

BMJ Open Benefits and limitations of business process model notation in modelling patient healthcare trajectory: a scoping review protocol

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ABSTRACT

Introduction The adoption of business process model notation (BPMN) in modelling healthcare trajectory can enhance the efficiency and efficacy of healthcare organisations, improve patient outcomes while restraining costs. Existing systematic reviews have been inconclusive regarding the effectiveness of BPMN in modelling healthcare trajectory. The aims of this scoping review are to map and aggregate existing evidence on the benefits and limitations associated with BPMN in healthcare trajectory, highlighting areas of improvement on BPMN and its extensions in healthcare. We will assess BPMN's ability to model key dimensions or concepts of the healthcare process and to meet the needs of stakeholders. The review will highlight the advantages of this approach to support clinical activities and decision-making processes associated with the healthcare trajectory, proposing a conceptual framework for improving the use of BPMN in healthcare.

Methods and analysis This study will be performed in accordance with the methodological framework suggested by Arksey and O'Malley. A wide range of electronic databases and grey literature sources will be systematically searched using predefined keywords. The review will include any study design focusing on the application of the BPMN approach for optimising healthcare trajectories, published in either English or French from 1 January 2004 to 9 December 2021. Two reviewers will independently screen titles, abstracts and full-text articles and select articles meeting the inclusion criteria. A customised data extraction form will be used to extract data. The results will be presented using descriptive statistics and thematic analysis on qualitative data.

Ethics and dissemination Research ethics approval is not required. Review findings will be used to advance understanding about BPMN, its extensions and application in healthcare trajectory optimisation. The review will develop recommendations on tailoring BPMN strategies for optimising care pathways and decision-making processes. Findings will be disseminated in peer-reviewed journals, conferences and discussions with relevant organisations and stakeholders.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Stakeholders will be consulted and engaged throughout the study review process.
- ⇒ Our scoping review will conform to the rigorous methodology indicated by Arksey and O'Malley, and improved by Levac *et al* and further refined by the Joanna Briggs Institute.
- ⇒ Both peer-reviewed and grey literature will be considered to ensure a comprehensive coverage.
- ⇒ The search strategy in electronic databases considered articles published between January 2004 and December 2021, while abstracts and full-texts selection will be limited to French and English language.
- ⇒ The quality appraisal of publications captured will not be assessed, as it is beyond the aim of a scoping review.

INTRODUCTION

With the continuous challenges facing healthcare organisations in the past few years,^{1–3} many strategies have focused on process improvements with the objective of enhancing efficiency and efficacy to improve patient outcomes while controlling costs.^{4,5} Through the years, health expenditure and financing have increased substantially in developed countries such as the USA and Canada.^{6–9} In 2019, Canada spent 10.8% of its gross domestic product on healthcare expenses according to the Organisation for Economic Cooperation and Development (OECD).⁹ This ratio reached 17.7% at the same time in the USA, where the national health spending is projected to reach US\$6.2 trillion by 2028, growing at an average annual rate of 5.4%.^{8,9} However, compared with other OECD countries, the USA performs poorly on process, outcome and patient experience metrics, as well as life expectancy.^{10,11} Life expectancy in the USA was the lowest at 78.8 years



compared with a range from 80.7 to 83.9 years for other OECD countries.¹⁰ The infant mortality rate in the USA was 5.8 per 1000 live births and the maternal mortality rate was 17.4 per 100 000 births in 2018, both higher than the mean rates for any OECD country.^{11–15} Canada is another developed country performing poorly in terms of infant and maternal mortality, with 4.7 fatalities out of every 1000 live births and 10.2 maternal deaths per 100 000 births.^{11 16}

The lack of control in processes used to deliver medical care is clearly a major problem in the context of preventable medical errors with lethal damages and high economic costs in many hospitals.^{17–19} Since the released *Crossing the Quality Chasm*^{20 21} by the Institute of Medicine (USA), numerous national and international organisations including the Academies of Sciences²² and the WHO^{23 24} have made repeated calls to develop a framework for advancing the quality of care, ensuring that care is safe, effective, efficient, patient-centred, timely and equitable.²⁰ To do this, healthcare organisations and systems must develop solutions that enhance both efficiency and efficacy of improving healthcare organisation and patient outcomes while restraining costs. Efforts to improve clinical and care pathways have shown such benefits.^{25–27} Over the last decades, articles have revealed that mapping healthcare trajectories allowed to decrease the variation of professional practices and to standardise care processes.^{17–19} This practice has many benefits such as improving the accessibility, fluidity, quality, performance and sustainability of healthcare services.^{25 28}

