domain to capture a heterogeneous perspective on implementing artificial intelligencebased clinical decision support tools.

opposed to intelligence displayed by humans or animals. It is most often operationalised using a computerised system that can substitute human intelligence in the performance of specific tasks.² Henceforth, we will adopt the term AI to include both machine learning (ML) and non-ML-based AI. AI is an evolving and emerging field that is increasingly being leveraged to facilitate clinical decisionmaking in healthcare. AI leverages not only the large quantity of health data generated from various sources such as electronic medical records, laboratory data, diagnostic imaging and biosensors to aid healthcare providers to make clinical decisions² but also other non-data-dependent AI methods such as symbolic AI, an approach that trains AI systems the same way the human brain learns. Using this data-driven approach, AI systems within healthcare can learn, by analysing past medical information (clinical data) of patients with similar health conditions to recognise patterns in clinical data, prognosticate, suggest evidence-based treatment options, diagnose conditions and assist in care planning. The advantage of AI in healthcare is that it can facilitate personalised medicine-tailor decisions and therapies to



each patient using their unique profile (combination of factors) to precisely deliver the right healthcare for the right patient at the right time, which can improve the quality of care.³

Studies show that using AI in healthcare has several benefits: AI can facilitate disease diagnosis, interpret patient clinical information, help select treatment plans, automate surgery, apply risk stratification for primary prevention and enhance clinical decision-making. Studies also highlight that in some areas, AI performance can be as reliable as a human expert (eg, serum analysis,^{5 6} drug–drug interaction alert system,^{7 8} reviewing radiology images,⁹⁻¹¹ dermoscopic melanoma diagnosis¹² and fundus photograph evaluation for diabetic retinopathy¹³ 14). Clinical decision support (CDS) tools can leverage AI to provide timely information for patient care, help inform decisions about patient care, support clinical teams by facilitating routine tasks, filter information, and warn of potential problems that have been shown to impact patient outcomes and quality of healthcare. 15 16 CDS includes a variety of tools and interventions, computerised and non-computerised. With the advancement in health information technology and digital transformation of medicine, the development of computerised CDS, software designed as an active knowledge system using two or more items of patient data to generate case-specific advice to assist clinicians and patients in clinical decisionmaking, is increasingly common.¹⁷ CDS systems have been used to support clinical decision-making for rare diseases, ¹⁸ in oncology ¹⁹ (specifically breast cancer), ²⁰ heart disease, ²¹ diabetes, ²² Alzheimer's disease, ²³ chronic kidney disease²⁴ and chronic obstructive pulmonary disease.²⁵ Evidence from these applications suggests CDS can improve patient care.

Several systematic reviews highlight that the use of CDS tools can improve the quality of care delivered and reduce inappropriate practice variation, healthcare provider overload and burnout, and inappropriate use of healthcare resources. ^{26–29} Studies specifically examining the effectiveness of AI-based CDS tools suggest that these benefits also extend to AI-based CDS. ^{30–32} Importantly, inappropriate use of CDS tools can lead to negative consequences such as deterioration of the quality of care, patient safety concerns, as well as ethical issues, ³³ highlighting the need for appropriate implementation of CDS tools. To maximise the potential benefits of AI-based CDS, while minimising the potential harms, they need to be thoughtfully designed and implemented using evidence-based approaches and rigorously evaluated. ³⁴

What is known about implementation of AI-based CDS? Some studies have explored specific aspects of AI-based CDS tools, such as ethical, legal, data-related (integration, trust and privacy) and human factors, and a systematic review has synthesised determinants of CDS in chronic disease. These studies have identified transparency of the algorithms underlying the AI-based CDS tools, lack of proper regulation (liability and accountability) and the negative impact on the patient–physician relationship as

concerns with using AI-based and non-AI-based CDS. ^{35 36} The literature also highlights that there is an inadequate understanding of the end user's needs, poor integration of medical data into CDS tools, poor usability and applicability of the tools, concerns around data privacy and cybersecurity. ^{35–38} While these studies are crucial to our understanding of implementation of AI-based CDS, they do not provide a comprehensive assessment of barriers and facilitators to implementing AI-based CDS tools which are positioned at the intersection of these foundational studies.

