JBI MANUAL FOR EVIDENCE SYNTHESIS

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JBI Manual for Evidence Synthesis

Welcome to the new edition of the *JBI Manual for Evidence Synthesis.* This manual guides authors who wish to conduct systematic and scoping reviews following JBI methodologies. Each chapter is devoted to the synthesis of different types of evidence to address different types of clinical and policy-related questions.

JBI is an international evidence-based healthcare organisation that works with 90+ Universities, Health Facilities and NGOs (known as the JBI Collaboration) worldwide. The organisation focuses on improving health outcomes globally by producing and disseminating research evidence, software, training, resources and publications relating to evidence-based healthcare. Learn about the JBI approach to evidence-based healthcare.

JBI and its Collaborating Entities promote and support the synthesis, transfer and implementation of evidence by identifying feasible, appropriate, meaningful and effective healthcare practices to assist in the improvement of healthcare outcomes globally. One of our strengths is in the conduct of systematic reviews that reflect a broad, inclusive approach to evidence and accommodate a range of diverse questions and study designs.

The first three editions of the *JBI Manual for Evidence Synthesis* were published in book format, since 2017 subsequent editions have been published online.

This Manual is presented in an online wiki format to facilitate rapid inclusion of developments and updates to JBI methodologies and methods for evidence synthesis. A PDF version of the *JBI Manual for Evidence Synthesis* is available to download here. The PDF version is updated periodically (see date), however, it may not contain all the latest revisions to the Manual. Users are advised to cross-reference the relevant sections of the PDF with the online manual during the conduct of their review.

Links to previous versions and versions in languages other than English are also provided at the end of this manual for your reference/convenience.

What's New in this Edition?

- Every chapter in this edition is being extensively revised throughout 2024 following a new template to achieve consistency and prevent duplication of effort and material in alignment with instructions for authors prescribed by *JBI Evidence Synthesis*.
- A new table of contents has been added for easier navigation
- Each Chapter now includes a "Resources" section at the end, which includes links to additional publications, videos, and other supplementary materials.
- Methodologies that have interim guidance provided through publications by JBI Methodology Groups now have an "Interim Guidance" section on the Chapter landing page.
- Three chapters have been removed with links provided to external methodological guidance which has been approved for use by the JBI Scientific Committee (namely for systematic reviews of prevalence and incidence; diagnostic test accuracy and measurement properties).
- New information has been included related to Equity, Diversity and Inclusion, Synthesis Prioritization and Living Evidence considerations for evidence syntheses.
- A new section has been added that includes methodological guidance on activity relevant to all syntheses (i.e. searching, languages other than English, knowledge user engagement, and predatory publishing).
- A new section has been added that provides an overview of the development and approvals process for content published in the Manual.

Updates
This version of the *JBI Manual for Evidence Synthesis* includes changes that correspond to the latest methodological developments determined by JBI Methodology Groups and approved by the JBI Scientific Committee, the latest developments in the JBI SUMARI software and feedback from end users.

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1. JBI Systematic Reviews

Contents

1.1 Introduction

Evidence syntheses (systematic and scoping reviews) do not exist in isolation, and it is increasingly acknowledged that they form part of a broader “evidence ecosystem”.[1] Just as in any other complex ecosystem, there are structures and relationships in the global evidence ecosystem that are required to interact and integrate to function coherently and effectively.[2] In this regard, evidence syntheses are now well recognized as a critical component of evidence-based healthcare and evidence-based research, essential to facilitate the trajectory of evidence towards improving future, related activity.

Advances in methodological development over the last three decades have been considerable. This has included a proliferation of new methodologies, methods, tools, and resources to address the many and diverse questions that arise across health science and practice and to synthesize a broad spectrum of evidence types. Alongside these methodological advances, we have also witnessed the development of standards (such as the PRISMA statement and its associated extensions), which have been designed to support authors to transparently report on the conduct of systematic reviews[3] and frameworks (such as GRADE) to rate the certainty of evidence.[4]

While significant progress has been made with evidence synthesis there remain both challenges and opportunities for the global synthesis community. These relate to concerns about research waste and prioritisation;[5] consideration of issues related to equity, diversity, and inclusion;[6] the potential (and risks) of leveraging artificial intelligence and machine learning;[7] the production of “living” reviews;[8] and the development of strategies for co-production and meaningful engagement with a variety of potential end users.[9]

This new edition of the *JBI Manual for Evidence Synthesis* attempts to provide comprehensive guidance to authors not only in relation to a broad spectrum of systematic review methodologies, but also concerning some of the issues highlighted above.

1.1.1 The JBI Approach

JBI has long understood that evidence can take many forms and that policy and practice are influenced by a variety of understandings and sources of evidence related to feasibility,

appropriateness, meaningfulness, and effectiveness.[10, 11] As a result, there are currently eight methodologies for systematic and scoping reviews included in this Manual, as follows:

1. Systematic reviews of qualitative evidence
2. Systematic reviews of effectiveness
3. Systematic reviews of textual evidence
4. Systematic reviews of economic evidence
5. Systematic reviews of etiology and risk
6. Mixed methods systematic reviews
7. Umbrella reviews
8. Scoping reviews

Some of these methodologies are particularly unique to JBI including those that guide the conduct of qualitative reviews and reviews of textual evidence. JBI has maintained a long standing, pluralistic approach to what constitutes evidence reflects the need to synthesize the best available evidence to respond to the diversity of questions from health care and is reinforced by JBI's focus on Feasibility, Appropriateness, Meaningfulness and Effectiveness. [11]

Importantly it should be recognized that systematic reviews constitute an important and legitimate form of scholarly enquiry, underpinned by rigorous and sophisticated units of secondary analysis. The science of synthesis has evolved considerably since its inception more than 30 years ago as has the technology developed to support it. JBI's premier synthesis software, JBI SUMARI (https://sumari.jbi.global/) facilitates the entire systematic review process from protocol to report and includes team and contributor management for effective and efficient collaboration.

1.1.2 Development process

The development process for JBI evidence synthesis methodologies and methods and accompanying guidance is rigorous and regularly reviewed.[11]

The *JBI Scientific Committee* is responsible for oversight of all methodological development, comprising a Chair, a range of ex-officio positions from across JBI programs, regional representation from the JBI Collaboration and JBI methodology groups.

JBI Methodology Groups align to each Chapter presented in this manual, to each unique type of evidence synthesis. Each group comprises a Chair and Convenor who work with experts in the field to develop formal guidance for those wishing to engage in work related to JBI programs. Methodology Groups conduct a wide variety of research activities (surveys, exemplar reviews, pilot studies, workshops) to inform and consolidate guidance. Each group is required to report regularly on progress to the JBI Scientific Committee where issues are raised for discussion and debate.

JBI Working Groups are formed to respond to specific, defined issues (such as predatory publishing) that have broad applicability across the diverse types of reviews presented in this Manual and are time limited.

All guidance contained in this Manual has been ratified by the JBI Scientific Committee prior to publication. New methodologies may be included in the manual if submitted by an appropriate JBI Methodology Group and approved by the JBI Scientific Committee. Manuscripts aligned to the latest developments in methodology and methods presented in this Manual are also published periodically in *JBI Evidence Synthesis*.

1.1.3 External Methodological Guidance

The following external synthesis methodologies have been endorsed for adoption by the JBI Scientific Committee as follows:

Systematic reviews of prevalence and incidence

The PERSyst (Prevalence Estimates Reviews – Systematic Review Methodology Group) is an academic, collaborative group, with the aim to develop and to disseminate methods for systematic reviews of prevalence and cumulative incidence. Methodological articles published by the group can be found here: https://persyst.group/ . Although this is an external methodology JBI's synthesis software, JBI SUMARI, can support reviews of this nature.

Systematic reviews of diagnostic test accuracy

The *Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy* is the official guide that describes in detail the process of preparing and maintaining systematic reviews of test accuracy for Cochrane. The *Handbook* has been produced by the Cochrane Screening and Diagnostic Test Methods Group. It is a guide for those conducting systematic reviews of test accuracy and a reference for more experienced authors and is available at: https://training.cochrane.org/handbook-diagnostic-test-accuracy

Systematic reviews of measurement properties

Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) is an initiative of an international multidisciplinary team of researchers with a background in epidemiology, psychometrics, medicine, qualitative research, and healthcare who have expertise in the development and evaluation of outcome measurement instruments. A comprehensive user manual for systematic reviews of outcomes measurement instruments is available on the COSMIN website: https://www.cosmin.nl/tools/guideline-conducting-systematic-review-outcome-measures/

1.2 Planning a JBI Review

Prior to developing a protocol for your review, some preliminary investigation of the literature is recommended to determine if studies are available on the topic of interest. If you have a strong indication that there are no studies available on your review topic, your energies may be better directed towards a different endeavor than conducting an 'empty' review.

To avoid duplication, reviewers are advised to register their review title (see Section 1.2). It is also recommended that reviewers search major electronic databases to determine that there have been no recently published systematic reviews on the same topic prior to registration of a review title. A search of the Cochrane Database, PubMed/MEDLINE, the PROSPERO registry and Epistemonikos database, as well as our online journal, JBI Evidence Synthesis will assist in establishing whether or not a recent review report exists on the topic of interest. The results of this search should be mentioned in the background of the systematic review protocol and review. If a systematic review on the topic of interest has already been conducted, consider the following questions to establish if continuing with the review topic will be strategic.

- Is it a high-quality, well-conducted systematic review?
- Is there a specific gap in terms of population or intervention outcome that has not been addressed in the identified review?
- Is there new, published evidence related to the topic that will likely reveal a new result or interpretation?

If a systematic review (or protocol) already exists on your topic, think carefully about conducting your review. To reduce duplication and a waste of human resources, it may be best not to conduct your review. However, there may be important reasons why you should still conduct your review. Your inclusion criteria may differ in terms of the population, context, interventions and even study types. Additionally, you may plan to use a different method for searching, critical appraisal and synthesis. In these cases, duplication may be appropriate. The other systematic review may also have some flaws in its conduct and reporting which warrants a new review.

Authors may also wish to consider the technical resources available to them. The conduct of a systematic review is greatly facilitated by access to extensive library and electronic databases and the use of citation management software, as well as software designed specifically to facilitate the conduct of a systematic review such as JBI SUMARI.

When preparing to undertake a systematic review, consideration needs to be given to the human as well as the technical resources needed to complete the review. To maintain the required rigorous standards and alleviate risk of bias in the review process, a JBI review requires a minimum of two reviewers to conduct a systematic review to adequately complete the work to the standards dictated in this Manual. Authors should always consider the submission guidelines before submitting a manuscript to a journal. The skills and expertise required for a systematic review will vary depending on the nature of the review being undertaken and the methodology utilized. It is therefore recommended that a JBI systematic review is conducted by a team comprising of individuals who possess the skills and knowledge required to conduct the review to a standard acceptable for publication in an international scientific periodical.

Depending upon the type of review being conducted, review teams should ideally consist of members with:

- Knowledge of general JBI systematic review methodology such as formulating a review question, defining inclusion criteria and critical appraisal.
- An information scientist or research librarian with specialized skills to develop and implement a comprehensive search strategy.
- Specific methodological expertise required for the type of review being undertaken, for example, knowledge of the statistical methods to be used, experience in qualitative synthesis, or experience with economic analyses for economic evaluations.
- Knowledge of the topic area. Representation from relevant knowledge user groups (for example, clinicians, patient representatives, researchers, policy makers) is recommended, particularly where the review is being undertaken by systematic reviewers/methodologists rather than topic experts.
- The ability to write a report in English to a publishable standard.

From the outset, the review team should consider expected contributions to the review project and eventual authorship. Some members of the review team may be better recognized in the acknowledgements of the published report rather than as authors (see ICMJE criteria); their specific contribution should be provided, as well as their name. Conversely, part of the review team may be formally organized as a “Review Panel”, where some of the individuals with the attributes listed above provide formal advice and oversight throughout the conduct of the review including reviewing the draft protocol and final manuscript submissions or providing specific insight into the interpretation of data and formulating recommendations for practice and research for example. The names, contact details and areas of specialty of each member of the review panel should be included in both the protocol and the report.

1.3 The review protocol

Preparation of review protocol is an essential step in the conduct of any JBI systematic or scoping review. Publication of a review protocol in a peer reviewed journal is not essential however, a protocolmustbe completedand made publicly available, *prior*to the conduct and publication of the systematic or scoping review.

Itis important to acknowledge and justify all deviations from the protocol in the review manuscript. The reporting guidelines in thePRISMA-P statement are a useful resource for authors to ensure required details are being reported in their protocol, as are the templates available in the JBI SUMARI software. While preparing the review protocol authors should commence the process to register their work (see section 1.4).

1.4 Registering a review

JBI Systematic review authors must register their review. This enables other reviewers to identify reviews that are currently underway and helps to avoid unnecessary duplication of research.

JBI requires that protocols of eligible review projects are registered with PROSPERO, the international prospective register of systematic reviews prior to the conduct and publication of the review. The systematic review should include the registration number provided by PROSPERO as well as the reference to the published protocol at the beginning of the 'Methods' section of the review report. Scoping reviews cannot be registered in PROSPERO; other research servers such as Open Science Framework, provide a ready platform for both registration as well as to provide access to pertinent data.[12] Registration records, either in PROSPERO or on another registry or server should be updated if changes are made to the project and as the review project progresses towards completion.

Members of the JBI Collaboration can register their review titles with JBI via completion of the online Systematic Review Title Registration Form. Once titles become registered with JBI, they are listed on the website. Titles are subsequently removed when the full protocol is publicly available, either published or posted to an accessible website.

1.5 Publishing a JBI systematic review

Authors should consider where they plan to submit their systematic review for publication from the outset. Systematic reviews that adhere to JBI methodology are published in many international peer-reviewed journals. JBI has two multi-disciplinary international journals that publish JBI systematic reviews: JBI Evidence Synthesis and JBI Evidence Implementation. Both journals are published by Wolters Kluwer Health/Lippincott Williams and Wilkins. The target audience for JBI systematic reviews are academics and health professionals from across the health disciplines, including nurses, doctors, allied health professionals, managers, administrators, and decision-makers in healthcare. The JBI journals accept submissions of all systematic review types that are presented in this Manual and scoping reviews that align to the scope of each journal.

1.6 Reporting and conduct standards

Reporting standards like those produced for primary research designs (CONSORT, STROBE etc) have also been prepared for systematic reviews. The PRISMA 2020 statement,[3] or Preferred Reporting Items for Systematic Reviews and Meta-Analyses provides a 27 item checklist for review authors on how to report a systematic review and systematic review abstract. JBI endorses the PRISMA statement. An extension to the PRISMA statement, PRISMA-P, outlines standards for systematic review protocols,[3] while an extension to the PRISMA statement PRISMA-ScR provides reporting standards for scoping reviews. Both are similarly endorsed by JBI.

Review authors should follow the *JBI Evidence Synthesis* author guidelines or the guidelines of other journals they are submitting to. Many journals will require a completed PRISMA checklist to be submitted with the review manuscript.

Beyond the Chapters in this Manual that provide guidance for the conduct of different types of systematic reviews, other useful guidance also exists for the conduct of systematic reviews from other groups such as the Centre for Reviews and Dissemination (CRD), GRADE, Cochrane, EPPI-

Centre, the Agency for Healthcare Research and Quality (AHRQ), reporting initiatives in the EQUATOR network, and the Institute of Medicine (IOM).

1.7 Disclosures and contributions

Transparency regarding contributions of individuals and organizations, perceived conflicts of interest and sources of funding aligned to any published research also apply to JBI systematic reviews and should be presented under their own subsections.

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Authors should provide details regarding any sources of funding for the review project. The role of all funders in the review process, if any, should be explicitly described. If the review is funded, then any potential conflicts of interest or intellectual bias of the funders should be specified in the review and the protocol.

Conflict of interests

All review authors should disclose any potential conflict of interest or any professional or intellectual bias. A statement should be included which declares the absence of any conflicts of interest and which describes a potential conflict of interest for authors for whom it has arisen. If consumers or other stakeholders assisted the authors with regards to the completed work, any potential conflict of interest or intellectual bias should be disclosed.

The review team should provide details regarding the management of any such conflicts or biases.

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2. Methodological considerations

This section includes guidance that is relevant to all types of systematic and scoping reviews. It is developed by working groups comprising experts from across JBI's global evidence network that report to the JBI Scientific Committee.

Contents

2.1 Equity, Diversity, and Inclusion

Equity, Diversity, and Inclusion (EDI) are at the core of JBI's vision, mission, model for evidence-based healthcare and global community spanning more than 40 countries. JBI encourages authors to consider Equity, Diversity and Inclusion in the planning and conduct of systematic and scoping reviews. Further information and guidance, including checklists, regarding Equity, Diversity and Inclusion in evidence syntheses can be found in Chapter 16 of the Cochrane Handbook as follows:

Welch VA, Petkovic J, Jull J, Hartling L, Klassen T, Kristjansson E, Pardo Pardo J, Petticrew M, Stott DJ, Thomson D, Ueffing E, Williams K, Young C, Tugwell P. Chapter 16: Equity and specific populations. In: Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, Welch VA (editors). *Cochrane Handbook for Systematic Reviews of Interventions* version 6.4(updated August 2023). Cochrane, 2023. Available from http://www.training.cochrane.org/handbook .

Additional resources can be found on the https://methods.cochrane.org/equity/projects/evidence-equity/progress-plus , including the PROGRESS-Plus tool to identify characteristics that stratify health opportunities and outcomes.

Individual chapters in this manual may also include information and guidance specific to the methodology and consideration of issues related to EDI including but limited to the Qualitative methodology chapter.

