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# Systems for assessing the certainty or confidence of evidence in healthcare: a scoping review protocol

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## ABSTRACT

**Objective:** This scoping review aims to identify existing systems, frameworks, and approaches for assessing certainty or confidence in quantitative, qualitative, and mixed methods evidence, providing a foundation for developing a unified framework tailored to mixed methods reviews.

**Introduction:** Assessing the certainty or confidence in evidence is essential for developing health care recommendations, yet current frameworks are often limited to either quantitative or qualitative paradigms. With the rise of mixed methods research, which integrates quantitative and qualitative evidence to address complex health care questions, there is a growing need for systems capable of evaluating certainty across these diverse evidence types.

**Inclusion criteria:** This scoping review will include systems, frameworks, or approaches explicitly developed to assess the certainty or confidence in evidence from quantitative, qualitative, or mixed methods studies. Eligible papers must describe the methodology, criteria, or principles of these systems or discuss their development, validation, or theoretical foundations. Systems focused solely on critical appraisal or quality assessment of individual studies will be excluded unless they integrate these assessments into a broader framework for assessing certainty in a body of evidence.

**Methods:** This review will be conducted in accordance with the JBI methodology for scoping reviews and reported using the Preferred Reporting Items for Systematic Reviews and Meta-analyses extension for scoping reviews (PRISMA-ScR) guidelines. A comprehensive 3-step search strategy will identify published, unpublished, and gray literature from databases, organizational websites, and reference lists. Data will be extracted using a piloted extraction table and presented in tables, figures, and a narrative summary to map existing systems, frameworks, or approaches for assessing certainty or confidence in evidence.

**Review registration:** Open Science Framework: [osf.io/36n78](https://osf.io/36n78)

**Keywords:** certainty of evidence; confidence in evidence; evidence assessment; evidence synthesis; mixed methods

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## Introduction

In health care research, assessing the certainty or confidence in evidence of both quantitative and qualitative studies is essential for developing comprehensive recommendations and guidelines. *Certainty of evidence* typically refers to “the extent of our confidence that the estimates of the effect are correct.”<sup>1(p.1)</sup> The term is often used in a quantitative context, where statistical metrics provide a basis for estimating effect sizes and confidence intervals. Conversely, *confidence in evidence* is often aligned with qualitative research and represents the extent to which an evidence synthesis finding accurately reflects the phenomenon of interest.<sup>2</sup> These terms, though distinct, are used interchangeably within evidence synthesis to describe how trustworthy and applicable a body of findings is across a context. Assessing certainty or confidence differs significantly from simply appraising methodological quality or identifying study design. While methodological quality focuses on internal validity, rigor, and design features (eg, whether a study was randomized or controlled), certainty or confidence in evidence encompasses additional layers of evaluation that address the robustness and applicability of the entire body of evidence. It reflects the extent to which findings across multiple studies are consistent, reliable, and relevant to real-world settings.<sup>1,2</sup>

Traditional frameworks for evaluating evidence have historically catered to either quantitative or qualitative paradigms, reflecting their distinct criteria and methods for assessment. For example, the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) is widely used to evaluate evidence strength and recommendation certainty from quantitative data, often relying on measurable outcomes and effect sizes.<sup>3</sup> In contrast, tools such as Confidence in the Evidence from Reviews of Qualitative research (CerQual)<sup>4</sup> and Confidence in the Evidence from Reviews of Qualitative Research (ConQual)<sup>5</sup> assess confidence in qualitative evidence, emphasizing context, coherence, and representational accuracy. Yet, with the increased use of mixed methods (where quantitative and qualitative data are integrated to provide a more holistic understanding), there is a growing need for systems that address the complexities of integrating and assessing certainty across these diverse evidence types. Current systems do not adequately address the unique challenges and complexities posed

by mixed methods reviews, highlighting the need for adaptable frameworks that can evaluate certainty or confidence in a mixed methods context to better support health care recommendations and practices.