To understand implementation of AI-based CDS tools, we can also draw upon advances in implementation sciences. Like other healthcare innovations, the process of implementing CDS tools is important to their success to improve care. 39 Implementing AI-based CDS tools into clinical practice is highly complex, likely requiring strategies that consider a wide range of stakeholders (healthcare system administrators, healthcare providers, and patients and family/caregivers), engaging these stakeholders in the development and implementation, 40 and considering the context is critical. To this end, communication and education about tools⁴¹ and leveraging champions of the tool (who are trusted by their peers, comfortable with technology, and understand technical workflow and challenges) are evidence-based strategies that have been found to be effective at implementing innovations into healthcare and may be useful for implementing AI-based CDS tools. However, understanding the determinants of implementing and uptake of AI-based CDS tools in healthcare is the first step in developing implementation strategies/interventions and may be partially to blame for the slow adoption of the currently available AI-based CDS tools into clinical practice.⁴²

The objective of this scoping review is to map and synthesise barriers and facilitators that can inform the implementation and adoption of AI-based CDS tools in healthcare. Accordingly, the research questions are (1) what barriers and facilitators have been identified that determine implementation and adoption of AI-based CDS tools in clinical practice; and (2) what strategies and interventions have been used to promote the implementation of AI-based CDS in clinical practice and what is their effectiveness.

METHODS AND ANALYSIS

Given our objective is to map and synthesise the evidence on the implementation and adoption of AI-based CDS, a scoping review methodology will be used. This scoping review will be conducted following the Joanna Briggs Institute methodology⁴³ and will be reported using the Preferred Reporting Items for Systematic reviews and Meta-Analysis extension for Scoping Reviews checklist.⁴⁴ The protocol is reported according to the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols.⁴⁵

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Table 1 Search keywords: the following keywords will be used for each of the concepts			
Concept*	Relevant keywords		
Clinical decision support	exp Decision Support Systems, Clinical/ OR Decision-support* OR "Clinical support system" OR "clinical decision support system" OR "Clinical decision support" OR "evidence-based" OR "evidence-based support" OR "support system" OR exp Clinical protocols OR clinical guideline* OR clinical guidance*		
Implementation and barriers and facilitators	implement* OR "implementation strategy" OR strateg* OR barrier* OR enabler* OR facilitator* OR determinant* OR satisfaction* OR perception* OR experience*		
Artificial intelligence and machine learning	"Artificial intelligence" OR "AI" OR "Machine Learning" OR "ML" OR "Deep Learning" OR "Augmented Intelligence" OR "Reinforcement Learning" OR "Neural Network" OR "Unsupervised Machine Learning" OR "Supervised Machine Learning" OR "Random Forest" OR "Support Vector Machine" OR "Decision Tree" OR "Classification" OR "Rule-based" OR "Symbolic Artificial Intelligence" OR "Symbolic AI"		
*Concept will be combined using with 'OR'.	g the Boolean and proximity operators 'AND', and the search terms within each concept will be combined		

Search strategy and information sources

The search strategy will be developed in collaboration with a research librarian (DL). The draft MEDLINE search strategy is presented in online supplemental appendix A. The search strategy combines structure databasespecific subject headings (as available) and keywords/ synonyms, which are presented in table 1. Search terms for each concept are connected through the Boolean operator 'AND', while search terms within each concept will be combined using 'OR'. The search terms will be tailored to each database, which includes MEDLINE, Embase, CINAHL, APA PsycINFO and the Cochrane Library. To minimise publication bias, grey literature sources (government and non-government reports and conference proceedings, including NeurIPS) will also be searched to identify studies of relevance to this review. Similarly, to avoid missing any relevant literature, we will also search the reference lists of included studies and those of relevant systematic reviews. The search strategy includes studies published from database inception. We will not limit searches by study design or language.