2.2 Synthesis Prioritization

JBI encourages authors to consider both local and global priorities when determining knowledge needs for evidence syntheses. Typically, local priorities are more frequently addressed and are determined in collaboration with policymakers, health services and knowledge users. As per the https://jbi.global/jbi-model-of-EBHC , it is asserted that this context-driven approach is more likely to result in successful implementation and sustainable impact.

However, we also encourage authors to consider alignment with global priorities such as the https://sdgs.un.org/goals (SDGs) as part of their topic prioritization process. It is incumbent all of those who contribute to the global evidence ecosystem to avoid duplication of effort and research waste, to address global health challenges and to advance global health outcomes, which form a critical part of our vision and mission; we encourage authors to embrace similar values towards the conduct of their work. Further information regarding the role of evidence syntheses in addressing SDGs can be located here: https://www.sdgsynthesiscoalition.org/

2.3 Living Evidence

Living evidence is an approach that requires the production of evidence syntheses, guidelines and policy briefs that are continually updated to incorporate new, relevant evidence as it becomes available. There is an increasing impetus for the adoption of this approach whereby policymakers, researchers and other knowledge users work in partnership addressing priority topics. While there are challenges to be overcome there are also opportunities. If you and your review team are interested in knowing more about living evidence syntheses, we encourage you to explore the following resources:

https://www.aliveevidence.org/

https://community.cochrane.org/review-development/resources/living-systematic-reviews

2.4 Searching – COMING SOON

This guidance is currently under development by the relevant JBI Working Group.

2.5 Languages Other Than English – COMING SOON

This guidance is currently under development by the relevant JBI Working Group.

2.6 Knowledge User Engagement – COMING SOON

This guidance is currently under development by the relevant JBI Working Group.

2.7 Predatory Publishing – COMING SOON

Interim guidance related to the inclusion of studies from predatory journals in systematic review can be found here:

Munn, Z; Barker, T; Stern, C; Pollock, D; Ross-White, A; Klugar, M; Wiechula, R; Aromataris, E; Shamseer, L. Should I include studies from “predatory” journals in a systematic review? Interim guidance for systematic reviewers. *JBI Evidence Synthesis* 19(8):p 1915-1923, August 2021. | DOI: 10.11124/JBIES-21-00138

3. Systematic reviews of qualitative evidence

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Contents

3.1 Introduction and purpose of this guidance

Methodological development for quantitative systematic reviews of effects has broad scientific consensus, however the same cannot be said across the field qualitative synthesis. In qualitative synthesis, the normative features ascribed to systematic reviews of quantitative data have been challenged, adopted, rejected, or transposed to different extents into analogous concepts and methods more attune to the nuances of the critical and interpretive research paradigms.

The purpose of this chapter is to provide the rationale, methodology and methods for meta aggregation as an approach to qualitative synthesis. Its developmental history is grounded in philosophic perspectives with the needs and expectations of evidence to inform health care decision-making. Meta aggregation is a method that mirrors the accepted conventions for systematic review whilst holding to the traditions and requirements of qualitative research (it aggregates findings in to a combined whole that is more than the sum of the individual findings in a way that is analogous with meta analysis).

3.2 Introduction to qualitative evidence and evidence-based healthcare

Introduction

This section provides an introductory perspective on qualitative synthesis, the relationship between evidence, qualitative evidence and health care practice and sets out a framework for considering the philosophic traditions associated with forms of research. A brief outline of some of the debates regarding qualitative synthesis is presented, although not with the intent of comprehensively addressing the significant variety of positions, but rather to assist in situating meta aggregation (the JBI approach to qualitative synthesis) as a methodology and where it sits within the wider debates. Importantly, key operational assumptions have been included in this section, as have the definitions of core terms for the process of extracting and synthesizing qualitative data. These definitions inform meta aggregation and represent a distinctive difference from other methods of qualitative synthesis that rely on the reviewer to re-interpret literature. The term meta aggregation is the formal name of the methodology, however, aggregative review, aggregative synthesis or meta synthesis are used interchangeably in this manual.

What is qualitative research?

Qualitative evidence or qualitative data allows researchers to analyze human experience and cultural and social phenomena (Jordan 2006). Qualitative evidence has its origins in research methods from the humanities and social sciences and seeks to analyze the complexity of human phenomena in naturalistic settings and from a holistic perspective (Ailinger 2003). The term ‘qualitative’ refers to various research methodologies including ethnography, phenomenology, qualitative inquiry, action research, discourse analysis and grounded theory. Research methods include interviews, whether group or individual and observation (either direct or indirect). Researchers who use qualitative methodologies seek a deeper understanding, aiming to “study things in their natural setting, attempting to make sense of, or interpret, phenomena in terms of the meanings people bring to them” (Denzin 2005).

In the healthcare or medical context, qualitative research:

“...seeks to understand and interpret personal experiences, behaviors, interactions, and social contexts to explain the phenomena of interest, such as the attitudes, beliefs, and perspectives of patients and clinicians; the interpersonal nature of caregiver and patient relationships; the illness experience; or the impact of human suffering”. (Wong and Haynes 2004).

Qualitative evidence has a particular role in exploring and explaining why interventions are or are not effective from a person centered perspective, and address questions related to the usability, meaningfulness, feasibility and appropriateness of interventions. Similarly, qualitative evidence is able to explain and explore why an intervention is not adopted in spite of evidence of its effectiveness (Black 1994). The strength of qualitative research lies in its credibility (i.e. close proximity to the truth), using selected data collection strategies that “touch the core of what is going on rather than just skimming the surface” (Greenhalgh 1997).

Qualitative Evidence and Healthcare

Qualitative methods and data are increasing in usage in evidence-based healthcare research. Instead of quantifying or statistically portraying the data or findings, qualitative research focuses on individuals and gives voice to the patient/client or provider in the healthcare decision-making

process. As an example, the question: ‘What proportion of smokers have tried to give up?’ leads to statistical answers while the question ‘Why do people continue to smoke?’, leads the researcher into exploring the ideas and concerns people who smoke tobacco may have about their smoking habits (Greenhalgh 1997).

Qualitative research is undertaken because it:

“...has an important role in evidence-based health care, in that it represents the human dimensions and experiences of the consumers of health care. This type of research does not answer questions concerning the effectiveness of health care; rather it provides important information about such things as the appropriateness of care and the impact of illness. It also provides a means of giving consumers a voice in the decision-making process through the documentation of their experiences, preferences, and priorities...” (Evans 2002).

Qualitative research plays a significant role in understanding how individuals and communities perceive health, manage their own health and make decisions related to health service usage. It can assist to understand the culture of communities, in relation to implementing changes and overcoming barriers. It can also inform planners and policy makers about the manner in which service users experience health as well as illness, and can be used to evaluate activities of health services such as health promotion and community development.

Acknowledgement of the contribution that qualitative research findings make in improving the quality and relevance of healthcare conditions is increasing. As an example, *Systematic reviews. CRD's guidance for undertaking reviews in health care* published by the Centre for Reviews and Dissemination at the University of York states that ‘There is growing recognition of the contribution that qualitative research can make to reviews of effectiveness’ as it helps to develop an understanding of the people, the practices and the policies behind the mechanisms and interventions (CRD 2009).

Qualitative evidence comprises data that is expressed in terms of the meaning or experiences of acts or events rather than in terms of a quantitative measurement. (Barbour 1999, Moffatt et al. 2006, Forman et al. 2008) Arguably one of the best features of its contribution to research inquiry lies in its stories and accounts of living and its richness of meanings within its words (Forman et al. 2008).

Philosophical perspectives, research methodologies and methods

A philosophical perspective encompasses our assumptions of the theory and the research methodologies that guide research. There are three prevailing philosophical or guiding paradigms in current western health care research. The first is the positivist – or empirico- analytical –paradigm, often associated with quantitative evidence (see Chapter 3) while the other two, the interpretive and critical paradigms, are largely associated with qualitative evidence. In the interpretive paradigm, theory is inductive and concerned with exposing implicit meaning; it aims at understanding. The critical paradigm, like the interpretive, is inductive, however it aims to emancipate knowledge and practice. Each paradigm is encompasses a diversity of research methodologies and methods (methods being the specific approach to data collection).

An outline of the key research methodologies and methods associated with the interpretive and critical paradigms is shown in Table 2.1.

Table 2.1: A summary of qualitative philosophy, methodologies and methods.

	Methodologies	**Data Collection Methods**
Interpretivism *Seeks to understand. Sees knowledge in the possession of the people.*	**Phenomenology** Seeks to understand people’s individual subjective experiences and interpretations of the world. **Ethnography** Seeks to understand the social meaning of activities, rituals and events in a culture. **Grounded Theory** Seeks to generate theory that is grounded in the real world. The data itself defines the boundaries and directs development of theory.	Interviews. Focus groups Observations. Field work. (Observations, Interviews) Interviews.Field observations. Purposeful interviews Textual analysis.

Critical enquiry *Seeks to change.*	**Action research** Involves researchers participating with the researched to effect change. **Feminist research** Seeks to create social change to benefit women. **Discourse Analysis** assumes that language socially and historically constructs how we think about and experience ourselves, and our relationships with others.	Participative group work Reflective Journals. (Quantitative methods can be used in addition to qualitative methods). Qualitative in-depth interviews. Focus Groups. (Quantitative methods can be used in addition to qualitative methods). Study of communications, written text and policies.

3.3 Introduction to qualitative systematic reviews

There is no hierarchy of evidence among methodologies for qualitative studies. A meta aggregative systematic review does not require any distinction between critical or interpretive studies. The units of analysis sought from qualitative papers are the findings, presented as themes, metaphors or concepts as identified by the researchers (not the reviewer). Accordingly, meta aggregative reviews include a range of methodological studies in order to capture the whole of a phenomenon of interest, rather than merely a one dimensional aspect. The rationale for this is that the traditions of the methodology employed in a study are considered to be embedded within the findings, rather than distinct to the findings. This implies that when a finding is extracted, the perspective or context that the study author intended for the finding is not lost, but is embedded in the extraction.

The synthesis of qualitative data

The perspectives of primary qualitative researchers has had a significant impact on development of methods for qualitative synthesis. It has been proposed that this may in part due to the fact that primary qualitative researchers conceive of paradigms as emblematic of their ability to situate not only themselves but also their work in relation to knowledge generation. As Chin and Jacobs (1987) assert, knowledge as subjective truth requires a researcher or author to explicitly state their chosen paradigm as it has implications for how a reader will understand the written word and how the methodology and methods will be read and understood.

This is no less appropriate in qualitative synthesis. Indeed, Sandelowski and Barroso (2007), although reluctant to create or promulgate rules for qualitative synthesis, posit that the first rule (if any should exist) is that the methods of synthesis should not violate the philosophic foundations (i.e. paradigm) of the approach used. It is evident then that while synthesis is a different process to primary research, the principles and processes of qualitative synthesis must be sensitive to the core assumptions of the critical and interpretive paradigms. The synthesis of qualitative data is also contested among qualitative researchers themselves, based on philosophical and methodological differences between the different qualitative research approaches (Sandelowski et al. 1997, Thorne et al. 2004).

Of the views that characterize the ongoing debate surrounding the meta-synthesis of qualitative evidence, one area of focus is the perceived degree of ‘interpretiveness” of the approach to data analysis. There has been extensive debate in the literature as to what constitutes an’interpretive’ review, and whether some qualitative synthesis approaches are more or less interpretive than others. These debates tend to focus on the synthesis component of the systematic review, and attempt to classify the whole of a review methodology on the basis of whether the synthesis component can be labelled as either ’inductive’ or ’deductive’. A further issue is whether qualitative synthesis methodologies should fit within the accepted conventions for systematic review or whether qualitative synthesis methodologies should be more reflective of primary qualitative methodologies. Approaches to qualitative synthesis that are more aligned with primary qualitative methodologies may not require reviewers to undertake comprehensive searching, appraisal to establish quality is not considered important, and data extraction and synthesis may be iterative and based upon the re-interpretation of published data.

3.4 The JBI Approach to qualitative synthesis

JBI uses a meta-aggregative approach to the synthesis of qualitative evidence. Meta aggregation is sensitive to the nature and traditions of qualitative research while being predicated on the process of systematic review (Pearson 2004). The meta-aggregative approach is sensitive to the practicality and usability of the primary author’s findings and does not seek to re-interpret those findings as some other methods of qualitative synthesis do. A strong feature of the meta-aggregative approach is that it seeks to enable generalizable **statements in the form of recommendations to guide practitioners and policy makers** (Hannes and Lockwood 2011). In this regard, meta

aggregation contrasts with meta-ethnography or the critical interpretive approach to qualitative evidence synthesis, which have a focus on re-interpretation and theory generation rather than aggregation.

JBI recognizes the usefulness of alternate interpretive approaches such as meta-ethnography, as well as narrative synthesis and thematic synthesis. By way of illustration:

- the usefulness of meta- ethnography lies in its ability to generate theoretical understandings that may or may not be suitable for testing empirically,
- narrative synthesis of text is useful in drawing together different types of research evidence (e.g. qualitative, quantitative, economic), and
- thematic synthesis is of use in drawing conclusions based on common elements across otherwise heterogeneous studies.

JBI considers, however, that these approaches do not seek to provide guidance for action and aim only to 'anticipate' what might be involved in analogous situations and to understand how things connect and interact. Meta-aggregation is the preferred JBI approach for developing recommendations for action. The JBI SUMARI software is designed to facilitate meta-aggregation, however it can also be used successfully in meta-ethnography and other interpretive processes as a data management tool.

The core assumptions detailed in subsequent sections of this Chapter include:

- The requirement for an *a priori* protocol that describes all steps in the review, decisions on how they will be undertaken and appends all templates that will be used during the review;
- Comprehensive and exhaustive searching, independent critical appraisal and standardised data extraction;
- Synthesis of findings that authentically represents the aggregation of data from primary studies;
- Presentation of a meta-aggregative schematic that represents the findings and their aggregation in to categories, and the aggregation of categories in to synthesized findings; and
- The development of recommendations for policy or practice with assigned grades of recommendation.

3.5 Core definitions in meta-aggregative reviews

The operational definitions that characterize meta-aggregation describe the data to be synthesized, and explain what each step looks like.

Finding:

- A finding is a verbatim extract of the author's analytic interpretation of their results or data.

In undertaking the synthesis component of a meta-aggregative review, each finding that is extracted from a paper is accompanied by an illustration.

An illustration is defined as

- A direct quotation of a participant's voice, field-work observation or other supporting data from the paper.

For each extracted finding, a level of credibility is allocated, and this is completed in JBI SUMARI as the data for the finding and its accompanying illustration are entered. Levels of credibility are described in Section 2.7 of this chapter.

Category:

A category is a brief description of a key concept arising from the aggregation of two or more like findings and is accompanied by an explanatory statement that conveys the whole, inclusive meaning of a group of similar findings.

When two or more findings are combined to form a category, a category description is also created. A category description is defined as:

- An explanatory statement that conveys the whole, inclusive meaning of a group of similar findings.

A category illustration is developed by the review team, it is an explanatory statement that conveys the whole inclusive meaning of a group of similar findings.

Synthesized finding:

A synthesized finding is an overarching description of a group of categorized findings. Synthesized findings are expressed as 'indicatory' statements that can be used to generate recommendations for policy or practice.

As with categories, a description is created for each synthesized finding. The description for a synthesized finding is defined as:

- An explanatory statement that conveys the whole, inclusive meaning of a group of similar categories

These core definitions are the basis of meta aggregation and represent a goodness of fit with systematic review that is much closer than many other qualitative approaches to synthesis.

3.6 Developing a qualitative review protocol

This section outlines the components of a systematic review protocol of qualitative evidence and provides guidance on the information that each component should contain. Specifically, it provides guidance on each of the following components: title, review objectives/questions, background, inclusion criteria, search strategy, critical appraisal, data extraction, data synthesis, narrative summary, references, and appendices.

3.6.1 Title of a qualitative review protocol

The title should be informative and give clear indication of the topic of the review. Titles should not be phrased as questions and there should be congruency between the title, review objectives/questions and inclusion criteria. The title of the protocol should be structured and reflective of the core elements of the PICo (see section 2.6.2 Review question). The title should always include the phrase "...: a qualitative systematic review protocol", for example, to allow easy identification of the type of document it represents. A JBI review requires at least two reviewers. The names of all reviewers, affiliations for each author including their JBI centre affiliations and email address for the corresponding author should be included.

3.6.2 Review question

Clarity in the review questions assists in developing a protocol and also ultimately, the conduct of the review proper. The review question/s guide and direct the development of the specific review criteria and facilitate more effective searching, and provides a structure for the development of the full review report. Although a range of mnemonics have been described for different types of review (and research) questions, for a JBI qualitative synthesis, the PICo mnemonic also be used to construct a clear and meaningful question for a JBI systematic review of qualitative evidence. The PICo mnemonic stands for the Population, the Phenomena of Interest and the Context. There is no need for an outcome statement in qualitative synthesis (see Chapter 3). The expression of the phenomena of interest represents the outcome, therefore a specific outcome section or statement is not recommended in meta aggregation.

The review question and PICo mnemonic can provide potential readers with a significant amount of information about the focus, scope and applicability of a review to their needs. It should be apparent if the review is examining meaning or lived experience or a specific phenomena of interest is to be examined. Similarly, including the context in the question assists readers to situate the review.

A qualitative review will have a primary question. If that question sufficiently addresses the review objectives, there is no need for secondary or sub questions. However, as per the illustrations below, some questions benefit from one or more sub questions that delve into particular attributes of context, population or phenomena of interest.