Mixed methods reviews combine the strengths of quantitative and qualitative research to provide a more nuanced understanding of complex health care phenomena. As these reviews become increasingly essential in informing health care guidelines and best practices, there is a pressing need for a dedicated framework or system that can assess the certainty or confidence in the combined evidence from such reviews. Current frameworks lack a comprehensive approach for mixed methods reviews, leading to potential gaps in the assessment of evidence quality and its application to practice. For example, for a mixed methods systematic review examining the effectiveness of an intervention to improve mental health outcomes, quantitative data might demonstrate a statistically significant reduction in symptoms, while the qualitative data may provide insights into patient experiences and barriers to adherence. Through a process of data transformation, the quantitative findings could be qualified, allowing for integration with the qualitative themes to generate a recommendation for practice. Alternatively, the 2 streams of evidence could be juxtaposed, with the quantitative evidence supporting the efficacy of the intervention, and the qualitative evidence offering contextual richness that highlights important factors for successful implementation. In either approach, the recommendation is drawn not only from measurable outcomes but also from the lived experiences and perceptions of patients, making the recommendations more applicable in real-world settings. However, without a unified framework for evaluating the certainty across both data streams, it becomes challenging to fully assess the confidence in these integrative conclusions.

Given the lack of a universally agreed system for assessing certainty or confidence in evidence from mixed methods reviews, this scoping review aims to address a critical gap by identifying existing systems, frameworks, or approaches designed to evaluate the certainty or confidence of quantitative, qualitative, and mixed methods evidence. This review will systematically explore the criteria, standards, and guiding principles used across these approaches. The ultimate objective is to inform the development of a novel system or framework tailored specifically for mixed

methods reviews, thereby enhancing the rigor and reliability of evidence synthesis in health care practice recommendations.

A preliminary search of PubMed did not reveal any scoping reviews addressing this issue. However, an existing protocol registered with Open Science Framework<sup>6</sup> is focused on determining the current state of methodological approaches for assessing the certainty of evidence in mixed methods systematic reviews. Although this protocol appears to cover similar ground, a closer examination reveals a considerable difference in its scope. The existing protocol is limited to frameworks and methodologies employed in assessing certainty in mixed methods systematic reviews, excluding those focused solely on quantitative or qualitative evidence. In contrast, our review takes a broader, more comprehensive approach. It will include systems, frameworks, and approaches that are used to assess the certainty or confidence of evidence in purely quantitative, purely qualitative, and mixed methods reviews. By incorporating this wider range of evidence types, our review will allow for a more rigorous examination of the existing methods, offering valuable insights into the underlying principles and potential for cross-application between different types of evidence. This inclusivity will provide stronger and more nuanced foundations for the development of a novel framework specifically suited to mixed methods reviews, thereby ensuring that the resulting system is robust, adaptable, and capable of addressing the complexities inherent in integrating different types of evidence within health care research.

### Review questions

- i) What systems, frameworks, or approaches exist for assessing the certainty or confidence of quantitative, qualitative, and mixed methods evidence in health care?
- ii) What criteria, standards, or guiding principles are used in these systems, frameworks, or approaches to evaluate the certainty or confidence of evidence?

### Inclusion criteria

#### Participants

Given the objective of this review focuses on systems, frameworks, or approaches, participants are not applicable to this review.

### Concept

This scoping review will consider any system, framework, or approach explicitly developed to assess the certainty or confidence in evidence from quantitative, qualitative, or mixed methods studies. Eligible papers must include a description of the framework, system, or approach including their methodology, criteria, standards, or guiding principles, or discuss their development, validation, testing, or adaptation. Papers that explore the philosophical or theoretical foundations will also be included.