Eligibility criteria

Studies will be eligible if they report either determinants (barriers and facilitators) or describe the implementation or adoption of AI-based CDS tools in clinical practice or other healthcare settings (regardless of the success of the implementation). Studies conducted in any clinical care setting and involving care of patients of all age groups will be included. This includes but is not limited to outpatient/ambulatory care, urgent care or acute care. Studies will be excluded if they: (1) describe CDS that are not AI (or ML) based; (2) describe patient-facing decision aids that did not involve a healthcare provider or (3) describe the effectiveness of AI-based CDS tools but do not describe the implementation.

Studies of any design will be eligible, including but not limited to mixed-methods studies, qualitative studies (interviews, focus group discussions) and quantitative studies (eg, survey, observational, randomised control trials, quasi-experimental). Reviews (eg, systematic reviews, scoping reviews, narrative reviews, rapid reviews) will be eligible; however, the primary sources of evidence will be included, and data presented in the reviews will be considered duplicate data. Published articles including conference abstracts, opinion papers, editorials and brief communication will be included in this study.

Selection of sources of evidence

Titles and abstracts will be screened for eligibility in duplicate by two independent reviewers. Reviewers will initially screen 50 references together to ensure consistency between reviewers. In the title and abstract screening phase, any study selected for inclusion by at least one reviewer will be included for full-text screening. The full-text articles will be screened in duplicate by two independent reviewers to determine eligibility. The reviewers will initially review five full-text articles together to ensure reviewers are consistently applying the eligibility criteria. Disagreement between reviewers will be resolved through discussion and consensus or consulting a third reviewer. For studies that are excluded, the reason for exclusion will be recorded. Evidence sources and screening will be managed using Covidence.

Data charting process and data items

References for all included studies will be uploaded and managed through EndNote and a standardised data abstraction form (Excel) will be developed by the authors. The data abstraction form will be piloted by two trained reviewers for two studies and revised as needed. This pilot testing process will be repeated until all relevant data are consistently captured and the authors are satisfied that data are being accurately and comprehensively captured. Data will be abstracted in duplicate by two independent reviewers. Reviewers will review five included studies together to ensure reviewers are consistently abstracting data independently. Discrepancies in the abstracted data will be discussed and resolved by the two reviewers. Once the two reviewers agree that the

Table 2 Data abstraction framework				
Bibliometrics	Study characteristics/population	Study designs	Outcomes	
Authors Year of publication Title Country Journal	Study setting (outpatient/ambulatory care, urgent care or acute care) Clinical domain of intervention (eg, cardiology, oncology, neurology, dermatology, hepatology and so on) Sample size Age Gender Sex	Mixed-methods study designs Qualitative study designs Quantitative study designs	Barriers and facilitators reported during implementation of Al-based CDS tools Strategies reported for the successful implementation of Al-based CDS tools Users' experiences and measures of effectiveness such as implementation outcomes, patient outcomes, process outcomes	

data abstraction is reliable, one reviewer will abstract the data, and the second reviewer will check/verify the data abstraction. Any disagreement in the abstracted data will be resolved through discussion and consensus between the two reviewers, or a third reviewer will be consulted.

The data abstracted for studies that meet eligibility include: bibliometric information, study design, study characteristics, population (study setting, clinical discipline, sample size, age, sex) and outcomes (reported barriers and facilitators for implementation of AI-based CDS tools, implementation strategies, reported user experiences and any implementation outcomes). The draft data items to be abstracted from each study are presented in table 2.