For example, the primary question (aligned directly to the objective) below relates to the nursing profession, however, the sub questions delve into the particular issues related to professionally trained nurses and student nurses as distinct sub populations (Rittenmeyer et al. 2012):

- *What are the experiences of lateral or horizontal violence in the profession of nursing?*
- *What is the experience of lateral or horizontal violence for professional nurses?*
- *What is the experience of lateral or horizontal violence for student nurses?*

In this example, the PICo elements can be readily identified: the Population of interest are nurses, professional or student. The Phenomenon of interest is their experience with lateral or horizontal violence and the context, which has not been explicitly stated in the question in this case may be in tertiary care or in the health system of a particular country for example.

3.6.3 Introduction

Every systematic review requires a clear and meaningful introduction section. Given the international circulation of systematic reviews, it is important to state variations in local understandings of clinical practice (including ‘usual practice’), health service management and client or patient experiences. The introduction should describe and situate the phenomena of interest under review, as well as the population and context. The introduction should cover the main elements of the topic under review. The purpose of the introduction is to:

- situate the PICo and put the inclusion criteria into context,

- provide context to the review
- define key terms and list operational definitions
- refer to existing international literature to support and inform the inclusion criteria,
- provide indication that the review question has not been addressed previously, and
- justify the rationale and conduct of the review.

The introduction should avoid synthesizing findings from multiple authors given this is exactly what your review will aim to achieve, it should however, provide some indication that there is evidence available that will be included in your review and inform your question.

As mentioned above, the introduction should include a statement that a preliminary search for existing systematic reviews on the topic has been conducted (state the sources searched e.g. *JBI Evidence Synthesis*, Cochrane Database, CINAHL, PubMed, PROSPERO where relevant). If there is an existing systematic review, it should be specified how the proposed review will differ.

The introduction should conclude with an overarching review objective that captures and aligns with the core elements/mnemonic of the inclusion criteria (e.g. PICo). The stated objective should clearly indicate what the review project is trying to achieve. For publication in *JBI Evidence Synthesis*, all references should be listed in full using the Vancouver referencing style, in the order in which they appear in the review. Abbreviated journal titles must be used in accordance with the United States National Library of Medicine.

3.6.4 Inclusion criteria

This section of the protocol details the basis on which studies will be considered for inclusion into the systematic review and should be as clear and unambiguous as possible. The inclusion criteria for a review are not designed to applied independently of each other, therefore each should be presented as mutually exclusive criteria and repetition between elements of the PICo is not necessary.

3.6.4.1 Types of participants

There needs to be a clear and direct link between the review question, title and the participant characteristics in the inclusion criteria.

For example, the population characteristics for conservative treatment for men may consider:

- Age ranges (18-75)
- Sex (male)
- A diagnosis of prostate cancer (diagnosed within the last six months, either new, or recurrent disease)
- Staging of severity of prostate cancer (I-IV)

The population should be clearly described and avoid ambiguity that may confound study selection.

Specific exclusion based on any participant or population characteristics should also be articulated in this section. In this example, patients with secondary tumor or metastasized cancer will be excluded.

3.6.4.2 Phenomena of interest

There should be congruence between the review question, title and the phenomena of interest.

In the example of men diagnosed with prostate cancer, the phenomena of interest are their experiences with receiving conservative treatment. Details of the treatment in this case should have been well defined in the background section, though maybe reiterated briefly here as a guide for the study selection phase of the review when these criteria will be applied.

3.6.4.3 Context

In a qualitative review, context will vary depending on the objective and question(s) of the review. Context may include but is not limited to consideration of:

- cultural or sub-cultural factors,
- geographic location,
- specific racial or gender based interests, or
- detail about the specific setting (such as acute care, primary health care, or the community).

There is no requirement for an outcome statement in qualitative reviews as the expressed phenomena of interest is the outcome.

3.6.4.4 Types of studies

There should be a match in this section between the methodology of the primary research studies to be considered for the review and the review question.

The JBI SUMARI software offers standardized text consisting of statements regarding the types of studies considered for inclusion in a meta aggregative review. Any of the following 3 options provide an appropriate structure for a qualitative review:

- Option 1: This review will consider studies that focus on qualitative data including, but not limited to, designs such as phenomenology, grounded theory, ethnography, action research and feminist research.
- Option 2: This review will consider interpretive studies that draw on the experiences of <insert text> with <insert text> including, but not limited to, designs such as phenomenology, grounded theory, ethnography, action research and feminist research.
- Option 3: This review will consider critical studies that explore <insert text> including, but not limited to, designs such as action research and feminist research.

As can be seen from the three set text options above, creating a protocol for an interpretive or critical or generalist systematic review depends on the nature of the question being addressed. Interpretive reviews are conducted to aggregate evidence related to social interactions that occur within health care, or seek to establish insights into social, emotional or experiential phenomena. Critical reviews might be conducted to explore issues such as power or change. A critical *and* interpretive review might be conducted to bring both elements together.

A narrow approach in terms of focusing solely on either interpretive or critical designs alone is not recommended unless there is a clear, rationale and theoretically informed requirement to do so. The international consensus is heavily in favor of inclusive reviews of literature across both the critical and interpretive paradigm.

3.6.4.5 Example inclusion criteria

How the PICo elements of a review question are presented in the inclusion criteria is illustrated below on this example taken from Rittenmeyer and colleagues (2012) addressing the objective of nurses experiences with lateral and horizontal violence (see Section 2.6.2).

Inclusion Criteria

Types of Participants

This review will consider studies that include licensed nurses and student nurses. For purposes of this review 'licensed nurse' refers to a nurse who holds a license to practice nursing at any level. Due to the ambiguity of nomenclature, different titles for licensed nurse will be considered, including but not limited to registered nurse, practical nurse, vocational nurse.

Phenomena of Interest

The phenomenon of interest for this review is the actual experience of horizontal/lateral violence.

Context

This review will consider any setting where licensed or student nurses practice.

Types of studies

This review will consider studies that focus on qualitative data including, but not limited to, designs such as phenomenology, grounded theory, ethnography, and action research. Descriptive qualitative studies that describe the experience or describe the effects of the experience will also be considered.

3.6.5 Search strategy

This section details how the reviewers plan to search for and locate relevant studies. The process describing searching has been standardized in JBI SUMARI and is illustrated below. A systematic review should consider papers published by both commercial and academic publishers as well as grey literature. Rather than compete with the published literature, grey literature has the potential to complement and communicate findings to a wider audience. Grey or Gray literature is also known as Deep or Hidden Web material may include: Theses and Dissertations, Reports, blogs, technical notes, non-independent research or other documents produced and published by government agencies, academic institutions and other groups that are not distributed or indexed by commercial publishers. Systematic literature searching for qualitative evidence presents particular challenges. Some databases lack detailed thesaurus terms either for qualitative research as a genre or for specific qualitative methods. Additionally, changes in thesaurus terms mean that reviewers need to be cognizant of the limitations in each database they may use. The help of an experienced research librarian/information scientist is recommended.

The time frame chosen for the search should be justified and any language restrictions stated (e.g. only studies published in English will be considered for inclusion). The databases to be searched

must be identified listed, including the search platform used where necessary, along with a completed search strategy for one major databases which should be presented as Appendix I of the review protocol.

The search strategy is described as a three-phase process:

Phase one consists of two steps:

1. the identification of initial key words based on knowledge of the field to perform an initial search where the reviewer creates a logic grid of key words from titles and abstracts; and
2. the analysis of text words contained in the titles and abstracts of papers, and of the index terms used in a bibliographic database to describe relevant articles in order to build comprehensive and specific search strategy for each included database.

Phase two involves implementing database-specific searches for each database included in the protocol.

Phase three involves the review of the reference lists of all studies that are retrieved for appraisal to search for additional studies.

The process describing searching has been standardized in SUMARI as follows:

The search strategy will aim to find both published and unpublished studies. An initial limited search of MEDLINE and CINAHL has been undertaken followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe article. This informed the development of a search strategy which will be tailored for each information source. A full search strategy for #name the relevant database# is detailed in Appendix 1. The reference list of all studies selected for critical appraisal will be screened for additional studies.

Information sources:

The databases to be searched include:

Insert databases here

The search for unpublished studies will include:

Insert sources here

This standardized text is editable, and includes fields for reviewers to specify content relevant to their available resources. As mentioned, reviewers are required to state the databases to be searched and, if including unpublished studies, what sources will be accessed. An additional paragraph that addresses whether hand searching will be conducted, which sources will be subject to hand searching (e.g. the searching of journals that are not indexed in electronic databases), should be added to the review protocol as part of Phase 2 if required. The search strategy should also describe all limitations to the scope of searching in terms of dates, resources to be accessed or languages. Each of these may vary depending on the nature of the topic being reviewed, or the resources available to the review team.

Limiting by date:

Limiting the search by date may be used where the focus of the review is on a more recent intervention or innovation. However, potentially relevant studies as well as seminal, early studies in the field may be missed if the limit set is too recent thus date limits should be used in an informed way, based on knowledge of key papers relevant to the review question that must be cited to provide evidence for the decisions made to limit the search.

Limiting by resources accessed:

Limiting the search to a small number of databases is a hot topic in systematic review searching. The validity of systematic reviews relies in part on access to an extensive range of electronic databases for literature searching. There is inadequate evidence to suggest a particular number of databases, or even to specify if any particular databases should be included. The comprehensiveness of searching and the documentation of the databases searched is a core component of the systematic review's credibility.

Limiting by language:

Limiting by language is a common practice in settings with lack of ready access to translators. The caveat associated with excluding papers based upon language is that important cultural contexts or findings may be missed. The exclusion of selected languages also means the review audit trail is incomplete. If limiting by language is required, it is preferable to search inclusively, and keep a record of numbers of studies per language group. This allows the reader to identify how many studies have been identified, but are not included, therefore promoting transparency in the process.

Alternatively, many papers in languages other than English are abstracted in English, from which reviewers may decide to retrieve the full paper and seek to collaborate with other entities regarding translation.

Therefore, literature searching should be based on the principle of comprehensiveness, with the widest reasonable range of databases that are considered appropriate to the focus of the review.

3.6.6 Assessment of methodological quality

Qualitative studies that are eligible for inclusion in the review must be assessed for methodological quality. There are a variety of checklists and tools available to assess research syntheses and systematic reviews. Most checklists use a series of criteria that can be scored as being “met” or “not met” or “unclear” and in some instances as “not applicable”. The decision as to whether or not to include a study can be made based on meeting a pre-determined proportion of all criteria, or on certain criteria being met. It is also possible to weight certain criteria differently. Decisions about a scoring system or any cut-off for exclusion should be made in advance and agreed upon by all reviewers before critical appraisal commences. The protocol, therefore, should detail how selected studies will be assessed for quality, e.g. use of a predetermined cut off score.

All included studies need to be critically appraised using the standard JBI critical appraisal instrument for qualitative research that is available in Appendix 3.1 of this chapter (further details regarding the appraisal questions can be found in Appendix 3.2). The assessment criteria are built into JBI SUMARI. The tool is designed to be used with two independent reviewers conducting the critical appraisal of each research synthesis selected. Reviewers are blinded to each other’s assessment and assessments can only be compared once initial appraisal of an article is completed by both reviewers. Where there is a lack of consensus, discussion between reviewers should occur. In some instances it may be appropriate to seek assistance from a third reviewer. The source of the JBI critical appraisal tool for research syntheses should be cited in the protocol.

NB: If the best available evidence for your question is narrative text, expert opinion or policy rather than qualitative research, these studies should be analysed using the text and opinion module of JBI SUMARI. Such reviews become a JBI Textual Evidence Review (see 5. Systematic Reviews of Textual Evidence) rather than a qualitative review of evidence, and therefore the review title, question and criteria should be reviewed against the expectations of a textual evidence review.

3.6.7 Data extraction

Standardized data extraction tools promote the extraction of similar data across all of the included studies and are required for JBI systematic reviews. The protocol should detail what data the reviewers plan to extract from the included studies and the data extraction tool should be appended to the protocol (see Appendix 3.3). The set text from SUMARI describes this process:

Qualitative data will be extracted from papers included in the review using the standardized data extraction tool from JBI SUMARI by two independent reviewers. The data extracted will include specific details about the populations, context, culture, geographical location, study methods and the phenomena of interest relevant to the review question and specific objectives. Findings, and their illustrations, will be extracted and assigned a level of credibility.

3.6.8 Data synthesis

The protocol should also describe how the findings extracted from the included studies will be synthesized. Qualitative research findings should be pooled using JBI SUMARI as per the set text below:

Qualitative research findings will, where possible be pooled using JBI SUMARI with the meta-aggregation approach. This will involve the aggregation or synthesis of findings to generate a set of statements that represent that aggregation, through assembling the findings and categorizing these findings on the basis of similarity in meaning. These categories are then subjected to a synthesis in order to produce a single comprehensive set of synthesized findings that can be used as a basis for evidence-based practice. Only unequivocal and credible findings will be included in the aggregation. Not-supported findings will be presented separately. Where textual pooling is not possible the findings will be presented in narrative form.

3.6.9 Conflicts of interest and acknowledgements

Details of requirements in these sections are described in Section 1.6 of this Manual.

Conflicts of interest
A statement which either declares the absence of any conflicts of interest or which describes a specified or potential conflict of interest should be made by the reviewers in this section.

Acknowledgements
Any acknowledgements should be made in this section e.g. sources of external funding or the contribution of colleagues or institutions. It should also be noted if the systematic review is to count towards a degree award.

3.7 Systematic review and synthesis of qualitative data

This section provides guidance on the components that should comprise a JBI systematic review report of qualitative evidence and the information that each component should contain. It illustrates how each component of the review is managed by SUMARI and the outputs that can be expected if JBI SUMARI has been used by the reviewer(s). This section also provides a brief outline of how the systematic review should be formatted and the stylistic conventions that should be used to ensure the review meets the criteria for publication in *JBI Evidence Synthesis*. Specifically, guidance is provided on the following components: layout of the report, inclusion criteria (i.e., PICo), search strategy, critical appraisal, data extraction, data synthesis, results, and conclusions. The section also presents a series of questions designed to prompt the reviewer to check that certain key information or requirements have been adequately addressed in the review.

3.7.1 Title

The title should be clear, explicit and reflect the core elements of the review. Titles should not be phrased as questions or conclusions and there should be congruency between the title, review objectives/questions and inclusion criteria. The title should include the phrase ‘a systematic review’.

3.7.2 Abstract

This section forms a structured abstract of the main features of the systematic review. It must be no longer than 500 words and should contain no abbreviations or references. The abstract must accurately reflect and summarize the systematic review with the main focus on the results of the review.

The abstract should report the essential elements of the review using the following sub-headings in this order:

- **Objective**: State an overarching review objective structured using the key components of the inclusion criteria (approximately one to two sentences).
- **Introduction**: Briefly describe what is already known on the topic and what this review will add to the evidence-base (approximately two to three sentences).
- **Inclusion criteria:** Summarize the inclusion criteria as it relates to the type of review being conducted. Present the information in one or two sentences – **NOT** under individual subheadings.
- **Methods:** List the key information sources searched (those that provided the majority of included studies), any limits placed on the scope of the search (e.g. language), and the date range, or the date of the last search. If the recommended JBI approach to critical appraisal, study selection, data extraction and data synthesis was used, simply state it as such (without naming the actual tool). Otherwise, briefly describe any notable deviations to the methodological approach taken (e. g. criteria used to exclude studies on the basis of methodological quality etc.).
- **Results**: The bulk of the abstract should be reserved to convey the main results of the review.
  - As a general rule, report the number and type of included studies and participants, as well as any pertinent study characteristics. Summarize the overall quality of the included studies and notable aspects of rigor for qualitative reviews).
  - Report the number of findings and categories and final synthesized findings. Depending how many are presented in the review, the synthesized findings may be presented here or abridged summarized statements.
- **Conclusions**: Provide a conclusion based on a general interpretation of the results considering, for example, the methodological quality of the included studies and any limitations of the review. Briefly convey key implications for practice and/or research.

3.7.3 ConQual 'Summary of Findings'

CONQual (Note: the output Summary of Findings table from the CONQual process should be presented after the review Abstract)

In ConQual, each paper is initially ranked from High to Very Low – qualitative papers are ranked as High, while text and opinion papers are ranked Low (Munn et al. 2014). From this starting point, each paper is then graded for Dependability, and then Credibility as per the schema below. ConQual Score Calculation:

1. **Initial Ranking** scale for qualitative studies
   a. High
   b. Moderate
   c. Low
   d. Very Low

Assign a pre-ranking of papers, using the following schema:

– High for qualitative studies

– Low for expert opinion

Dependability

The ranking per paper moves up or down (or stays the same) depending on the Dependability Score as follows:

4-5 ‘yes’ responses, the paper remains unchanged

2-3 ‘yes’ responses: move down 1 level

0-1 ‘yes’ responses: move down 2 levels

The Dependability score is based on the following specific questions from the critical appraisal scores for included studies related to the appropriateness of the conduct of the research with research aims and purpose:

1. Is there congruity between the research methodology and the research question or objectives?
2. Is there congruity between the research methodology and the methods used to collect data?
3. Is there congruity between the research methodology and the representation and analysis of data?
4. Is there a statement locating the researcher culturally or theoretically?
5. Is the influence of the researcher on the research, and vice-versa, addressed?

Credibility

- Assign a level of credibility to the synthesised finding by cross checking how many findings of what type were included in the categories associate with the synthesized finding:

– **Unequivocal (U)** – relates to evidence beyond reasonable doubt which may include findings that are matter of fact, directly reported/observed and not open to challenge.

– **Credible (C)** – those that are, albeit interpretations, plausible in light of data and theoretical framework. They can be logically inferred from the data. Because the findings are interpretive they can be challenged.

– **Not Supported (NS)** – when 1 nor 2 apply and when most notably findings are not supported by the data

- Rank according to the following scoring rubric for each synthesised finding:

    All unequivocal findings: remains unchanged.

    mix of unequivocal/credible findings: downgraded one (-1).

    credible/not supported findings: downgraded three (-3).