In this context, several tools have been developed to support process improvement through process mapping. Among these methods, business process modelling notation (BPMN) is an approach that consists of representing processes as a network of activities and tasks.^{29–31} This structured approach supported by the Object Management Group since 2005 and adopted as an international standard by the International Organization for Standardization since 2012, is in its second version (BPMN V.2.0).^{30–32}

In recent years, a few reviews^{33–36} have been conducted to analyse whether the BPMN approach can become a useful tool to improve the effectiveness and quality of healthcare processes. For instance, Loya *et al*³³ used a service-oriented architecture in clinical decision support and provided evidence that BPMN was not commonly used for clinical decision support systems, despite being the preferred standard for business process modelling in healthcare. Mincarone *et al*³⁴ demonstrated that BPMN provides a good level of formalisation, a standardised communication framework between multiple stakeholders, good user comprehensibility and easier inter-professional analyses. De Ramón Fernández *et al*³⁵ suggested that BPMN is useful for standardising processes that have some variability due to its possibility to incorporate variations or changes. Moreover, Zarour *et al*³⁶ analysed various BPMN extensions (eg, decision modelling notation) that can be used to improve its efficiency in many domains,

showing that healthcare was among the most targeted area. The overall conclusion of these reviews^{33–36} is that BPMN seems to be increasingly used in healthcare organisations to the point of becoming a standard in process improvement methods. However, these articles^{33–36} acknowledged the difficulties and challenges when implementing BPMN in the health sector. Indeed, a limitation of these articles^{33–36} is that none of them put the use of BPMN to improve healthcare trajectories or patient care trajectory as its primary focus. Loya *et al*³³ focused on the use of BPMN for supporting clinical decisions and stated that BPMN has potential to optimise clinical pathways, but they did not assess this possibility. The papers of Mincarone *et al*³⁴ and De Ramón Fernández *et al*³⁵ mainly focused on clinical processes, briefly addressing healthcare trajectories, resulting in a shallow analysis on this subject. Finally, Zarour *et al*³⁶ targeted many BPMN extensions that could improve its effectiveness, but their research was not exclusive to healthcare setting.

Our literature review builds on these previous reviews^{33–36} by providing an in-depth analysis of the ability of BPMN to effectively improve the quality of clinical practices, the security, and the fluidity of the care process and to propose tangible results on the patient experience in a patient-centred care and services logic. Moreover, we will analyse the opportunities and limitations related to the integration of BPMN extension.

Considering the above gaps in the literature, the primary aim of this scoping review is to identify and map existing evidence on the main benefits and limitations associated with the use of BPMN in healthcare trajectory modelling. To do so, we will assess its ability to model key dimensions or concepts of the healthcare process and to meet the needs of stakeholders. The review will also highlight the capacity of the BPMN approach and its extensions to support clinical activities and decision-making processes associated with the healthcare trajectory and propose a conceptual framework for improving the use of BPMN in healthcare practices.

METHODS AND ANALYSIS

We chose to undertake a scoping review as the best method to map the available evidence regarding the benefits and limitations of BPMN in modelling patient healthcare trajectory.^{37–39} The present review will be conducted following the methodological frameworks described by Arksey and O'Malley,³⁷ and improved by Levac *et al*,³⁸ and further refined by the Joanna Briggs Institute (JBI).⁴⁰ The standardised methodology included six stages for scoping review: (1) identifying the research question, (2) identifying relevant articles and grey literature, (3) selecting articles, (4) charting the data, (5) collating, summarising and reporting the data and (6) consulting with relevant stakeholders, thereby enabling knowledge translation. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR)^{39 41} has also been used to guide the reporting of

this protocol and will also subsequently be used to structure the reporting of the full review. Furthermore, we will take an iterative and reflexive approach throughout the review process, particularly to refine our study selection and data extraction steps to the best target meeting our objective. This protocol is registered through the Open Science Framework.⁴² The development of the scoping review will start in May 2022 and it should be finalised in September 2022.