Data analysis

Bibliographical data, the population and the setting for included studies will be summarised using descriptive statistics. The identified determinants (barriers and facilitators) will be described by synthesising the identified determinants according to the Theoretical Domains Framework (TDF). 46 The TDF was developed 47 and validated⁴⁸ by a collaboration of experts in behavioural and implementation science who, through review of relevant theories and consensus methods, identified 14 determinants of implementation. The interventions used to implement AI-based CDS will be synthesised using the Effective Practice and Organisation of Care (EPOC) taxonomy of interventions. 49 For studies that report the effectiveness of interventions to implement AI-based CDS, the outcome variables measured will be mapped and the measures of effectiveness will be summarised using descriptive statistics. The determinants and interventions will also be categorised and mapped to the TDF and EPOC according to the success of the implementation (per the effectiveness outcomes) of the AI-based CDS.

Patient and public involvement

In the conception of this review, patients and the public were not involved. However, an Advisory Committee who advise the authors on the larger programme of research, consisting of diverse stakeholders including clinicians, health system administrators, and patients and family/

caregivers will be involved in knowledge mobilisation. The findings of this study will be presented to the Advisory Committee and the patients and family/caregivers will be provided an additional opportunity to discuss the findings separately from the other Advisory Committee members (clinicians and health system administrators) to obtain their feedback on our interpretation and summary of the evidence.

DISCUSSION

AI-based CDS tools present immense potential for facilitating and improving care delivery and patient health. AI-based CDS tools can make use of existing health data to facilitate clinical decisions and increase evidencebased care leading to high-quality, personalised medicine which has been found to improve health outcomes, avoid unwarranted practice deviations, and reduce the financial burden on individuals and organisations.⁵⁰ The growing volume of health data, the rapidly expanding role of digital technologies in healthcare, and the availability of diverse treatment options make the development and use of AI-based CDS tools in care delivery a timely and needed innovation. Many studies have highlighted the importance of AI-based CDS tools in healthcare practice; however, the adoption of AI-based CDS into clinical practice remains slow. 42 Understanding the determinants of implementing and adopting AI-based CDS tools in healthcare is vital to reap the benefits that AI-based CDS can yield. Implementation science plays an important role in delivering evidence-based medicine that optimises healthcare delivery and enhances health. 51-53 A key tenet of implementation science is understanding the determinants of adopting innovations into clinical practice by end users to design implementation strategies that leverage facilitators to use and minimise barriers. Determinants of use are unique to each innovation; therefore, it is essential to understand the determinants of AI-based CDS tools to inform the development and implementation of AI-based CDS tools.

The proposed scoping review has several strengths; we will adhere to the most rigorous methodological guidelines

for scoping reviews, and we will employ a comprehensive search strategy using several academic databases and grey literature sources. The evidence synthesised in this study will help map the gaps in the evidence of implementation of AI-based CDS, what has worked and what needs to be improved for effective implementation of AI-based CDS tools. This scoping review also provides foundational evidence for further research programmes to implement AI-based CDS tools. Specifically, the result of this scoping review will inform the development of an implementation strategy for an AI-based CDS tool to guide the care of patients with coronary artery disease, which includes wide dissemination of the findings of this study to key end users of AI-based CDS tools. Our scoping review will focus on all clinical care environments to identify contextual factors that may help us understand factors that may predict the determinants of implementation across the healthcare system.

ETHICS AND DISSEMINATION

This scoping review protocol summarises our approach to understanding the existing evidence surrounding the implementation of AI-based CDS tools in healthcare settings. Ethics approval is not required for this study, as our objectives from this synthesis are to review and map the existing literature. The findings of this review will be published in a peer-reviewed journal and presented at various academic conferences. Importantly, the summary of this scoping review will be widely presented among decision-makers, health system administrators, healthcare providers, and patients and family/caregivers.

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Contributors KS conceptualised and led this work and assisted with the development of the search strategy and manuscript draft. BB and DL developed the search strategy, and JL and KS critically revised and approved the search strategy. BB drafted the manuscript. KS, DL and JL provided guidance in refining the concept and revising the final manuscript. KS is accountable for all aspects of the work and ensures that questions related to the accuracy or integrity of all parts of the work are appropriately investigated and resolved.

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Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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