    *table is modified from source

Please note: For JBI qualitative reviews not-supported findings should not be included in the meta-aggregative process.

With the ConQual Score established for each synthesised finding, the Summary of Findings table can now be completed. *Cite Munn et al. 2014* when integrating ConQual.

Summary of Findings Table

Systematic review title: insert title here Population: describe population of interest Phenomena of interest: insert the specific phenomena of interest Context: Concise description of the key contextual factors					
Synthesised Finding	Type of research	Dependability	Credibility	ConQual Score	Comments
Insert each synthesized finding, and complete the columns per synthesized finding, keeping the rows aligned					

3.7.4 Introduction

The introduction should be comprehensive and cover all the main elements of the topic under review. It should be presented in complete prose, avoid lists and use sub headings sparingly and to improve logical flow of content and readability. Reviewers will find that the background information provided with the protocol needs modification or extension following the conduct of the review proper; the

introduction of the review should not be a duplicate of that presented in the published protocol. The introduction should detail any definitions important to the review. The background information in this section must be sufficient to put the inclusion criteria into context and clear indication why the review is important and the rationale for its conduct. The introduction should conclude with a statement that a preliminary search for previous systematic reviews on the topic was conducted (state the sources searched e.g. *JBI Evidence Synthesis*, Cochrane Database, CINAHL, PubMed, PROSPERO). If there is a previous systematic review on the topic, it should be specified how the proposed review differs.

The introduction should conclude with an overarching review objective that captures and aligns with the core elements/mnemonic of the inclusion criteria (e.g. PICo). The stated objective should clearly indicate what the review project is trying to achieve. For publication in *JBI Evidence Synthesis*, all references should be listed in full using the Vancouver referencing style, in the order in which they appear in the review. Abbreviated journal titles must be used in accordance with the United States National Library of Medicine.

3.7.5 Inclusion criteria

This section of the review details the basis on which studies were considered for inclusion in the systematic review and should be as clear and unambiguous as possible.

Types of participants

The types of participants should be appropriate for the review objective(s) and question(s). The reasons for the inclusion or exclusion of participants should be explained in the background.

Phenomena of interest

There should be congruence between the review objective(s) and question(s) and the phenomena of interest. How the phenomena relate to the topic under review should be clear and detailed in the background section.

Context

In a qualitative review, context will vary depending on the objective of the review. Context may include, but is not limited to, consideration of cultural factors such as geographic location, specific racial or gender based interests, or detail about the specific setting (such as acute care, primary health care, or the community).

Types of studies

There should be a match in this section between the methodology of the primary research studies that were included in the review.

3.7.6 Methods

This section of the review report is reserved for the methods used to conduct the review and should be presented under the relevant subheadings (see Section 2.7.5 points 1-4), including any deviations from the method outlined in the *a priori* protocol. In empty reviews for example, this section should not refer to methods that were not performed.

Directly below the Methods heading provide the following information:

- State and appropriately cite the JBI methodology that was employed in the conduct of the review and synthesis.
- Refer to and cite the *a priori* protocol that was published, or accepted for publication (e.g. 'in press'), in *JBI Evidence Synthesis*.
- If the protocol has been registered with PROSPERO, provide registration information including registration number (e.g. PROSPERO CRD42015425226).

3.7.6.1 Search strategy

This section details how the reviewers searched for relevant studies. Detailed search strategy for all the sources searched should be appended to the review including record of the dates the searches were conducted. A JBI review should consider papers published by commercial and academic publishers as well as grey literature. The time frame chosen for the search should be justified and any language restrictions stated (e.g. only studies published in English were considered for inclusion).

3.7.6.2 Assessment of methodological quality

This section should detail the approach to critical appraisal, not the assessment results, and should be consistent with the protocol. Any deviations from the protocol must be reported and explained. The report should detail the criteria that were considered when determining the methodological quality of papers considered for inclusion in the review. JBI tools (i.e. JBI-Qualitative Appraisal Instrument) should be used. Critical appraisal tools used ideally should be cited appropriately in the

methods section. If a modified tool was used, the *a priori* protocol where it was first presented should be cited.

3.7.6.3 Data extraction

Standardized data extraction tools that promote extraction of similar data form all of the included studies and are recommended. The review should detail what data the reviewers extracted from the included studies. The *a priori* protocol or this Manual with the original data extraction tool can be cited to indicate the tool used. Data extraction in a meta aggregation is a multi phase process, with the general details of papers, including the citations details, the population, phenomena of interest, and context as well as methodology, methods, settings and cultural information retrieved from papers before moving to extraction of the findings. The approach and process used to extract findings from the results of the included studies should be presented with enough detail to be readily reproducible. Indicate what data were considered findings in the review (i.e. themes, metaphors, etc.) and the process by which findings were identified (i.e. repeated reading of text).

Extracting findings is both the second phase of data extraction, and the first step in data synthesis.

- A finding is defined as a verbatim extract of the authors analytic interpretation accompanied by either a participant voice, or fieldwork observations or other data.

Each finding extracted is to be accompanied by an illustration from the same text that informs the finding.

- An illustration may be either a direct quotation of participant voice, field-work observations or other supporting data

Levels of credibility

As a finding is extracted and its accompanying illustration entered in the JBI SUMARI software, a level of ‘Credibility’ is allocated based on the reviewers perception of the degree of support each illustration offers for the specific finding it is associated with.

There are 3 levels of credibility as described below, and reviewers should document in this section of their review report HOW the decision was made to allocate these levels, and what (if any) issues arose during the process, or whether there was good agreement between the review team members.

- **Unequivocal** (findings accompanied by an illustration that is beyond reasonable doubt and; therefore not open to challenge);
- **Credible** (findings accompanied by an illustration lacking clear association with it and therefore open to challenge)
- **Not Supported** (findings are not supported by the data).

3.7.6.4 Data synthesis

This section should detail the approach to data synthesis, not the results of the synthesis. The review should detail how the reviewers synthesized the data extracted from included studies and detail the meta-aggregative approach and how it was applied across all included studies. . Any deviations from the methods outlined in the protocol need to be clearly documented in the review to maintain transparency.

Data synthesis in a meta aggregative review requires the reviewers to undertake a 3 step process, beginning with:

1. Extraction of all findings from all included papers with an accompanying illustration and establishing a level of credibility for each finding;
2. Developing categories for findings that are sufficiently similar, with at least 2 findings per category;
3. Developing one or more synthesized findings of at least 2 categories.

Please note: Although findings which are not supported should be extracted from studies, they must be presented separately (see Section 2.7.11); they are not included in the meta-aggregation.

Reporting the methods of data synthesis requires reviewers to describe:

- what data was considered ‘findings’ in their review (i.e. was it limited to themes and metaphors, or did it include other analytic data from the papers that might have been an author observation rather than a thematic analysis);
- the process by which findings were identified (i.e. repeated reading of text, or selection of themes from the results section only;
- how findings were grouped in order to develop categories (i.e. was it based on similarity in wording, or concepts;
- how category descriptions were created (i.e. by single reviewer, or by consenus process between reviewers/review group members);

- how synthesized findings and their accompanying descriptions were created and finalized.

3.7.7 Results

This section of the review report has distinct sub-sections describing the process of study inclusion, the methodological quality of the eligible studies, detailed characteristics and description of the included studies and, importantly, the findings of the review and results of the synthesis processes.

3.7.7.1 Study inclusion

The opening to this section should allow the reader to clearly follow how the included studies were identified and selected for inclusion in the review. There should be a narrative description of the process accompanied by a flowchart (from PRISMA Statement); details to be reported include narrative summary of the numbers of studies identified, numbers screened, studies selected for retrieval and included/excluded and their reasons for exclusion, numbers appraised and included /excluded, numbers included in the qualitative synthesis.

3.7.7.2 Methodological quality

This section should focus on methodological quality as determined by the relevant critical appraisal checklist. There should be a narrative summary of the overall methodological quality of the included studies, which can be supported (optional) by a table showing the results of the critical appraisal (see Table 2.2 for example). Where only few studies are identified, or there are specific items of interest from included studies, these should be addressed in the narrative also, particularly where studies were deficient, or particularly good. Use of Unclear and not applicable should also be explained in the text.

Table 2.2. Critical appraisal results for included studies using the JBI-Qualitative Critical Appraisal Checklist

Study	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10
Author(s) [ref]	Y	Y	Y	N	Y	U	Y	N	Y	U
Author(s) [ref]	Y	N	Y	Y	Y	U	Y	N/A	Y	Y

Y - Yes, N - No, U - Unclear, N/A - not applicable

If appraisal tools are not appended to the review report (citation only), the appraisal questions should be added as a footnote/caption to the table (Table 2.2) so readers can clearly interpret the information presented.

3.7.7.3 Characteristics of included studies

This section of the results should also include an overall description of the included studies (with reference to the table of included study characteristics in the appendices), with the main aim to provide some context to the results section and sufficient detail for the reader to confirm that the studies match the eligibility criteria for the review and to determine if the included studies are similar enough to combine in meta-synthesis. This includes the descriptive and demographic features (e.g. the country and setting of the study) of the included studies, methodology of included studies, total population size for combined included studies, geographic context of included studies and participant characteristics, characteristics of the interventions, or phenomena of interest as well as the main clinical characteristics, as they relate to the review objective and the inclusion criteria. Specific items /points of interest from individual studies may also be highlighted here and synthesized in narrative.

3.7.7.4 Findings of the review

Review findings or results are preferentially structured according to the phenomena of interest for reviews that include qualitative data. A meta-aggregative schematic/overview flowchart should constitute part of this section.

The meta-aggregative schematic table must be accompanied by sufficient narrative to explain the categories and synthesized findings, and the similarity of meaning informing each category and synthesized finding to the reader of the report.

Findings and illustrations (including their levels of credibility) should be located in an appendix, or may be incorporated into the body of the report. Not-supported findings must not be included in the meta-aggregative synthesis. There should be a logical and informative presentation of the findings, categories and synthesized findings using only credible and unequivocal findings.

Meta-Aggregative Overview Flowchart

Authors can choose to include a meta-aggregative overview flowchart. See below for an example:

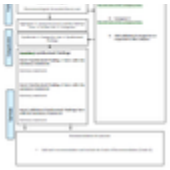

Figure 2.1: Meta-Aggregative Overview Flowchart (Davis et al. 2014)

3.7.8 Discussion

This section should very briefly summarize and then concentrate on the discussion of the the results of the synthesis as well as any limitations of the primary studies included in the review and of the review itself (i.e. language, access, time frame, study design, etc.). **DO NOT** repeat the results of the review. The results should be discussed in the context of current literature, practice and policy. It will also include a narrative discussion of the review results in comparison with other external literature, and against the broad directions established in the introduction of the review.

This section should also discuss the strength of the evidence (for each main outcome in reviews of effects); any limitations of the included studies (e.g. methodological quality, inconsistencies or errors in reporting, etc.); and any limitations or issues that arose during the conduct of the systematic review itself (e.g. limitations of the search; the impact of deviations from protocol, etc.).

The application and relevance of the findings to relevant stakeholders (e.g. healthcare providers, patients and policy makers) should also be discussed, and where applicable, an indication of whether the findings are generalizable to other populations or healthcare settings.

3.7.9 Conclusions and Recommendations

Conclusions

This section should begin with an overall conclusion based on the results. The conclusions drawn should match with the review objective/question.

Recommendations for practice

The recommendations for practice should be context specific and enable a reader to consider the applicability to practice. E.g. suggesting in a general sense that '*…more education should be provided* …' is not a useful contribution.

Instead, provide direction for a specific type of education on a specified topic for the specific participants. It should be stated how the findings of the review are proposed to impact on clinical practice in the area. If there is sufficient evidence to make specific recommendations for practice, then the appropriate JBI Grade of Recommendation should be assigned to each recommendation.

Recommendations for research

This section should include clear, detailed specific recommendations for future research based on gaps in knowledge identified from the results of the review. The implications for research should not be generic statements on a phenomena of interest without providing specific detail on:

- what phenomena should be investigated,
- the context in which it should be investigated, and
- the specific populations to be considered

By this stage in a systematic review, the international literature on the topic has been comprehensively reviewed, and authors therefore well placed to provide meaningful, researchable recommendations. While drafting implications for research, consider what information you would find helpful if you were planning to do further research on the topic.

3.7.10 Conflicts and acknowledgements

Details of requirements in these sections are described in Section 1.6 of this Manual.

Conflicts of interest

A statement which either declares the absence of any conflicts of interest or which describes a specified or potential conflict of interest should be made by the reviewers in this section.

Funding

Authors should provide details regarding any sources of funding for the review project. The role of all funders in the review process, if any, should be explicitly described. If the review is funded, then any potential conflicts of interest or intellectual bias of the funders should be specified in the review.

Acknowledgements

Any acknowledgements should be made in this section e.g. sources of external funding or the contribution of colleagues or institutions. It should also be noted if the systematic review is to count towards a degree award.

3.7.11 Review appendices

There are several required appendices for a JBI review:

Appendix 1: Search strategy

- A detailed and complete search strategy for all of the major databases and other sites and sources searched must be appended. Major databases that were searched must be identified, including the search platform used where necessary. All search filters with logic employed should be displayed, including the number of records returned.

Appendix 2: Data extraction instrument

- The data extraction instrument used must be appended i.e JBI SUMARI Data Extraction Form for Interpretive & Critical Research.

Appendix 3: List of excluded studies

- Studies excluded following examination of the full-text should be listed along with their reason for exclusion at that stage (i.e. a mismatch with the inclusion criteria). This may be as a separate appendix or itemized in some fashion within the one appendix with those studies excluded at the critical appraisal stage. Reasons for exclusion following appraisal should be provided for each study (these reasons should relate to the methodological quality of the study, not study eligibility).

Appendix 4: Table of included study characteristics

- A table of included studies is required to provide quick reference to important details extracted from of the studies included in the review.

Appendix 5: Findings and illustrations

- An appendix presenting findings and their supporting illustrations (Not-supported findings must be included in this appendix, but must have ‘Not-Supported’ in place of the illustration) with levels of credibility and their citation/reference should be provided if this material is not already presented in the body of the review report.

3.8 Chapter references

Ailinger, R. Contributions of qualitative evidence to evidence based practice in nursing. Revista Latino-americana de Enfermagem. 2003, 11(3): 275-279.

Barbour, R. The case for combining qualitative and quantitative approaches in health services research." Journal of Health Service Research Policy 1999, 4(1): 39-43.

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Davis K, White S, Stephenson M. The influence of workplace culture on nurses’ learning experiences: a systematic review protocol of qualitative evidence. The JBI Database of Systematic Reviews and Implementation Reports, 2014, (12):45 – 58.

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Forman J, Damschroder L, Kowalski C, Krein S. Qualitative research methods: key features and insights gained from use in infection prevention research." American Journal of Infection Control 2008, 36(10): 764-771.

Greenhalgh T. Papers that go beyond numbers (qualitative research). BMJ 1997, 315(7110): 740-743.

Hannes K, Lockwood. C. Pragmatism as the philosophical foundation for the Joanna Briggs meta-aggregative approach to qualitative evidence synthesis. Journal of Advanced Nursing 2011, 67(7): 1632-1642.

Jordan Z, Pittman P. A short history of a big idea. Melbourne, The Joanna Briggs Institute, 2006.

Moffatt S, Mackintosh J, Howel D. Using quantitative and qualitative data in health services research - what happens when mixed method findings conflict? BMC Health Services Research 2006 6: 28.

Munn Z, Porritt K, Lockwood C, Aromataris E, Pearson A. Establishing confidence in the output of qualitative research synthesis: the ConQual approach. *BMC Medical Research Methodology*, 2014, 14:108

Pearson, A. Balancing the evidence: incorporating the synthesis of qualitative data into systematic reviews. JBI Report 2004, 2(2): 45-65.

Rittenmeyer L, Block M, Mathaler M, Misner S, Moore E, Wegnere G, Fleefisch K A comprehensive systematic review on lateral/horizontal violence in the profession of nursing. JBI Database of Systematic Reviews and Implementation Reports 2012, 10(42): 17.

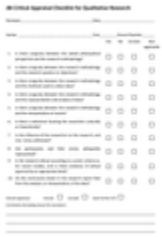
Sandelowski M, Barroso J. Handbook for Synthesizing Qualitative Research. New York, Springer Publishing Company, 2007.

Sandelowski M, Docherty, Emden C. Focus on qualitative methods. Qualitative meta synthesis: issues and techniques." Research in Nursing and Health 1997, 20: 365-371.

Thorne S, Kearney MH, Noblit G, Sandelowski M. Qualitative meta synthesis: reflections on methodological orientation and ideological agenda." Qualitative Health Research 2004, 14(10): 1342-1365.

Wong S, Haynes R. Developing optimal search strategies for detecting clinically relevant qualitative studies in Medline. Stud Health Technol Inform 2004, 107(1): 311-316.

Appendix 3.1: JBI Critical Appraisal Checklist for Qualitative Research



Appendix 3.2: Discussion of JBI Qualitative critical appraisal criteria

1. Congruity between the stated philosophical perspective and the research methodology

Does the report clearly state the philosophical or theoretical premises on which the study is based? Does the report clearly state the methodological approach adopted on which the study is based? Is there congruence between the two? For example:

A report may state that the study adopted a critical perspective and participatory action research methodology was followed. Here there is congruence between a critical view (focusing on knowledge arising out of critique, action and reflection) and action research (an approach that focuses on firstly working with groups to reflect on issues or practices, then considering how they could be different; then acting to create a change; and finally identifying new knowledge arising out of the action taken). However, a report may state that the study adopted an interpretive perspective and used survey methodology. Here there is incongruence between an interpretive view (focusing on knowledge arising out of studying what phenomena mean to individuals or groups) and surveys (an approach that focuses on asking standard questions to a defined study population); a report may state that the study was qualitative or used qualitative methodology (such statements do not demonstrate rigor in design) or make no statement on philosophical orientation or methodology.