Stage 1: identifying the research question

As the focus of scoping reviews is on summarising the breadth of evidence, the research questions should be broad while keeping in mind the review's main purpose.^{37 38 40 41} Thus, we started with, 'What is known about the application of BPMN methodology in healthcare organization?' A preliminary search was conducted through some electronic databases including International Prospective Register of Systematic Reviews, JBI Database of Systematic Reviews and Implementation Reports, Cochrane Database of Systematic Reviews, and National Center for Biotechnology Information, which revealed three systematic reviews of modelling healthcare processes using the BPMN methodology.^{33–36} Although findings from these reviews^{33–36} supported the use of BPMN as an effective methodology to optimise healthcare processes, no conclusions on the effectiveness were drawn. The reason may be that these reviews^{33–36} were not mainly focused on the use of BPMN to improve healthcare trajectories.

In addition, we adopted the JBI's Population Concept and Context (PCC) framework⁴⁰ to formulate the

objectives and research questions, and to conceptualise the study and report characteristics in terms of eligibility criteria (table 1). We then consulted with experienced colleagues³⁰ on our predefined set of questions to provide further input and feedback.

In line with our purpose to comprehensively map the extent, range and nature of evidence examining the use or application of BPMN within the healthcare trajectory, we formulated four specific research questions to guide this review:

1. What are the objectives for using BPMN in healthcare organisation? What are the expected results and what are the needs to be met?
2. What are the key variables, elements, concepts and dimensions targeted by the BPMN approach?
3. Can the BPMN approach meet these expectations in healthcare trajectory? Specifically,
 - a. What are the strengths (advantages) and weaknesses (limitations) of the BPMN in modelling healthcare trajectory?
 - b. What are the effectiveness of using BPMN approach and its extensions in modelling healthcare trajectory?
 - c. What are their opportunities and constraints in modelling healthcare processes?
4. What are the improvements or alternatives proposed to optimising healthcare trajectory?

For the purposes of this review, the term healthcare trajectory focuses on the patient's care pathway across the continuum of care. Thus, it can be the clinical pathway when it focuses on the organisational scale, but also the care

Table 1 Population Concept and Context framework⁴⁰ for illustrating the scope and defining inclusion and exclusion criteria of the review

	Inclusion	Exclusion
Population	Participants of interest are the healthcare stakeholders (knowledge users) involved directly or indirectly with the use of BPMN during the healthcare trajectory or clinical process. The healthcare stakeholders (knowledge users) will include patients, healthcare professionals (eg, nurses, physicians, other professionals), administrators and decision-makers who were involved at least once in the healthcare trajectory or clinical processes (clinical or care pathways).	Literature that does not apply BPMN in health trajectory (eg, healthcare process, clinical process, process of care, patient care process, healthcare trajectory, clinical pathways, patient care management). Since we are interested in the efficacy and limitations of BPMN in healthcare trajectory, this needs to be evidence-based (analyse a case clinical pathway) and not speculative.
Concept	The concept is the application of BPMN in healthcare trajectory and/or clinical processes to evaluate the capacity of BPMN to optimise healthcare performance. Articles that reported any healthcare intervention and/or clinical processes modelling with BPMN, including the improvement of the quality assessment and decision-making processes, the capacity to understand the internal clinical procedures, the ability to communicate those procedures in a standard manner, the ability to adjust to new internal challenges quickly and patients' outcomes will be included.	
Context	The context for this review will consider articles conducted in any clinical setting (eg, inpatient, outpatient) or healthcare settings (eg, hospitals, health centres, nursing homes). Articles conducted in any part of the world are eligible to be included in this review	Literature related to BPMN occurring outside of healthcare trajectory (eg, clinical process, process of care, patient care process, patient trajectory, clinical pathways, patient care management)
Types of evidence	Reviews (eg, systematic, or narrative reviews), peer-reviewed research articles, full-text articles are specific to modelling patient care trajectory incorporate the use of BPMN as a methodological approach and published in either English or French.	Articles published before 2004, not written in either English or French. Editorial articles, abstracts or posters, protocols for planned articles, strategy, or guidelines. Articles where full text is unavailable. Study do not indicate the use of BPMN as a methodological approach. Study focuses on other healthcare elements, such as professional development and performance management but not specifically on patient care trajectory.