Publications offering only general descriptions or overviews of existing frameworks without contributing further to the understanding of their foundational methodology or philosophical or theoretical underpinnings will be excluded. For example, papers that merely outline a framework or describe it at a high level, without discussing how it was developed, validated, tested, or adapted, will not be considered. Similarly, papers that provide only brief mentions of the framework's application without addressing the underlying principles, criteria, or methodology will be excluded. In addition, studies that apply a system, framework, or approach to assess evidence in specific systematic reviews or practice guidelines, without exploring the framework's development or adaptability will not be considered. Finally, systems, frameworks, or approaches focused solely on critical appraisal or quality assessment of individual studies (eg, tools that focus solely on evaluating study design or internal validity) will not be included unless they integrate these assessments into a broader framework for assessing certainty or confidence in a body of evidence.

In this scoping review, we use the terms *systems*, *frameworks*, and *approaches* inclusively to refer to any structured method, process, or set of criteria developed to assess the certainty or confidence of evidence in health care. While these terms may have nuanced differences in some contexts, our aim is to capture all relevant developments in this area regardless of their labelling. As such, we do not distinguish between them analytically but include them all under the broader scope of mechanisms for assessing evidence certainty or confidence.

### Context

The context for this scoping review is broad and will include any system that has been used in health care research for assessing certainty or confidence of the

evidence. This review will include frameworks from any country and health care settings, reflecting a global perspective.

### *Types of sources*

This scoping review will include primary studies, secondary research, methodological papers, or textual evidence. All papers will be included regardless of the language in which they are published. For non-English papers, DeepL Translator (DeepL, Cologne, Germany) will be used to translate any titles and abstracts in languages the authors are not fluent in. Where articles are deemed relevant for full-text review, they will be translated using DeepL and, if still considered relevant, they will be translated by a professional translator. No publication date restrictions will be applied.

## **Methods**

The proposed scoping review will be conducted in accordance with the JBI methodology for scoping reviews<sup>7,8</sup> and reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-analyses extension for scoping reviews (PRISMA-ScR).<sup>9</sup>

### *Search strategy*

The search strategy will be used to find both published and unpublished papers, and a 3-step strategy will be utilized. We undertook an initial limited search of PubMed and CINAHL to identify the initial set of search terms (Step 1). This was followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe each article. This informed the development of a search strategy that will be tailored for each information source (Step 2). A full search strategy for PubMed is detailed in Appendix I. The search strategy was developed in consultation with a librarian at The University of Adelaide who has expertise in evidence syntheses. Finally, the reference list of the included papers will be examined for additional relevant articles (Step 3).

The following databases will be searched for published, unpublished, and gray literature: PubMed, Embase (Elsevier), CINAHL (EBSCOhost), Scopus, Web of Science, ProQuest Dissertations and Theses Global (ProQuest), and Google Scholar.

The following websites will also be searched for relevant sources: GRADE, JBI, Cochrane Collaboration, The Campbell Collaboration, Guidelines International Network (GIN), The National Institute for

Health and Care Excellence (NICE), World Health Organization, Agency for Healthcare Research and Quality (AHRQ), The Evidence for Policy and Practice Information and Co-ordinating Centre (EPPI-Centre), National Institute for Health Research (NIHR), and Scottish Intercollegiate Guidelines Network (SIGN). The selected websites represent internationally recognized organizations that are leaders in evidence-based practice and guideline development. These were chosen for their relevance and authority in the development, evaluation, and dissemination of systems, frameworks, and approaches for assessing the certainty or confidence in evidence.

### *Source of evidence selection*

Following the search, all identified citations will be collated and uploaded into Endnote v.21 (Clarivate Analytics, PA, USA), and duplicates removed. The references will then be uploaded into Covidence (Veritas Health Innovation, Melbourne, Australia) to facilitate the screening process. The screening process will begin with piloting of 10 records, where 2 authors will independently screen a subset of titles and abstracts to ensure consistency. Once the piloting is complete, these 2 authors will independently screen all titles and abstracts against the inclusion criteria.

The full text of selected citations will be assessed in detail against the inclusion criteria by 2 independent reviewers. Reasons for exclusion of full-text studies that do not meet the inclusion criteria will be recorded and reported in the final scoping review. Any disagreements that arise between the reviewers at each stage of the study selection process will be resolved through discussion or with a third reviewer. The results of the search will be reported in full in the final report and presented in a PRISMA flow diagram.