2. Congruity between the research methodology and the research question or objectives

Is the study methodology appropriate for addressing the research question? For example:
A report may state that the research question was to seek understandings of the meaning of pain in a group of people with rheumatoid arthritis and that a phenomenological approach was taken. Here, there is congruity between this question and the methodology. A report may state that the research question was to establish the effects of counselling on the severity of pain experience and that an

ethnographic approach was pursued. A question that tries to establish cause-and effect cannot be addressed by using an ethnographic approach (as ethnography sets out to develop understandings of cultural practices) and thus, this would be incongruent.

3. Congruity between the research methodology and the methods used to collect data

Are the data collection methods appropriate to the methodology? For example:

A report may state that the study pursued a phenomenological approach and data was collected through phenomenological interviews. There is congruence between the methodology and data collection; a report may state that the study pursued a phenomenological approach and data was collected through a postal questionnaire. There is incongruence between the methodology and data collection here as phenomenology seeks to elicit rich descriptions of the experience of a phenomena that cannot be achieved through seeking written responses to standardized questions. There is congruity between the research methodology and the representation and analysis of data.

4. Congruity between the research methodology and the representation and analysis of data

Are the data analyzed and represented in ways that are congruent with the stated methodological position? For example:

A report may state that the study pursued a phenomenological approach to explore people's experience of grief by asking participants to describe their experiences of grief. If the text generated from asking these questions is searched to establish the meaning of grief to participants, and the meanings of all participants are included in the report findings, then this represents congruity; the same report may, however, focus only on those meanings that were common to all participants and discard single reported meanings. This would not be appropriate in phenomenological work.

5. There is congruence between the research methodology and the interpretation of results

Are the results interpreted in ways that are appropriate to the methodology? For example:

A report may state that the study pursued a phenomenological approach to explore people's experience of facial disfigurement and the results are used to inform practitioners about accommodating individual differences in care. There is congruence between the methodology and this approach to interpretation; a report may state that the study pursued a phenomenological approach to explore people's experience of facial disfigurement and the results are used to generate practice checklists for assessment. There is incongruence between the methodology and this approach to interpretation as phenomenology seeks to understand the meaning of a phenomenon for the study participants and cannot be interpreted to suggest that this can be generalized to total populations to a degree where standardized assessments will have relevance across a population.

6. Locating the researcher culturally or theoretically

Are the beliefs and values, and their potential influence on the study declared? For example:

The researcher plays a substantial role in the qualitative research process and it is important, in appraising evidence that is generated in this way, to know the researcher's cultural and theoretical orientation. A high quality report will include a statement that clarifies this.

7. Influence of the researcher on the research, and vice-versa, is addressed

Is the potential for the researcher to influence the study and for the potential of the research process itself to influence the researcher and her/his interpretations acknowledged and addressed? For example:

Is the relationship between the researcher and the study participants addressed? Does the researcher critically examine her/his own role and potential influence during data collection? Is it reported how the researcher responded to events that arose during the study?

8. Representation of participants and their voices

Generally, reports should provide illustrations from the data to show the basis of their conclusions and to ensure that participants are represented in the report.

9. Ethical approval by an appropriate body

A statement on the ethical approval process followed should be in the report.

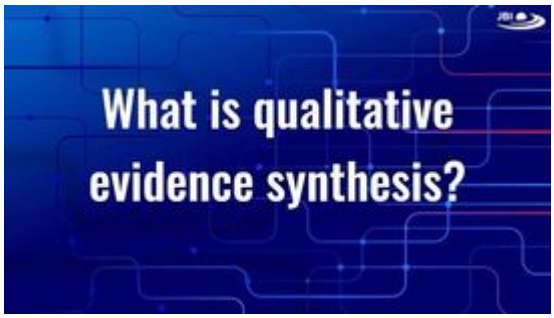
10. Relationship of conclusions to analysis, or interpretation of the data

This criterion concerns the relationship between the findings reported and the views or words of study participants. In appraising a paper, appraisers seek to satisfy themselves that the conclusions drawn by the research are based on the data collected; data being the text generated through observation, interviews or other processes.

Appendix 3.3: JBI Qualitative data extraction tool

Systematic Reviews of Qualitative Evidence Resources

Digital Resources



What is qualitative evidence synthesis?

In this short video Prof Catrin Evans explains what is a qualitative systematic review and the value of this type of evidence synthesis.

Equity, Diversity and Inclusion within the Qualitative Systematic Review Process

Prof Catrin Evans presents at JBI iGNITE on methods and approaches for attending to equity, diversity and inclusion within the qualitative systematic review process.

Qualitative evidence synt implementation

In this #JBI LIVE webinar A importance and reasoning synthesis; the process of h synthesis can be formed in recommendations for policy

Publications

The “quality” of JBI qualitative research synthesis: a methodological investigation into the adherence of meta-aggregative systematic reviews to reporting standards and methodological guidance

Munn, Z et al, 2021

This methodological review sought to determine the extent to which a selection of meta-aggregative systematic reviews follow the available guidance, with a view to establishing compliance and identifying potential areas for improvement.

4. Systematic reviews of effectiveness

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Contents

- Appendix 4.4: Discussion of JBI appraisal criteria for Quasi-Experimental Studies (non-randomized experimental studies)
- Systematic Reviews of Effectiveness Resources

Interim Guidance

JBI Methodology Groups are continuously working to improve, update and further the science of JBI Evidence Syntheses. JBI Methodology chapters are updated when there have been significant changes to a methodology, as determined by the JBI Scientific Committee. Interim guidance for steps, sections or stages of a review methodology is often provided via publications ahead of formal chapter updates. Please see below for relevant interim guidance:

The revised JBI critical appraisal tool for the assessment of risk of bias for randomized controlled trials

Barker et al 2023

JBI recently began the process of updating and revising its suite of critical appraisal tools to ensure that these tools remain compatible with recent developments within risk of bias science. Following a rigorous development process led by the JBI Effectiveness Methodology Group, this paper presents the revised critical appraisal tool for the assessment of risk of bias for randomized controlled trials.

4.1 Introduction to quantitative evidence and evidence-based practice

Quantitative evidence is generated by research based on traditional scientific methods that generate numerical data. The methods associated with quantitative research in healthcare have developed out of the study of natural and social sciences. It was suggested that quantitative evidence in medicine originated in eighteenth century Britain, when surgeons and physicians started using statistical methods to assess the effectiveness of therapies for scurvy, dropsy, fevers, palsies, syphilis, and different methods of amputation and lithotomy (Trohler 2000). Since these beginnings, quantitative research has expanded to encompass aspects other than effectiveness, such as incidence, prevalence, etiology of disease, psychometric properties, and measurement of physical characteristics, quality of life, and satisfaction with care.

JBI quantitative reviews focusing on evidence of effectiveness examine the extent to which an intervention, when used appropriately, achieves the intended effect. Evidence about the effects of interventions may come from three main categories of studies: experimental studies, quasi-experimental studies and observational studies. Ideally, evidence about the effectiveness of interventions should come from good quality randomized controlled trials (RCTs) that explore final clinical end points (or patient important outcomes) such as morbidity, mortality, and quality of life (not surrogate end points which may include laboratory tests for example) (Brignardello-Petersen et al 2015). Good empirical evidence exists to indicate that RCTs that explored final clinical end points frequently contradicted (refuted) clinical studies that explored surrogate end points and also the results of observational studies (Brignardello-Petersen et al 2015). Some authors have claimed that results from RCTs and observational studies provide consistent results. Thus, the issue of the agreement of the results from RCTs and observational studies remains controversial (Brignardello-Petersen et al 2015).

Although high quality RCTs exploring final clinical end points are considered the “reference standard” (Brignardello-Petersen et al 2015), reviewers should be aware that results from any single RCT cannot be considered as “final” because results from new RCTs may contradict results from previous RCTs (Brignardello-Petersen et al 2015).

Reviewers should be aware that there is no unique universally accepted terminology for the quantitative study designs. Also, there is no unique comprehensive set of descriptions for the different study designs considered here.

Experimental studies meet three conditions: manipulation, control and random assignment. Specifically, the researchers manipulate the intervention of interest and the control condition and they randomly allocate the participants to the intervention or control group (Shadish et al 2002). Random allocation refers to an authentically random process such as the toss of a coin or use of a table of random numbers (Shadish et al 2002). Randomized controlled trials with different designs (parallel design, cross-over design, cluster design) are examples of experimental studies. There are also existing experimental studies (the intervention of interest and the control condition are manipulated by the researchers) where the allocation may not use an authentically random process. For example, if investigators use alternate group allocation like even and odd dates, they cannot ensure that each participant has an equal chance of landing in either group. Experimental studies without authentic random allocation but using systematic alternate group allocation methods mentioned above are experimental studies with pseudo-randomization, or pseudo-RCTs. Quasi-experimental studies are studies where the intervention of interest and the control condition are controlled (manipulated) by

the researchers, however, the allocation of participants is not a random, systematic or pseudo-random allocation (Shadish et al 2002). Frequently, participants self-select into groups or the researchers decide which persons should get the intervention and which persons should get the control (Shadish et al 2002).

Observational studies are studies where the intervention of interest and the control condition are not controlled (manipulated) by the researchers and where researchers only observe the presence or absence of the intervention of interest and of the outcome of interest. There are diverse types of observational studies, which can be broadly categorized into analytical observational studies (cohort studies, case-control studies, and analytical cross-sectional studies) and descriptive observational studies (case reports and case series). In a cohort study, investigators select participants based on presence or absence of exposure to an intervention of interest and compare prospectively for the occurrence of the outcome of interest. In a case-control study, researchers select “case” participants or those with the outcome of interest and “control” participants, without the outcome of interest, to compare groups for past exposure or absence of exposure to the intervention. In an analytical cross-sectional study, investigators select participants without reference to the intervention or the presence of the outcome of interest. They then simultaneously examine the groups for the presence or absence of exposure to the intervention of interest and the presence or absence of the outcome of interest. In case reports and case series researchers simply describe the characteristics of participants and the outcomes of interventions.

4.2 Development of a protocol for a systematic review of effectiveness evidence

An *a priori* systematic review protocol is important because it pre-defines the objectives and methods of the systematic review. A review protocol provides the plan or proposal for the systematic review. Any deviations from the review protocol should be discussed in the systematic review report.

The review protocol describes:

- the context and rationale for the review, including what is already known and uncertainties,
- the study selection criteria (inclusion/exclusion criteria),
- the outcome measures, interventions, and comparisons considered,
- the proposed search strategy for identifying relevant studies,
- the procedures for study selection,
- the critical appraisal process and instruments,
- the data extraction process and instruments,
- the process for resolving disagreement between reviewers in study selection, data extraction, and critical appraisal decisions, and
- the proposed approaches to synthesis

4.2.1 Title of the systematic review protocol

A clear, descriptive title is important to allow readers and users to readily identify the scope and relevance of the review. The clearer and more specific a title is, the more readily a reader will be able to make decisions about the potential relevance of the systematic review. The protocol title should accurately describe and reflect the content of the review protocol and include relevant information with regards the types of participants, types of interventions and comparators and the outcomes considered in the review. The title should be concise and should not be phrased as a question. The title of the review protocol should explicitly identify the publication as a protocol for a systematic review. The following convention is recommended: ‘a protocol for a systematic review’. Following the guidance mentioned, for systematic reviews of effectiveness we recommend the following convention: *'The effectiveness of [intervention] compared to [comparator] on [outcome]: a protocol for a systematic review*'.

4.2.2 Review question(s)

The review protocol should provide an explicit and clear statement of the review questions addressed in the review. The review questions should specify the focus of the review (effectiveness), the types of participants, types of interventions and comparators, and the types of outcomes considered. Usually, reviewers use the PICO mnemonic (population, intervention, comparator and outcome) to construct a clear and meaningful review objective/question regarding the quantitative evidence on effectiveness of interventions.

Examples of review questions: *‘In community dwelling patients with stable, moderate-to-severe chronic obstructive pulmonary disease’*:

1. *What is the effect of inspiratory muscle training versus no specific training on dyspnea and functional ability?*
2. *What is the effect of inspiratory muscle training versus no specific training on inspiratory muscle strength and endurance?*
3. *What is the effect of inspiratory muscle training on hypoxemia and discomfort?*

There should be consistency between the review title and the review questions in terms of the focus of the review. Review authors are encouraged to read the article by Stern et al (2014) regarding the review questions and the inclusion criteria.

4.2.3 Introduction

The introduction of the review protocol should provide explicit and comprehensive information regarding the justification (rationale) for the conduct of the review in the context of what is already known. The introduction should be of sufficient length to discuss all of the elements of the proposed plan for the review; usually all the relevant information may be provided in approximately 1000 words. This section should be written in simple prose for non-expert readers. Usually, a systematic review is informed by international research and is conducted for an international readership, therefore, reviewers should include relevant international literature in this introductory section. There are exceptions, for example, where systematic reviews are conducted on a question relevant to a single country (for example, Australia or UK) or region (Africa) specific issues. However, with the exception of these reviews that use strict limitations on the inclusion criteria, a systematic review should include all relevant international literature. The introduction should provide sufficient details to justify the conduct of the review and the choice of inclusion criteria for the review (types of participants, types of interventions and comparators, the types of outcomes, and types of studies). The review protocol should provide all conceptual and operational definitions that are relevant for the review. It is the responsibility of the reviewers to ensure that their review is not a duplicate of an existing review. It is recommended that reviewers search major electronic databases to determine that there have been no recently published systematic reviews on the same topic. A search of the *JBI Evidence Synthesis*, Cochrane Database, MEDLINE, DARE, PROSPERO, EPISTEMONIKOS, and ACCESSSS will assist to establish whether or not a recent review exists on the topic of interest. Reviewers should report in the background section the details of this preliminary search. If systematic reviews on the topic of interest have already been conducted, reviewers should explain the differences between the existing reviews and the new proposal and provide an explicit justification for the need to conduct a new systematic review.

The introduction should conclude with an overarching review objective that captures and aligns with the core elements/mnemonic of the inclusion criteria (e.g. PICO). The stated objective should clearly indicate what the review project is trying to achieve. Example of a review objective: *'To synthesize the best available evidence related to using inspiratory muscle training to improve dyspnoea in patients with chronic obstructive pulmonary disease.'* This broad statement provides the general scope but must be further clarified with focused review questions.

The background section of the review protocol should provide information regarding:

- the importance of the topic (prevalence, incidence, morbidity, mortality, impact on quality of life; economic burden),
- concerns expressed by consumers, healthcare professionals, policy-makers,
- the specifics of diverse groups of patients (age, gender, ethnicity, severity of the disease, co-existing diseases) and settings,
- the intervention of interest and how it works,
- any uncertainties and conflicting reports regarding the effectiveness of the intervention of interest,
- other existing interventions with which the intervention of interest may be compared,
- the importance of different outcomes,
- how outcomes are measured (approaches, measurement instruments),
- the relevance of different research study designs in the examination of the topic of interest,
- relevant existing primary research studies,
- what is already known, including details about the existing systematic reviews, including meta-analyses, and
- the justification for the need for a new review and the objectives of the review project.

4.2.4 Inclusion criteria

The review protocol should provide explicit, unambiguous, inclusion criteria for the review. Inclusion criteria should be reasonable, sound (based on scientific arguments), and justified. These criteria will be used in the selection process, when it is decided if a study will be included or not in the review. Usually, it is enough to provide explicit inclusion criteria without specifying explicit exclusion criteria; it is implicitly assumed that exclusion is based on the criteria that are the opposite of those specified as inclusion criteria. However, sometimes, for clarity, in order to avoid any potential ambiguity, it is recommended to provide explicit exclusion criteria. Inclusion criteria for a review are not intended to be considered in isolation; in this regard they should be articulated so as to be as mutually exclusive as possible and not repeat information relevant to other aspects of the PICO.

Two categories of inclusion criteria should be considered: *inclusion criteria based on study characteristics*, and *inclusion criteria based on publication characteristics*. *Inclusion criteria based on study characteristics* are those related to the types of participants and settings, types of interventions, comparators, types and measurement of outcomes, and types of studies. *Inclusion criteria based on publication characteristics* are those related to publication date, language of publication, type of publication (published in commercial scientific databases; documents not

published in commercial databases, for example, trials documents). Usually, reviewers use the PICO mnemonic (participants, intervention, comparator and outcome) to construct a clear and meaningful review objective/question regarding the quantitative evidence on effectiveness of interventions. The reviewer uses the same PICO framework to develop inclusion criteria based on study characteristics. The inclusion criteria must provide adequate details about the conceptual and operational definitions of each element to enable reviewers to make reliable decisions when making decisions to include studies.

4.2.4.1 Population (types of participants)

This section should specify the details about types of participants considered for the review, for example, age; gender; ethnicity; diagnosis; diagnostic criteria; stage or severity of the disease; co-existing diseases. What are the most important characteristics of the population? (e.g., age, disease /condition, severity of illness, setting, gender, etc.).

Consider the following example regarding COPD, describe the population (*patients with COPD*), the severity of illness (*moderate-to-severe*), trajectory of the disease (*stable*), with a specific setting (*com munity dwelling*). Diagnostic criteria should be made clear to allow inclusion and exclusion; if reviewers anticipate subgroup analysis related to population characteristics, these subgroups should be reflected in the population inclusion criteria. For example, '*COPD includes patients with chronic bronchitis and emphysema but not asthma (fixed airway obstruction with forced expiratory volume in one second [FEV_1] less than <80% of predicted). According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) and the American Thoracic/European Respiratory Society Guidelines (ATS/ERS), the description of the severity of disease is as follows: stage II or moderate disease is an FEV_1 of 50-80% predicted; stage III or severe is an FEV_1 of 30-50% predicted and stage IV or very severe is an FEV_1 <30% predicted. Patients with reversible airway disease (improvement in FEV_1 >20% with fast acting bronchodilator) will be excluded because their response to training may relate more to changes in their airway obstruction than a training effect*.' Specific reference to population characteristics, either for inclusion or exclusion should be based on a clear, scientific justification rather than based on unsubstantiated clinical, theoretical or personal reasoning.