BPMN, business process modelling notation.

pathway when it focuses on the systemic scale. It consists first of the patient's journey through the sequencing of tasks and activities at all points of contact.^{43 44} It then integrates the professional actors involved in the care trajectory,^{45 46} the operation management of care delivery processes,^{47 48} the coordination structures,⁴⁹⁻⁵¹ the structural context of the system and organisations^{52 53} as well as the information trajectory along the healthcare trajectory.^{54 55} Thus, our understanding of the term healthcare trajectory is not limited to the operational aspect of the care process and to the pathophysiological process of a patient's disease state, but also refers to the organisation of all activities surrounding interactions between healthcare workers and patients, as well as the effectiveness of patient care processes and their effectiveness.

Therefore, our analysis will consider not only the operational outcomes of the application BPMN, but also its societal impact by assessing its potential to improve patient outcomes and experience. In addition, healthcare process mapping includes several different flows. On one hand, the main process follows the patient's journey through the process steps and the decision points guide the patient through the process.⁵⁶ On the other hand, the support processes and secondary flows include steps directly or indirectly linked to the main process such as administrative processes, information flow, organisational processes and examinations that do not require the presence of the patient (eg, laboratory results, pathological tests). Thus, several flows can be present and impact the care process (eg, information flow, drug flow, blood flow).

Therefore, this scoping review will focus on the potential of the BPMN and all its components to impact the results of healthcare trajectories directly or indirectly. Finally, the review will also consider proposals for extensions to BPMN have been put forward to integrate evidence-based medicine and guidelines to support clinical decision making, including the Decision Modelling Notation proposed by both the Object Management Group^{56 57} and the Computer Interpretable Guidelines.^{58 59}

Stage 2: identifying relevant articles

A comprehensive search strategy was developed with the assistance of an experienced health sciences librarian (FB). The search strategy will follow the three-step approach recommended by JBI scoping review guidelines⁴⁰ and will target the retrieval of both published and unpublished articles from electronic searches databases, focusing to BPMN modelling of patient care trajectory. The first step of the scoping review guidelines has been completed in preparation of this protocol (table 1), which involved an initial limited search on PubMed and ABI/Inform (ProQuest) databases, using the following selected keywords: "Healthcare Process" OR "Clinical Process" OR "Process of Care" OR "Clinical Pathways" OR "Patient care Process" OR "Healthcare trajectory" OR "Patient Care Management" OR "Critical Pathways" OR "Clinical Healthcare Pathways" AND "Business Process Model" OR "Business Process Modelling Notation" OR

"Business Process Model" OR "BPMN modelling" OR "Workflow" OR "Clinical Decision-Making" OR "Decision Support Systems" OR "Medical Process". The index words and the text words in the title and abstract of retrieved articles were analysed to identify search terms and refine the search strategy. In detail, we used an adjacency operator between the expression "Business Process" and terms (Model OR Method OR management) that seemed most relevant to us and consistent with previous published systematic literature reviews,³³⁻³⁶ as subject experts, in order to capture all potential articles using synonyms and words variations of the "Business Process Model Notation" concept, in addition to BPMN acronym. To find articles about patient "Healthcare Trajectory", a broad concept containing several components, we used a mix of general (eg, Practice Guidelines as Topic OR Workflow OR Clinical Decision-Making) and specific terms (eg, Patient Care Management OR Critical Pathways), both from controlled vocabulary (eg, MeSH terms) and keywords to avoid missing articles. We used the Boolean operator AND to restrict our search to articles specifically related to these two concepts.

In the second step, the search strategy will be adapted and implemented for each included information source (PubMed, Embase (Embase.com), Cumulative Index to Nursing and Allied Health Literature - CINAHL (EBSCO), Web of Science, ABI/Inform (ProQuest), Academic Search Premier (EBSCO) and Google Scholar) for potential eligible articles from 1 January 2004, year when BPMN was initially developed by the Business Process Management Institute, until 9 December 2021. In addition to the electronic database search, we will undertake a backward snowballing⁶⁰ search that will involve hand-searching the reference lists of the identified reviews^{33-36 61} in order to find other relevant articles. We will also perform a hand search of some relevant journals (eg, Institute of Electrical and Electronics Engineers, Health Informatics Journal, IOS Press - Studies in Health Technology and Informatics, Journal of Digital Imaging, Lecture Notes in Artificial Intelligence, Springer Procedia Computer Science, Recent Advances in Computer Engineering, Information Systems Journal, European Journal of Information System, Lecture Notes in Business Information Processing), search citations of relevant papers and scan the reference lists of relevant papers. The final search results will be exported to the Covidence systematic review software^{62 63} where duplicates will be removed. The full detailed search strategy for peer review and grey literature sources is included in online supplemental appendix 1.