### *Data extraction*

Data will be extracted from included papers using a data extraction table that will be developed by the authors; a draft extraction table is attached in Appendix II. Prior to full data extraction, a piloting phase will be conducted where a subset of papers will be used to test and refine the data extraction table. This piloting will help ensure that the extraction process is clear and consistent. Following piloting, 2 reviewers will independently conduct data extraction using the finalized extraction table. Key data for extraction will include the framework, system, approach name; purpose and scope; modifications or expansions; versions and iterations; theoretical

foundations and key theoretical influences; and description of the methodology used by the system, including criteria, standards, guiding principles, processes, and any specific tools or procedures involved in evaluating the certainty or confidence of the evidence.

Authors of research articles and other sources of literature may be contacted to request additional or missing data, where needed. Each author will be contacted for up to 3 times. If no response is received after these attempts, the review will proceed with the available data, and any missing information will be noted as a limitation.

### *Data analysis and presentation*

Data will be presented using tables and figures that align with the objectives of this scoping review. Tables will be used to organize and summarize key information regarding the identified systems, frameworks, or approaches, including their methodologies, criteria, standards, and guiding principles. Figures may include visual representations of the relationships between different systems or frameworks and their application to various types of evidence (quantitative, qualitative, and mixed methods). A narrative summary will accompany the tabulated data and figures to provide a comprehensive overview of the findings. This summary will highlight key themes and patterns observed across the systems, frameworks, and approaches, such as common methodologies, shared criteria, or guiding principles, and variations in how certainty or confidence is assessed for different types of evidence (quantitative, qualitative, or mixed methods). Additionally, the narrative will propose insights into how these findings can inform the development of a novel system or framework tailored specifically for mixed methods reviews.

### **Acknowledgments**

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### **Author contributions**

LL and CS: conceptualized the manuscript, reviewed the systematic reviews that followed the JBI methodology, and wrote the manuscript. HL, KC, CG, KR, SS, AV, and DP verified the findings and assisted in the writing of the manuscript. CJ, NK and JF assisted in refining the manuscript.

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## Appendix I: Search strategy

*PubMed*

Date searched: December 9, 2024

Search	Query	Results retrieved
#1	"evidence assessment"[Title/Abstract]	610
#2	"certainty of evidence"	5169
#3	"GRADE approach"[All Fields] OR "GRADE approach"[MeSH Terms]	4778
#4	"strength of recommendation"[All Fields]	1132
#5	"ConQual"[All Fields] OR "CerQual"	569
#6	"systematic review"[All Fields] OR "practice guidelines as topic"[MeSH Terms] OR "practice guidelines"[All Fields] OR "evidence synthesis"[All Fields]	525,061
#7	#1 OR #2 OR #3 OR #4 OR #5	9981
#8	#6 AND #7	8987

## Appendix II: Draft data extraction form

Study title	
Author, year of publication	
<b>Framework, system, approach details</b>	
Name of framework, system, approach	
Purpose and scope (eg, assessing quantitative, qualitative, or mixed methods evidence); specific context (eg, for health care only)	
Version or iteration (eg, original version, updated versions, modifications, or expansions)	
Theoretical foundation or influences (eg, philosophical or theoretical underpinnings, key theories, or concepts cited)	
<b>Methodology and processes</b>	
Description of methodology	
Criteria used to assess certainty (eg, rigor, coherence, credibility, consistency, relevance, other criteria)	
Standards or guiding principles	
Tools or procedures involved (eg, checklists, scoring systems, software)	
Specific processes for quantitative evidence	
Specific processes for qualitative evidence	
Specific processes for mixed methods evidence	
<b>Development, testing and adaptation</b>	
Development process (eg, who developed it, how it was conceptualized, methods used in development)	
Validation or testing (eg, studies or efforts to validate, test, or evaluate reliability and validity)	
Adaptation for specific contexts	
<b>Additional notes</b>	
Other relevant information	