4.2.4.2 Intervention (types of interventions)

What is the intervention? This section should specify the details about the intervention of interest for the review, for example, the nature of intervention, frequency, intensity, timing, and details about those administering the intervention. The same kind of information should be specified for all comparators considered in the review. Where possible, the intervention should be described in detail, particularly if it is multifaceted. A more detailed analytical framework can be used to refer to these complexities. If the review is examining a class or group of interventions, a comprehensive list of identified examples should be provided for the reader. Reviewers should plan any subgroup analysis based on different modes, timing, etc. of the intervention during the protocol stage and account for them in the inclusion criteria. For example, '*inspiratory muscle training includes any mode (threshold loading, resistive, hyperpneic,) practiced at least daily for no less than 4 weeks'* allows the reviewers to consider different types of training but specifies the minimum training period.

4.2.4.3 Comparison (types of comparators)

What is the intervention being compared with? (e.g., placebo, standard care, another therapy or no treatment). This section should detail what the intervention of interest is being compared with. The reviewer may wish to examine the comparative effectiveness of two treatments with a specific, head-to-head comparison. In the example (See Section 3.2.4.3), the reviewers may have specified inspiratory muscle training compared to cardiovascular conditioning. This level of detail is important in determining study selection once searching is complete. Systematic reviews of effectiveness based on the inclusive definition of evidence adopted by the JBI often seek to answer broader questions about multifaceted interventions and comparing the intervention of interest with all existing alternative interventions (comparators).

4.2.4.4 Outcomes

The review protocol should list all the outcomes considered. There is an international initiative known as The COMET (Core Outcome Measures in Effectiveness Trials) initiative, involved in the development and application of agreed standardized sets of outcomes for trials on specific conditions. Details are provided on the COMET website (http://www.comet-initiative.org/). Reviewers are encouraged to check the available standardized sets of outcomes for trials relevant for their reviews.

Outcomes should be measurable and appropriate to the review objectives and questions. Usually, only a limited number of primary outcomes and a limited number of secondary outcomes are considered for a review. Sometimes, if justified, it is acceptable to include multiple primary and secondary outcomes. However, the appropriateness of the number and scope of outcomes depend on the specifics of the review objectives and review questions (Aromataris 2015). The relevance of each outcome to the review objective/questions should be justified in the background section. Both beneficial outcomes (positive effects) and harms (negative effects, such as adverse effects or side

effects) should be considered as outcomes (Aromataris 2015). Essentially, primary outcomes are those outcomes that are the most important outcomes informing the review questions and the conclusions about the beneficial and harmful effects of the intervention of interest for a review (Aromataris 2015). Secondary outcomes are all other outcomes not specified as primary outcomes. A fundamental distinction is that between true endpoints and surrogate outcomes; true endpoints reflect the effects of treatment on aspects of patients' status considered the most important in terms of mortality and morbidity; surrogate outcomes are measured as "surrogates' for true endpoints, for reasons related to complexity, time, and costs of measurement of true endpoints (Tufanaru 2016). Examples of true endpoints are survival time in cancer and bone fractures in osteoporosis; examples of surrogate outcomes are time to progress from one stage to another stage in cancer and bone mineral density in osteoporosis (Tufanaru 2016).

It is recommended that whenever possible true endpoints should be used as primary outcomes, and that if surrogate outcomes are used as primary outcomes then an explicit justification should be provided for the use of a surrogate outcomes instead of true endpoints (Tufanaru 2016). It is expected that all outcomes specified *a priori* in the review protocol, will be explicitly addressed in the systematic review report, regardless of the existence or not of data from included studies on these outcomes (Aromataris 2015).

A further critical aspect refers to the measurement of the specified outcomes. It is recommended that reviewers present explicit information on available measurement instruments, including details about the validity and reliability properties of these instruments (Aromataris 2015).

As JBI endorses the use of the GRADE approach known as the 'Summary of findings' table, reviewers should be aware that the most important outcomes, that is, the primary outcomes specified in the review protocol should be addressed in the review report and should be explicitly presented in the GRADE Summary of findings' table. Details are provided in the GRADE Handbook (Schunnemann et al. 2013).

4.2.4.5 Types of studies

There are three approaches regarding choices for inclusion of studies based on their design in JBI systematic reviews. The first option is to clearly state in the protocol what study designs will be included (for example RCTs), and include only studies that are of this design in the review. This approach is transparent and at low risk of subjectivity during selection of studies. However, it runs the risk of leading to an empty review or a review with few included studies.

The second option is to consider using the hierarchy of study designs for including and excluding studies in the review. In this approach, authors may include other study designs if their preferential study designs are not located. If this is the case, there should be a statement about the primary study design of interest and the other types of studies that will be considered if primary study design of interest is not found. It is common to provide a statement that RCTs will be sought, and that in the absence of RCTs, other study designs will be included, such as quasi-experimental studies and observational studies. This is a pragmatic approach with the aim to include the best available evidence within a review.

The third option is to simply include all quantitative study designs (or all study designs up to a point of the hierarchy of evidence - for example experimental studies and cohort studies, both prospective and retrospective). This inclusive approach is acceptable as it allows for examination of the totality of empirical evidence and may provide invaluable insights regarding the agreement or disagreement of the results from different study designs. Where feasible, JBI prefers and suggests reviewers consider option 3, the most inclusive approach. However, for many topics, this will present a great deal of information which may not be of use to best inform effectiveness.

4.2.5 Search strategy

This section of a review protocol should provide explicit and clear information regarding two different aspects of locating studies: *all information sources* that will be searched for the review, and the *strate gies used for searching*. The aim of a systematic review is to identify all relevant studies, published or not, on a given topic. Searching should be based on the principle of comprehensiveness, with the widest reasonable collection of information sources that are considered appropriate to the review.

A systematic review of effectiveness aims to identify, at a minimum (see Section 3.2.4.5) all data derived from experimental trials (published or not) performed on a specific topic. Two recent international initiatives, one called 'All Trials' (http://www.alltrials.net/), and the other one called Restoring invisible and Abandoned Trials abbreviated RIAT (http://www.bmj.com/content/346/bmj.f2865) are fundamental in this regard.

The review protocol should list all information sources that will be used in the review: electronic bibliographic databases; search engines; trials registers; specific relevant journals; websites of relevant organizations; direct contact with researchers; direct contact with sponsors and funders of clinical trials; contact with regulatory agencies (for example, US FDA). The review protocol, ideally, should specify all the details (a line-by-line description) of the proposed search strategy used for

each electronic bibliographic database considered for the review. As a minimum, all the details of the proposed search strategy for at least one major electronic bibliographic database (such as PubMed) should be provided in an appendix. The review protocol should specify the timeframe for search, and any language and date restrictions, with appropriate justifications. The reviewers should consider the potential consequences of language and date search restrictions. If possible, authors should always seek the advice of an expert research librarian when developing a search strategy. Involvement of a research librarian in the development of a search strategy should be acknowledged. For JBI systematic reviews, the search strategy is often described as a three-phase process beginning with the identification of initial key words that are used in a limited number of databases (for example, PubMed and CINAHL); followed by an analysis of the text words contained in the title, abstract and index terms used to describe relevant articles. The second phase consists of the use of database-specific searches for each database specified in the review protocol. The third phase includes the examination of the reference lists of all studies already retrieved with the explicit aim to identify additional relevant studies. The list of all databases that will be considered for database-specific searches should be provided. Usually, a comprehensive search for a review of effectiveness includes a search of relevant multiple bibliographic databases (for example, PubMed, CINAHL, EMBASE etc.), a search of trial registers, a search of relevant grey literature sources, and a hand-search of relevant journals. Reviewers should provide enough information in order to persuade readers that the sources of information considered are relevant and comprehensive and the search strategy is comprehensive and sound. Reviewers are encouraged to read the article by Aromataris and Riitano (2014) regarding searching for evidence.

4.2.6 Selection of studies

This section should describe the process of study inclusion for all stages of selection (based on title and abstract examination; based on full text examination) and the procedures for solving disagreements between reviewers. The software used for the management of the results of the search should be specified (e.g. Covidence, Endnote). Selection is performed based on inclusion criteria (see section 3.2.4) pre-specified in the review protocol. In a systematic review study selection (both at title/abstract screening and full text screening) should be performed by two or more reviewers, independently. Any disagreements are solved by consensus or by the decision of a third reviewer. JBI reviewers are encouraged to read the article by Porritt et al (2014) regarding study selection and critical appraisal.

4.2.7 Critical appraisal

This section should describe the critical appraisal process and instruments that will be used in the review process and the procedures for solving disagreements between reviewers.

The goal of critical appraisal (assessment of risk of bias) is to assess the methodological quality of a study and to determine the extent to which a study has excluded or minimized the possibility of bias in its design, conduct and analysis. Bias refers to systematic errors in the design, conduct and analysis of quantitative studies that may impact the validity of inferences from these studies. Critical appraisal of the studies included in a systematic review is performed with the explicit goal of identifying the risk of diverse biases in these studies. JBI uses standardized critical appraisal tools for the assessment of risk of diverse biases encountered in quantitative studies. There are JBI standardized appraisal tools based on study design appropriate for JBI reviews of effectiveness (see Appendix 3.2 regarding the JBI standardized appraisal tools). JBI systematic reviews are required to use these JBI standardized appraisal tools.Reviewers should refer in the review protocol to the JBI standardized critical appraisal checklists and provide references for these checklists. It is not necessary to provide these checklists in appendices of the review protocol. If non-JBI appraisal tools are proposed then these tools should be briefly described and correctly referenced. In this case, an explicit justification for the use of non-JBI appraisal tools should be provided in the review protocol.

Two reviewers should perform independent critical appraisal of retrieved studies using the standardized critical appraisal checklists developed by JBI. The protocol should specify that any disagreements are solved by consensus or by the decision of a third reviewer. In experimental studies (randomized experimental studies and quasi-experimental studies) the most important biases are: selection bias, performance bias, attrition bias, detection bias, and reporting bias. In observational studies the most important biases are: selection bias, information bias, and confounding. The review protocol should specify that reviewers plan to report in narrative form and in tables the results of risk of bias (methodological quality) assessments for each aspect of methodological quality (randomization; blinding; measurement; statistical analysis etc.) for each individual study and the overall risk of bias of the entire set of included studies. The critical appraisal phase of the review should not be treated as a rapid ‘box ticking exercise’ on checklists, but rather as a complex, profound, critical, systematic, thorough examination of the risk of bias of each included study, a solid foundation for an appropriate synthesis of the results.

The review protocol should specify if and how the results of critical appraisal will be used for the exclusion of studies from the review. For example, if studies judged of low methodological quality will be excluded from the review, the details of the circumstances under which such decisions will be made and the explicit criteria or decision rules should be explicitly provided, including explanations for what is considered low methodological quality by reviewers. It is the decision of the review team if they want to exclude from the review studies judged of low methodological quality. Reviewers should

explain and justify their criteria and decision rules. The decision as to whether or not to include a study can be made based on meeting a predetermined proportion of all criteria, or on certain criteria being met. It is also possible to weight the different criteria differently. The decisions about the scoring system and the cut-off for inclusion of a study in the review should be made in advance and be agreed upon by all participating reviewers before critical appraisal commences. The review protocol should specify if and how the results of critical appraisal will be used in the synthesis (narrative synthesis or meta-analysis) of the results. It is recommended that the results of critical appraisal should be used in the synthesis phase of the review, for the critical examination of the impact of methodological quality of studies on results (including subgroup analysis or sensitivity analysis). JBI reviewers are encouraged to read the article by Porritt et al (2014) regarding study selection and critical appraisal.

4.2.8 Data extraction

This section of the review protocol should specify the data extraction process and instruments that will be used in the review process, as well as the procedures for solving disagreements between reviewers. Complete and accurate data extraction is essential for a good quality systematic review. Reviewers should carefully consider all the relevant data that should be extracted for the review given the focus of the review, the review objectives/questions, and the inclusion criteria. Details regarding the publication and the study, the participants, settings, the interventions, the comparators, the outcome measures, study design, statistical analysis and results, and all other relevant data (funding; conflict of interest etc.) should be carefully and accurately extracted from all included studies. In a review assessing effectiveness, thorough extraction of details of the intervention is essential to allow for reproducibility of an intervention that is found to the effective (Munn et al. 2014). In a JBI systematic review data extraction is performed by two or more reviewers, independently, using the standardized data extraction form developed by JBI. Any disagreements about data extraction are solved by consensus or by the decision of a third reviewer. If non-JBI data extraction forms are used these should be briefly described and the justification for their use should be explicitly indicated. The review protocol should specify if authors of studies will be contacted by reviewers in order to clarify existing data, to request missing data or additional data. The review protocol should specify the pre-planned approach for the situations when there are multiple reports (publications) for the same study, and for missing data and for data conversion/transformation.

4.2.9 Data synthesis

This section should describe how the data will be combined and reported in the systematic review. Essentially, in a systematic review of effectiveness there are two synthesis options: statistical synthesis (meta-analysis) and narrative summary (narrative synthesis). Details of the statistical models and methods and effect estimates that will be calculate and measures of statistical heterogeneity should be included (See Section 3.3). Authors should ensure that the effect estimates that will be calculate correspond to the type of data (dichotomous and/or continuous) they have suggested will be collected in their protocol (see Section 3.2.4.4). The review protocol should also explicitly specify the pre-planned approaches that will be used for the examination of publication bias, including the use of funnel plots and the use of statistical tests for the examination of publication bias (see Section 3.3.11).

The review protocol should explicitly specify that reviewers plan to use the GRADE approach for the reporting of the strength of evidence, including the reporting of the summary of findings table of evidence. The use of GRADE approach is currently endorsed by JBI and JBI reviewers must use it regardless of the synthesis approach employed, meta-analysis or narrative synthesis.

4.3 Meta-analysis

Meta-analysis refers to the statistical synthesis of quantitative results from two or more studies. The review protocol should state that statistical meta-analysis of data will be conducted if appropriate and that if meta-analysis is not possible, narrative synthesis will be conducted as the primary mechanism of data synthesis. Narrative summary should be included to supplement the technical details provided on the process and results even if meta-analysis is performed and to provide synthesis of data not captured in statistical meta-analysis.

Meta-analysis should be reserved for the results of studies that are considered similar enough from a clinical and methodological point of view (homogeneous studies). If studies are heterogeneous from a clinical or methodological point of view, then it is uncertain if it is appropriate to synthesize the respective studies into meta-analysis. Any meta-analysis where studies are heterogeneous from a clinical or methodological point of view will require substantial justification by the authors. Clinical heterogeneity refers to differences between studies with regards the participants, interventions, comparators, settings, and outcomes. Methodological heterogeneity refers to the study design and the methodological quality of the studies (risk of bias). Studies that are similar with regards the participants, interventions, comparators, settings, outcomes, study design, and risk of bias may be combined in meta-analysis. The judgement that studies are homogeneous enough and that it is appropriate to combine the studies in meta-analysis should be based on the understanding of the review question, the characteristics of the studies, and the interpretability of the results. The decision should not be based just on statistical considerations regarding heterogeneity (Sutton et al 2000).

The review protocol should specify the appropriate possible, reasonable details regarding the anticipated (pre-planned) meta-analysis:

- Objectives of the meta-analysis,
- Meta-analysis model (fixed effects model or random effects model) and the justification,
- Effect size to be used (OR, RR, etc.),
- Meta-analysis method (Peto method etc.) and justification,
- Statistical testing procedures used for the exploration of statistical heterogeneity (such as Q Cochran test) and the rules used for the interpretation of the results,
- Statistical indicator used for the quantification of statistical heterogeneity (such as I^2) and the rules used for the interpretation of the results,
- Pre-planned sensitivity analyses and their justification, and
- Pre-planned subgroup analyses and their justification.

4.3.1 Objectives of meta-analysis

The objectives of meta-analysis should be pre-specified in the review protocol. There are different legitimate objectives for a meta-analysis: to improve statistical power to detect a treatment effect, to estimate a summary average effect, to identify subsets of studies (sub-groups) associated with a beneficial effect, and to explore if there are differences in the size or direction of the treatment effect associated with study-specific variables (Normand 1999).

4.3.2 Statistical models for meta-analysis

There are three categories of statistical models for meta-analysis: the fixed effects model, random effects model, and mixed effects models (Hedges 1992). Only the first two models are used in JBI SUMARI for meta-analysis and discussed here. Using the fixed-effect model we assume that the true effect size for all studies is identical and the effect sizes estimated in studies are different only due to errors in estimating the effect size (Borenstein et al 2010). In the random-effects model we assume a distribution of effects, not a common identical effect size, and we assume that the meta-analysis summary effect size is an estimate of the mean of a distribution of true effects, not a common shared effect size identical for all studies (Borenstein et al 2010).

The proposed statistical model for meta-analysis should be explicitly indicated in the review protocol. When considering statistical inference, meta-analysis using the fixed effects model is appropriate if the aim is to draw statistical conclusions only about the studies included in the meta-analysis, and that the random effects model is appropriate whenever statistical generalizations beyond the included studies are considered (Cooper and Hedges 1994). Commonly, review authors want to generalize the conclusions beyond the actual studies included in meta-analysis, therefore we suggest that the default model for meta-analysis in JBI reviews should be the random effects model. However, it has been recommended by statisticians that the fixed effects model is the appropriate model whenever the number of studies is small (less than five studies) (Cooper and Hedges 1994; Murad et al 2015, p.511). Further details about the fixed effects and random effects models for meta-analysis, including a flowchart for the decisions regarding the selection of the meta-analysis model are provided by Tufanaru et al (2015).