Stage 3: selecting literature for inclusion

All retrieved articles will undertake two levels of screening. First, two reviewers (SAK and J-BG or LL) will independently screen titles and abstracts of each article against the established inclusion and exclusion criteria (table 1). To increase the reliability of screening by the two reviewers (SAK and J-BG or LL), a pilot test

will be conducted on 50 titles and abstracts to evaluate reviewer agreement in the screening process. Discrepancies will be resolved through discussion between the two reviewers and where agreement could not be reached, a third reviewer (PL, CP, CL or AC) will be consulted. Adjustments may also be made to the inclusion criteria if necessary to ensure consistent interpretation and application of the criteria. The researchers will discuss their selection of articles after this first round of screening, to arrive at preliminary consensus on the list of eligible articles. In the second step, the two reviewers will screen the full-text articles independently to determine if they meet the inclusion criteria. Reasons for the exclusion of full-text articles will be noted in Covidence⁶³ by each reviewer. Reviewers will again discuss their selection of articles after this second round of screening, to arrive at a final list of eligible articles. Discrepancies will again be resolved through discussion between the two reviewers and where agreement could not be reached, a third reviewer will be consulted. The screening process will be documented using a PRISMA flowchart for scoping review^{39 41} and by calculating the inter-rater reliability between reviewers using the Cohen's Kappa coefficient.⁶⁴

Stage 4: charting of information and data

Data will be extracted from every eligible article using a data extraction chart (*Charting Table*) tailored to the research questions. Its aim is to maintain a manageable amount of data, while ensuring a wide approach and breadth of coverage to obtain existing evidence on the benefits and limitations associated with BPMN in patient care trajectory. Two researchers (SAK and J-BG or LL) will independently extract the following study information: authorship, year of publication, country of origin, study purpose, patient care trajectory issues being addressed (eg, diabetes, chronic obstructive pulmonary disease, coronary heart disease, clinical pathways for contraception), study population/target users (eg, physicians, clinicians, nurses, pharmacists), setting/location of intervention (eg, primary care, acute care, rehabilitation, home care, long-term care, community, hospital), methodological approach (qualitative, quantitative, or mixed study), expected results study findings (eg, decreasing diagnostic delay, optimising of quality care, cost, reducing medical errors, standardising the decision-making process), type of outcomes/dimension analysed (eg, diagnostic times, waiting time for surgery, flexibility, improving key performance indicators, decision support systems). We will note the objectives and benefits, as well as the limitations of using BPMN and BPMN-extension approach. The proposed Charting Table is shown in online supplemental appendix 2. It will be trialled on five included articles and will be iteratively refined. Adjustments or expansions may also be made to the *Charting Table* if necessary to ensure that the research objectives or questions are well addressed. For instance, we may add additional categories of data deemed relevant to answer the research questions to the Charting Table.

Stage 5: collating, summarising and reporting the data

The main findings of the included articles will be summarised in Tabular format in a manner that reflects the objectives of the review. Following the PCC principles,⁴⁰ a narrative summary will accompany the Tabular results and link the different findings to the review objective and questions and will identify any knowledge gaps in the literature. To ensure rigour in this stage, two reviewers (SAK and J-BG or LL) will prepare a descriptive summary table of the extracted data and will highlight the key findings with input from the research team. The table will include a descriptive summary of the articles and a qualitative thematic analysis of the main results regarding characteristics of the BPMN approach used in each study (eg, objective, benefit, challenges, target users, redesign the clinical process), type of patient trajectory, characteristics of the research designs, outcomes of interest used to measure the effectiveness of BPMN (eg, reducing work time, and challenges and potential solutions learnt). We will identify barriers or limitations of BPMN for achieving improvement of healthcare processes, support activities and decision-making processes, and use that information to address our main objectives. The consultation stage of the scoping review, described in the following section, will contribute to fulfilling that objective and to establish a conceptual framework for improving the use of BPMN in healthcare trajectory modelling. Finally, if the extracted data allow it, a qualitative analysis will be conducted to discuss or nuance the evidence of BPMN effectiveness considering potential barriers and enablers identified by the authors. We will use the PRISMA-ScR to guide the final reporting of our results.