4.3.3 Effect sizes

In this section, effect sizes refer to quantitative indicators of the direction and magnitude of the effects of the interventions on outcomes. Common effect sizes reported in meta-analysis include the risk ratio (RR), risk difference (RD), odds ratio (OR), weighted mean difference (WMD), and standardized mean difference (SMD).

4.3.4 Considerations for the meta-analysis of dichotomous data

For meta-analyses, computation of the logarithm (log) of the RR or the log of OR, or the RD from each individual study may be used or the number of events and the total number of participants for each group. RR and RD may be computed for any experimental study (RCT) or quasi-experimental study or cohort studies. Odds ratios may be computed for any study design (experimental, quasi-experimental, cohort, case-control, or analytical cross-sectional studies). Fleiss (1994) discussed the statistical properties of the OR and concluded that the OR is the preferred effect size for the computation phase of the meta-analysis of binary data regardless of the study design of the studies. However, the OR is not easily interpretable. Therefore, reviewers should be careful in providing correct explicit interpretation of the odds ratios computed in meta-analysis. Reviewers should provide the results expressed using both absolute (RD) and relative (RR) effect sizes for meta-analysis of binary data. Reviewers should provide correct explicit interpretation of the computed effect sizes.

4.3.5 Considerations for the meta-analysis of continuous data

For the effect sizes related to differences in continuous data (WMD, SMD), the data regarding the mean response, the standard deviation, and the number of participants in each group are used. The difference in means is the difference between the mean response in the intervention group and the mean response in the control group. This may be the difference in the means between groups at the final measurement of outcomes, or it may be the difference between the means in their changes from baseline. The simple difference in means is also called the mean difference (MD) or the weighted

mean difference (WMD). We will use the term the WMD in this chapter. The WMD is used in meta-analysis of continuous data if all studies included in meta-analyses measured the outcome using the same measurement instrument. For meta-analysis computation the difference in means from each individual study are used. The results are expressed in the natural (clinical) units used for the common measurement instrument. If WMD is used, reviewers should provide explanations regarding the interpretation of the results expressed in units used for the common measurement instrument. The minimum score and the maximum score that are possible on the measurement instrument should be specified together with their interpretation. Also, reviewers should specify what change (difference) is considered significant from a practical or clinical point of view. Reviewers should explain the interpretation of a negative or positive difference. The standardized mean difference (SMD) is a difference in means that is standardized by using information on the variability of data (standard deviation). There are three methods (formulas) that are commonly used for the computation of SMD: Cohen's d, Hedges' adjusted g, and Glass's delta. These three formulae use different standard deviations in their computation. Currently, the JBI SUMARI software offers capabilities for the computation of Cohen's d. The SMD is used in meta-analysis of continuous data if the studies measured the same outcome but with different measurement instruments. For meta-analysis computation the SMD from each individual study are used. The results are expressed in units of standard deviation. Reviewers should provide explanations regarding the interpretation of the results. In order to facilitate the interpretation of the results it is recommended that reviewer's convert the results into natural (clinical) units by multiplying the results expressed in units of standard deviation with the standard deviation of the scores from a study on a known measurement instrument. The instrument chosen may be the most commonly used instrument or the instrument which has the best psychometric properties. Reviewers should explain the interpretation of differences and justify what is considered a small or medium or large difference; explanations should be provided for negative or positive differences.

4.3.6 Meta-analysis: Statistical Methods

Different statistical methods are available for meta-analysis: Mantel-Haenszel method, Peto's method, DerSimonian and Laird method, and the inverse variance method. The Mantel-Haenszel method, the Peto's method, and the inverse variance method are methods used with the fixed effects model of meta-analysis (Deeks et al 2008). The DerSimonian and Laird method is used with the random effects model of meta-analysis (Deeks et al 2008).

The inverse variance method may be used with all types of ratios and differences for example the log odds ratio, log relative risk, risk difference, mean difference (weighted mean difference) and standardized mean difference (Petitti 2000; Deeks et al 2008). The Mantel–Haenszel method may be used with ratios, typically with odds ratio, but can be applied to rate ratio and risk ratio (Petitti 2000). The Peto's method is used with odds ratios (Petitti 2000). DerSimonian and Laird method may be used with all types of ratios (odds ratio, risk ratio) and difference (weighted mean difference) and standardized mean difference (Petitti 2000; Deeks et al 2008).

There are different statistical methods (formulae) used to compute a standardized mean difference for each study including the Hedges' method, the Cohen's method, and the Glass method. If a fixed effects model is used for meta-analysis of standardized mean differences then the inverse variance method of meta-analysis may be used. If a random effects model is used for meta-analysis of standardized mean differences then the DerSimonian and Laird method may be used.

When deciding what method for meta-analysis to be used statistical considerations are important. When studies have small sample sizes and the number of events is small in these studies the inverse variance method may not be appropriate; in these circumstances, it may be preferable to use the Mantel-Haenszel method (Deeks et al 2008). Peto's method may produce serious under-estimates when the odds ratio is far from unity (large treatment effects) (Sutton et al 2000). If the number of studies to be combined is small, but the within-study sample sizes per study are large, the inverse-weighted method should be used (Sutton et al 2000, p.69). If there are many studies to combine, but the within-study sample size in each study is small, the Mantel-Haenszel method is preferred (Sutton et al 2000).

4.3.7 Subgroups in meta-analysis

Subgroups refer to diverse grouping of studies based on specific characteristics of the studies such as study design. These characteristics may include the types of participants, types of comparators, and the outcomes. For example, it is possible to group all randomized experimental studies in one subgroup and all observational studies in another group; similarly reviewers may wish to group all studies with young participants in one subgroup and all studies with older participants in another subgroup. For these subgroups, it is possible to perform meta-analysis and to report the summary effects computed within subgroups. Also, it is possible to compare the summary effects computed in diverse subgroups. It is recommended that if subgroup analyses are performed these should be limited in number, should be pre-planned in the review protocol, and explanation and justification should be explicitly provided. These analyses should be carefully interpreted.

3.3.8 Sensitivity analysis in meta-analysis

As there are many decisions involved in meta-analyses it is important to perform a sensitivity analysis in order to explore the impact of different decisions on results. For example, one sensitivity analysis may explore the impact of using different meta-analysis models. Another sensitivity analysis may explore the impact of excluding or including studies in meta-analysis based on sample size, methodological quality, or variance. If results remain consistent across the different analyses, the results can be considered robust as even with different decisions they remain the same/similar. If the results differ across sensitivity analyses, this is an indication that the result may need to be interpreted with caution.

4.3.9 Meta-regression

Meta-regression analysis aims to examine if characteristics of studies are associated with the magnitude and direction of the effect in studies included in meta-analysis. However, given the strict statistical circumstances under which it is appropriate to perform meta-aggregation and also the advanced statistical skills required to use meta-regression software, we cannot recommend the common use of these methods in meta-analysis in JBI reviews of effectiveness.

4.3.10 Heterogeneity

There are different statistical approaches for investigating heterogeneity, included the standard chi-squared test, the I square statistic, and Tau squared.

4.3.10.1 Standard chi-squared test (Cochran test)

The standard chi-squared test (Cochran Q test) for statistical heterogeneity tests the statistical hypothesis that the true treatment effects (the effect size parameters) are the same in all the primary studies included in meta-analysis (Sutton et al 2000). This statistical test uses a test statistic Q that has a chi-squared distribution on k-1 degrees of freedom (k represents the number of studies) under the statistical hypothesis; the corresponding p-value for the test statistic is examined (Sutton et al 2000). The statistical power of the test is in most cases very low due to the small number of studies; heterogeneity may be present even if the Q statistic is not statistically significant at conventional levels of significance such as 0.05. A cut-off significance level of 0.10 rather than the usual 0.05 has been advocated (Sutton et al 2000). If results of the test are statistically significant ($p<0.05$) the statistical hypothesis that the true treatments effects (the effect size parameters) are the same in all the primary studies included in meta-analysis (the hypothesis of homogeneity) is rejected, therefore, it is considered that there is statistical heterogeneity. With a small number of studies (< 20), the Q test should be interpreted very cautiously (Huedo-Medina et al 2006). It is not appropriate to decide the meta-analysis model (fixed or random effects model) based on the results of the Chi squared statistical test (Q test) for heterogeneity.

4.3.10.2 Quantification of the statistical heterogeneity: I squared

The I square statistic (I^2) represents the percentage of the variability in effect estimates that is due to heterogeneity (Deeks et al 2008). I^2 is the proportion of observed dispersion of results from different studies included in a meta-analysis that is real, rather than spurious (Borenstein et al 2009). The I^2 in dex can be interpreted as the percentage of the total variability in a set of effect sizes due to true heterogeneity (between-studies variability) (Huedo-Medina et al 2006). If $I^2 = 0\%$, this indicates that all variability in effect size estimates is due to sampling error within studies. If $I^2= 50\%$, it indicates that half of the total variability among effect sizes is caused not by sampling error, but by true heterogeneity between studies (Huedo-Medina et al 2006). I^2 is a percentage and its values lie between 0% and 100% (Higgins et al 2003). A value of 0% indicates no observed heterogeneity, and larger values show increasing heterogeneity (Higgins et al 2003). One proposed suggestion was to consider as low, moderate, and high heterogeneity for I^2 values of 25%, 50%, and 75% (Higgins et al 2003). Another guide to interpretation was proposed: 0% to 40% might not be important; 30% to 60% may represent moderate heterogeneity; 50% to 90% may represent substantial heterogeneity; 75% to 100% considerable heterogeneity (Deeks et al 2008). Authors of the guide mention that careful interpretation of the value of I^2 depends on magnitude and direction of effects and strength of evidence for heterogeneity (Deeks et al 2008). With a small number of studies (< 20) and/or average sample size (N <80) the statistical power for I^2 procedures is less than the usually recommended minimum value of 0.8 (Huedo-Medina et al 2006). With a small number of studies (< 20), both the I^2 confidence interval and the Q test should be interpreted very cautiously (Huedo-Medina et al 2006).

4.3.10.3 Tau-squared for random effects model meta-analysis

In random-effects meta-analysis, the extent of variation among the effects observed in different studies (between-study variance) is referred to as tau-squared, ^{2}, or Tau^2 (Deeks et al 2008). ^{2} is the variance of the effect size parameters across the population of studies and it reflects the variance of the true effect sizes. The square root of this number is referred to as tau (T). T^2 and Tau reflect the amount of true heterogeneity. T^2 represents the absolute value of the true variance (heterogeneity). T^2 is the variance of the true effects while tau (T) is the estimated standard deviation of underlying true

effects across studies (Deeks et al 2008). The summary meta-analysis effect and T as standard deviation may be reported in random-effects meta-analysis to describe the distribution of true effects (Borenstein et al 2009).

4.3.11 Publication bias

Publication bias occurs when published studies differ systematically from all conducted studies on a topic. Publication bias arises when studies with statistically significant results or positive results in a specific direction are more likely to be published compared to studies without statistically significant results or negative results. Reviewers should make all reasonable efforts to include in their systematic review all or most of all relevant studies, regardless of the nature of reports (published or unpublished. Publication bias can have a detrimental effect on the validity of systematic reviews (Deeks et al 2008). Funnel plots are a method of investigating the located studies in a meta-analysis for publication bias, they are scatter plots in which an effect estimate of each study is plotted against a measure of size or precision (i.e. standard error) (Deeks et al 2008). The largest studies should be closest to the 'true' value, with the smaller studies spread on either side; creating the shape of a funnel if publication bias is not present. If publication bias has had an effect on the studies available (and there are no other confounding factors) then the 'funnel' should be incomplete with an area missing (Deeks et al 2008). Generally the best way to minimise the impact of publication bias on a systematic review is the inclusion of trial registries and unpublished studies or grey literature (Lau et al 2006; Sterne et al 2011). Funnel plots suffer from numerous issues including low power, numerous alternative explanations for asymmetrical distribution of studies, and inaccurate researcher interpretations of plots (Lau et al 2006; Sterne et al 2011). However, they remain a useful and popular way of investigating publication bias (Deeks et al 2008). Potential reasons for funnel plot asymmetry other than publication bias include: poor methodological quality leading to exaggerated effects in smaller studies (which can be the result of poor methodological design, inadequate analysis, or fraud), true heterogeneity, artefactual causes (in some situations sampling variation can lead to an association between the two factors (effect estimate and measure of size or precision)) and chance (Sterne et al 2011). The visual inspection of funnel plots introduces great uncertainty and subjectivity. In a survey utilizing simulated plots, researchers had only 53% accuracy at identifying publication bias (Lau et al 2006). A very liberal minimum number of studies for the performance of a funnel plot to be justified is ten (Lau et al 2006).

Statistical tests for funnel plot asymmetry (also known as tests for publication bias) investigate the association between effect size estimate and measure of study size or precision. The most popular statistical tests for funnel plot asymmetry are Egger test, Begg test, and the Harbord test. These tests were developed based on the following assumptions: large studies are more likely to be published regardless of statistical significance; small studies are at the greatest risk for being lost; in small studies only the large effects are likely to be statistically significant therefore published small studies often show larger effect sizes compared to larger studies; small and unfavorable effects are more likely to be missing; small studies with large effect sizes are likely to be published (Jin et al 2015). Null statistical hypotheses for these tests reflect the hypothesis of symmetry of the plot, that is, the hypothesis of no publication bias. A finding of not statistically significant P-value for the asymmetry test does not exclude bias. These tests are known to have low power.

A statistical test for funnel plot asymmetry investigates whether the association between effect estimate and measure of study size or precision is larger than what can be expected to have occurred by chance (Sterne et al 2011). These tests are known to have low power and consequently a finding of no evidence of asymmetry does not serve to exclude bias (Sterne et al 2011).

The Begg's Test was proposed by Begg and Mazumdar in 1994. It is used for dichotomous outcomes with intervention effects measured as odds ratios. It is an adjusted rank correlation test (Jin et al 2015). It explores the correlation between the effect estimates and their sampling variances (Jin et al 2015). It is a very popular test, however, it has low power; some statisticians do not recommend its use. It is "fairly powerful" for meta-analysis of 75 studies; it has "moderate power" for meta-analysis of 25 studies (Begg and Mazumdar 1994). It is considered that the test has "appropriate" type I error rate (Jin et al 2015).

The Egger's test was proposed by Egger et al in 1997. It is used for continuous outcomes with intervention effects measured as mean differences. It is a "regression test", that is, it uses a linear regression approach (Jin et al 2015). The standard normal deviate (estimated effect size/estimated standard error) is regressed against the estimate's precision. It is a very popular test. It is considered that the test has "inappropriate" type I error rate when heterogeneity is present and the number of included studies is large (Jin et al 2015). The Egger test for funnel asymmetry is the most cited statistical test for publication bias.

The Harbord Test was proposed by Harbord et al in 2006. It is used for dichotomous outcomes with intervention effects measured as odds ratios. The test uses "a weighted regression model" (Jin et al 2015). It is considered that the test has "inappropriate" type I error rate when heterogeneity is present. It was contended that the Harbord Test has better error rate compared to Egger's test in balanced trials with little or no heterogeneity (Jin et al 2015).

4.4 Systematic review of effectiveness

A systematic review report is important because it provides all the details regarding the conduct of the systematic review and the best available evidence to inform the question posed by the review. Essentially, the content of the sections of the review protocol and the review report are conceptually the same, particularly the background and the methods section. The review protocol specified the proposed plan for the review; the review report reports the conduct of the review, what was actually performed and the results of the review undertaking. All deviations from what was pre-planned in the review protocol should be explicitly reported and justified in the review report.

4.4.1 Title

A clear, descriptive title is important to assist readers and users to readily identify the scope and relevance of the review. The review report title should accurately describe and reflect the content of the review, and should not be phrased as a question. The review title should explicitly identify the publication as a report for a finalized systematic review. It is important to indicate in the review title the focus of the review on effectiveness; we recommend the following convention: *'The effectiveness of [intervention] compared to [comparator] on [outcome]: a systematic review'*. The title of the review should be as descriptive as possible and reflect all relevant information. Ideally, the review title should include in a concise way the relevant information with regards to the types of participants, types of interventions and comparators and the types of outcomes considered in the review.

4.4.2 Abstract

This section forms a structured abstract of the main features of the systematic review. It must be no longer than 500 words and should contain no abbreviations or references. The abstract must accurately reflect and summarize the systematic review with the main focus on the results of the review.

The abstract should report the essential elements of the review using the following sub-headings in this order:

- **Objective**: State an overarching review objective structured using the key components of the inclusion criteria (approximately one to two sentences).
- **Background**: Briefly describe what is already known on the topic and what this review will add to the evidence-base (approximately two to three sentences).
- **Inclusion criteria:** Summarize the inclusion criteria as it relates to the type of review being conducted. Present the information in one or two sentences – **NOT** under individual subheadings.
- **Methods:** List the key information sources searched (those that provided the majority of included studies), any limits placed on the scope of the search (e.g. language), and the date range, or the date of the last search. If the recommended JBI approach to critical appraisal, study selection, data extraction and data synthesis was used, simply state it as such (without naming the actual tool). Otherwise, briefly describe any notable deviations to the methodological approach taken (e.g. criteria used to exclude studies on the basis of methodological quality etc.).
- **Results**: The bulk of the abstract should be reserved to convey the main results of the review.
  - As a general rule, report the number and type of included studies and participants, as well as any pertinent study characteristics. Summarize the overall quality of the included studies and notable aspects of risk of bias.
  - Report the results for all main outcomes (not only those that were statistically significant or clinically important). If meta-analyses were conducted report the summary measures (estimated effect) and confidence intervals and ensure statistics are presented in a standard way. If a meta-analysis was proposed but not conducted, report the reason (e.g. clinical or methodological heterogeneity). Where possible, indicate the number of studies and participants for each main outcome. Describe the direction of the effect (e.g. lower, fewer, greater, more, etc.) in a way that is understandable to patients and health care professionals (i.e. which group was favored and the size of the effect) and indicate the measurement scale used, where applicable.
- **Conclusions**: Provide a conclusion based on a general interpretation of the results considering, for example, the methodological quality of the included studies and any limitations of the review. Briefly convey key implications for practice and/or research.