Stage 6: consultation

The final consultation stage offers an ideal mechanism to enhance the validity of the study outcome while translating findings with the stakeholders or health professionals and patients.³⁸ Preliminary findings from this review will provide the background for workshop with the research team and stakeholders/knowledge users (eg, healthcare professionals, patients, decision-makers, administrators). The objectives of the workshop are to present and discuss the interim results of the synthesis. The meeting will generate a list of key practice recommendations, dissemination strategy and research priority areas to inform future research.

The workshop will be conducted with the research team with a focus on reviewing the results following feedback from the previous meeting, reviewing the final report, necessary modifications to findings and recommendations for precision and clarity. These consultations with all stakeholders, including clinicians, technicians, and patients, aim to materialise the findings of this review by discussing their applications in specific contexts. Therefore, despite Arksey and O'Malley³⁷ stated that consultation is optional, we find that our study is a fundamental step. Consequently, we plan to organise a workshop with all stakeholders in order to get their feedback on

the findings and to develop next steps in research and practice. The feedback from the stakeholder workshop and the results of the scoping review will be combined to clearly indicate the available evidence, gaps in research and future research priorities for improving the use of BPMN in healthcare trajectory modelling.

Patient and public involvement

In this study, patient and public involvement will be performed at the consultation stage and dissemination. Patients will be recruited from the Institut Universitaire de Cardiologie et de Pneumologie de Québec-Université Laval (IUCPQ-UL). We will work together with the IUCPQ-UL patient office for the recruitment and consultation of patient partners. Our consultation strategy comprises involving not only patients with specific health trajectory but also caregivers, healthcare and social professionals, and policymakers at different levels. It is expected that their contribution in the discussion of the scoping review results will inform the next steps of the project regarding the ability of BPMN to effectively improve the quality of clinical practices, the security and the fluidity of the care process. Therefore, our analysis will consider not only the operational outcomes of the application BPMN, but also its societal impact by considering the patient's health trajectory in healthcare organisation.

ETHICS AND DISSEMINATION

This scoping review is exempt from ethics approval because the work carried out will be based on published documents. The involvement of relevant study participants does not imply personal data collection, rather, we seek to have the key persons feedback on the information gathered through the bibliographic review. The aim of this project is to synthesise the literature about healthcare trajectory using BPMN approach to enhance conceptual clarity and understanding about key benefits and limitations and to extrapolate from this evidence base promising conceptual framework for improving the use of BPMN in healthcare trajectory. During the development of the scoping review a patient-partner will be engaged as a consultant and knowledge user. We anticipate the research will provide several key outputs including (1) a comprehensive review that will summarise existing literature on the BPMN approach; (2) an evidence base demonstrating the benefits and limitation of the BPMN approach in modelling patient trajectory; (3) a list of BPMN extensions that can be used to improve its efficiency in many domains; (4) a conceptual framework. Our findings will be disseminated in peer-reviewed journals, workshop, seminars and presentations and through discussions with relevant organisations, study participants and stakeholders. Our goal will be to disseminate our findings to a wide range of clinicians, leaders and administrators in all sectors, to researchers and to students entering the healthcare professions to enhance understanding about key benefits and limitations of BPMN approach for

optimising the patient trajectory. We believe the results will benefit clinicians by guiding their decision-making throughout the patient's trajectory, therefore reducing the medical error rate, optimising efficient resource management, and reducing the risks of complications due to poor clinical decisions. Those improvements should result in an optimisation of cost-efficiency for organisations and quality of care for patients.

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Contributors SAK, J-BG and AC led the design, search strategy and conceptualisation of this work and drafted the protocol. PL, FB, CL and CP were involved in the conceptualisation of the review design, inclusion and exclusion criteria and provided feedback on the methodology and the manuscript. SAK and LL were involved in data extraction forms. All authors provided feedback on the manuscript and approval to the publishing of this protocol manuscript.

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