4.4.3 GRADE 'Summary of Findings' table

The use of the GRADE approach is currently endorsed by JBI and JBI reviewers must use it regardless of the synthesis approach employed, meta-analysis or narrative synthesis. The GRADE 'Summary of Findings' table should be presented immediately below the abstract. The GRADE 'Summary of Findings' table can be developed following the guidance in the GRADE handbook (Schunnemann et al. 2013). Links to resources and support for using GRADE are available via the JBI Adelaide GRADE Centre.

4.4.4 Introduction

The introduction of the review report should provide explicit and comprehensive information regarding the justification (rationale) for the conduct of the review in the context of what was already known. Ideally, this section of the review report should be a revised, expanded, version of the introductory section from the review protocol. See Section 3.2.3 from the review protocol for further information regarding the content of the introduction.

The introduction should conclude with an overarching review objective that captures and aligns with the core elements/mnemonic of the inclusion criteria (e.g. PICO). The stated objective should clearly indicate what the review project is trying to achieve. For publication in *JBI Evidence Synthesis*, Vancouver style of referencing should be used throughout the protocol with superscript numbers without brackets used for in-text citations.

4.4.5 Review question(s)

The review question(s) should be explicitly stated in unambiguous terms. See the Section 3.2.2 of this Chapter for further information regarding the objectives and questions of a review of effectiveness.

4.4.6 Inclusion criteria

This section should describe the inclusion criteria used for the review. Information should be provided regarding the types of participants, types of interventions, comparators, types of outcomes, and types of studies actually considered and included in the review. See Section 3.2.4 for further details regarding specification of inclusion criteria in the systematic review report.

4.4.7 Methods

This section of the review report is reserved for the methods used to conduct the review and should be presented under the relevant subheadings (see Sections 3.4.6.1 to Section 3.4.6.5), including any deviations from the method outlined in the *a priori* protocol. In empty reviews for example, this section should not refer to methods that were not performed.

Directly below the Methods heading provide the following information:

- State and appropriately cite the JBI methodology that was employed in the conduct of the review and synthesis.
- Refer to and cite the *a priori* protocol that was published, or accepted for publication (e.g. 'in press'), in the *JBI Evidence Synthesis*.
- If the protocol has been registered with PROSPERO, provide registration information including registration number (e.g. PROSPERO CRD42015425226).

4.4.7.1 Search strategy

The search strategy section of a review report should provide explicit and clear information regarding all information sources that were actually used in the review, and the actual strategies used for searching. The review report should provide details regarding all information sources that were used in the review: electronic bibliographic databases; trial registers; relevant journals; websites of relevant organizations; etc. The review report, ideally, should specify all the details (a line-by-line description) of the actual search strategy used for each electronic bibliographic database used for the review and should be provided in an appendix. The review report should specify the timeframe for search, the date of last search for each database, and any language and date restrictions, with appropriate justifications.

4.4.7.2 Study screening and selection

The review report should describe the actual process of study screening and for all stages of selection (based on title and abstract examination; based on full text examination) and the actual procedures used for solving disagreements between reviewers.

4.4.7.3 Critical appraisal

The review report should specify the critical appraisal process and instruments that were actually used in the review process and the procedures for solving disagreements between reviewers. The review report should describe how the results of critical appraisal were used for the exclusion of studies from the review, if this is the case. The details of the decisions processes and criteria used for exclusion of studies based on results of critical appraisal should be explicitly provided. All details about the scoring systems and the cut-off scores for inclusion of studies in the review should be described and justified.

4.4.7.4 Data extraction

The review report should specify the data extraction process and instruments that were used in the review process and the procedures for solving disagreements between reviewers.

4.4.7.5 Data synthesis

The review report should explicitly specify how the data were combined and reported. Essentially, the review report should provide the details about all preformed analyses and their justifications. The synthesis approaches by which studies were combined should be described in as much detail as is reasonably possible and to enable them to be reproduced.

If meta-analysis was performed, the review report should specify the details regarding the performed meta-analyses. The report should specify:

- the objectives of the meta-analysis
- the effect size used (OR, RR, etc.)
- the meta-analysis model (fixed effects model or random effects model) and the justification
- the meta-analysis method (Peto method etc.) and the justification
- the statistical testing procedures used for the exploration of statistical heterogeneity (such as Q Cochran test) and the rules used for the interpretation of the results
- the statistical indicator used for the quantification of statistical heterogeneity (such as I^2) and the rules used for the interpretation of the results
- the performed sensitivity analyses
- the performed subgroup analyses

4.4.8 Results

This section of the review report has distinct sub-sections describing the process of study inclusion, the methodological quality of the eligible studies, detailed characteristics and description of the included studies and, importantly, the findings of the review and results of the synthesis processes.

4.4.8.1 Study inclusion

This section should provide a narrative summary of the search results and selection process and results. The number of papers identified by the search strategy and the number of papers that were included and excluded should be stated.

A complete and accurate report should be provided regarding:

- the number of studies identified by the search in diverse sources;
- the number of studies excluded after the examination of title and abstract against inclusion criteria;
- the number of full text articles retrieved for examination;
- the number of studies excluded after full text examination against inclusion criteria;
- the number of critically appraised studies;
- the number of studies excluded after critical appraisal;
- the final total number of included studies.

A flowchart using the PRISMA template for the reporting of the selection process should be included.

Ideally, a list of all excluded studies, excluded after full text examination and after critical appraisal, with the explicit reasons for exclusion, should be provided in appendices to the review. As a minimum, at least the list of studies excluded after critical appraisal and the reasons for exclusion should be reported. If no studies were excluded after critical appraisal then the list of all studies excluded after full text examination including the explicit reasons for exclusion, should be provided in appendices to the review.

4.4.8.2 Methodological quality

The review report should report in a comprehensive manner, in narrative form and in tables, the results of risk of bias (methodological quality) assessments for each aspect of methodological quality (randomization; blinding; measurement; statistical analysis etc.) for each individual study and the overall risk of bias of the entire set of included studies. This section must provide an overarching statement of the quality of the included studies as a whole (i.e. low, moderate, high, etc.) and a narrative summary of the methodological quality of the included studies against each of the critical appraisal criteria, with a clear indication of the risks of bias present across the included studies (e.g. performance bias, detection bias etc.). Reporting can be supported (optional) by a table showing the results of the critical appraisal (see Table 3.1 for example). Where only few studies are identified, or there are specific items of interest from included studies, these should be addressed in the narrative also, particularly where studies were deficient, or particularly good. Use of 'Unclear' and 'Not Applicable' should also be explained in the text.

Table 3.1. Critical appraisal results for included studies using the JBI-Critical Appraisal Checklist for randomised controlled trials

Study	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10
Author(s) [ref]	Y	Y	Y	N	Y	U	Y	N	Y	U
Author(s) [ref]	Y	N	Y	Y	Y	U	Y	N/A	Y	Y

Y - Yes, N - No, U - Unclear, N/A - not applicable

If appraisal tools are not appended to the review report (citation only), the appraisal questions should be added as a footnote/caption to the table (Table 3.1) so readers can clearly interpret the information presented.

4.4.8.3 Characteristics of included studies

This section should include a narrative summary of the details about the design and details of the included studies. Relevant characteristics of the included studies for which data were extracted and are needed to understand and interpret the results of the study should be synthesized in narrative. This includes the descriptive and demographic features (e.g. the country and setting of the study) of the included studies, as well as the main clinical characteristics, as they relate to the review objective and the inclusion criteria (e.g. PICOs). For example, in a review of effects, synthesize characteristics of the population, intervention, comparator, outcomes, and study design. Information on interventions should include treatment modalities and the amount, duration, frequency and intensity of the intervention any details related to the follow-up of the participants. Population characteristics should include the number of participants (i.e. study size) and demographic information such as age, gender and any information relevant to the specific review question (e.g. past medical history, diagnosis, co-morbidities).

Reviewers should provide an appendix of the review report summarized details of the included studies. The examination of the table of included studies should suffice to convince the readers that there is good match between the included studies and the inclusion criteria.

4.4.8.4 Results and meta-analysis

This section should be organized in a meaningful way based on the review objectives and questions and types of interventions, comparators, outcomes and types of studies. This section should provide comprehensive information regarding the results of all performed meta-analyses and additional analyses such as sensitivity analysis and sub-group analysis. Point estimates and interval estimates (confidence intervals) should be reported. Before presenting any meta-analysis results, the conduct of meta-analyses should be justified; reviewers should explicitly provide commentaries regarding the clinical, methodological, and statistical heterogeneity of the studies included in meta-analyses and the appropriateness of conducting meta-analyses. Summary results from meta-analyses should be reported as summary point estimates and interval estimates. The meta-analysis forest plots for all performed meta-analyses should be presented in this section. A narrative summary should complement the forest plots and provide additional commentaries and explanations for all performed meta-analyses (Munn et al 2014).

Reviewers should report the funnel plot for publication bias if such assessment was appropriate and performed. Reviewers should include the results of assessment of risk of publication bias, including the results of statistical tests for publication bias, if such tests were used.

Even if meta-analysis is performed, a narrative summary should be included to supplement the technical details provided on the process and results of meta-analysis and to provide synthesis of data not captured in statistical meta-analysis.

If meta-analysis is not performed, a narrative summary should be included. The narrative summary should provide an overall summary of the findings of the included studies and their biases, strengths and limitations. The essence of narrative summary is that the results are summarized in words and in tables without any statistical meta-analysis. Textual commentaries and tables are used in order to summarize the results from the included studies and to provide context information for these results, thus facilitating understanding of the summarized results.

4.4.9 Discussion

The aim of this section is to briefly summarize the main findings and then focus on the discussion of these results. Results should be discussed, compared and contrasted with what was already known from other sources, other than the review, usually at a minimum the literature mentioned in the background section, however, additional external literature may be discussed here in order to facilitate the understanding and positioning of the review results in a broader research and practice context. The applicability and generalizability of the review results should be discussed. The significance of the results should be discussed for individual studies and for meta-analyses. It is not enough to discuss the statistical significance of the results; the practical/clinical significance of the results should be discussed regardless of the statistical significance of the results. The minimum and maximum values for the scales of measurement or measurement instruments should be discussed and the values that are considered to represent the minimum important change from a clinical/practical point of view.

This section should provide a presentation of the limitations of included studies and the limitations of the review process. Limitations of each included study (limitations in the design and conduct of the research, including risk of bias) should be discussed. Also, the limitations of entire set of included studies should be discussed in terms of common limitations (including risk of bias). All limitations, issues and problems noted in the review process related to the search, selection of study, critical appraisal, data extraction, and data synthesis, should be discussed. The impact of the limitations of the studies and of the review process on the applicability and generalizability of the results should be considered.

4.4.10 Conclusions and recommendations

This section should include the overall conclusions of the review. The conclusions should provide direct answers to the review objectives /questions. These conclusions should be based only on the results of the review and directly inferred from the review results.

Recommendations for practice

This sub-section of Conclusions section should include the recommendations for practice inferred from the results of the review and inferred also based on the discussion of the generalizability of the results and the potential factors that may affect the applicability of results. Recommendations should be assigned a JBI Grade of Recommendation. Refer for the editorial by Munn 2015 for further discussion regarding the appropriateness of making recommendations in systematic reviews.

Recommendations for research

This sub-section of Conclusions should include the recommendations for future research inferred from the results of the review, specifically, inferred from the limitations, issues and problems noted in the review process related to the search, selection of study, critical appraisal, data extraction, and data synthesis.

4.4.11 Conflicts and acknowledgements

Details of requirements in these sections are described in Section 1.6. of this Manual.

Conflicts of interest

A statement which either declares the absence of any conflicts of interest or which describes a specified or potential conflict of interest should be made by the reviewers in this section.

Funding

Authors should provide details regarding any sources of funding for the review project. The role of all funders in the review process, if any, should be explicitly described. If the review is funded, then any potential conflicts of interest or intellectual bias of the funders should be specified in the review.

Acknowledgements

Any acknowledgements should be made in this section e.g. sources of external funding or the contribution of colleagues or institutions. It should also be noted if the systematic review is to count towards a degree award.

4.4.12 Review Appendices

There are several required appendices for a JBI review:

Appendix 1: Search strategy

- A detailed and complete search strategy for all of the major databases and other sites and sources searched must be appended. Major databases that were searched must be identified, including the search platform used where necessary. All search filters with logic employed should be displayed, including the number of records returned.

Appendix 2: Data extraction instrument

- The data extraction instrument used must be appended i.e JBI SUMARI Data Extraction Form.

Appendix 3: List of excluded studies

- Studies excluded following examination of the full-text should be listed along with their reason for exclusion at that stage (i.e. a mismatch with the inclusion criteria). This may be as a separate appendix or itemized in some fashion within the one appendix with those studies excluded at the critical appraisal stage. Reasons for exclusion following appraisal should be provided for each study (these reasons should relate to the methodological quality of the study, not study eligibility).

Appendix 4: Table of included study characteristics

- A table of included studies is required to provide quick reference to important details extracted from of the studies included in the review.

4.5 Chapter References

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Appendix 4.1: JBI Critical appraisal checklist for randomized controlled trials

JBI Critical Appraisal Checklist for Randomized Controlled Trials

Reviewer_____ Date_____

Author _____ Year_____ Record Number_____

	Yes	No	Unclear	NA
1. Was true randomization used for assignment of participants to treatment groups?				
2. Was allocation to treatment groups concealed?				
3. Were treatment groups similar at the baseline?				
4. Were participants blind to treatment assignment?				
5. Were those delivering treatment blind to treatment assignment?				
6. Were outcomes assessors blind to treatment assignment?				
7. Were treatment groups treated identically other than the intervention of interest?				
8. Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?				
9. Were participants analyzed in the groups to which they were randomized?				
10. Were outcomes measured in the same way for treatment groups?				
11. Were outcomes measured in a reliable way?				
12. Was appropriate statistical analysis used?				
13. Was the trial design appropriate, and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial?				

Overall appraisal: Include Exclude Seek further info

Comments (Including reason for exclusion)

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Appendix 4.2: Discussion of JBI appraisal criteria for randomized controlled trials

Critical Appraisal Tool for RCTs (individual participants in parallel groups)

Answers: Yes, No, Unclear or Not Applicable

1. **1. Was true randomization used for assignment of participants to treatment groups?**

The differences between participants included in compared groups constitutes a threat to the internal validity of a study exploring causal relationships. If participants are not allocated to treatment and control groups by random assignment there is a risk that the allocation is influenced by the known characteristics of the participants and these differences between the groups may distort the comparability of the groups. A true random assignment of participants to the groups means that a procedure is used that allocates the participants to groups purely based on chance, not influenced by the known characteristics of the participants. Check the details about the randomization procedure used for allocation of the participants to study groups. Was a true chance (random) procedure used? For example, was a list of random numbers used? Was a computer-generated list of random numbers used?

1. **2. Was allocation to groups concealed?**

If those allocating participants to the compared groups are aware of which group is next in the allocation process, that is, treatment or control, there is a risk that they may deliberately and purposefully intervene in the allocation of patients by preferentially allocating patients to the treatment group or to the control group and therefore this may distort the implementation of allocation process indicated by the randomization and therefore the results of the study may be distorted. Concealment of allocation (allocation concealment) refers to procedures that prevent those allocating patients from knowing before allocation which treatment or control is next in the allocation process. Check the details about the procedure used for allocation concealment. Was an appropriate allocation concealment procedure used? For example, was central randomization used? Were sequentially numbered, opaque and sealed envelopes used? Were coded drug packs used?

1. **3. Were treatment groups similar at the baseline?**

The differences between participants included in compared groups constitute a threat to the internal validity of a study exploring causal relationships. If there are differences between participants included in compared groups there is a risk of selection bias. If there are differences between participants included in the compared groups maybe the ‘effect’ cannot be attributed to the potential ‘cause’ (the examined intervention or treatment), as maybe it is plausible that the ‘effect’ may be explained by the differences between participants, that is, by selection bias. Check the characteristics reported for participants. Are the participants from the compared groups similar with regards to the characteristics that may explain the effect even in the absence of the ‘cause’, for example, age, severity of the disease, stage of the disease, co-existing conditions and so on? Check the proportions of participants with specific relevant characteristics in the compared groups. Check the means of relevant measurements in the compared groups (pain scores; anxiety scores; etc.). *[Note: Do NOT only consider the P-value for the statistical testing of the differences between groups with regards to the baseline characteristics.]*

1. **4. Were participants blind to treatment assignment?**

If participants are aware of their allocation to the treatment group or to the control group there is the risk that they may behave differently and respond or react differently to the intervention of interest or to the control intervention respectively compared to the situations when they are not aware of treatment allocation and therefore the results of the study may be distorted. Blinding of participants is used in order to minimize this risk. Blinding of the participants refers to procedures that prevent participants from knowing which group they are allocated. If blinding of participants is used, participants are not aware if they are in the group receiving the treatment of interest or if they are in any other group receiving the control interventions. Check the details reported in the article about the blinding of participants with regards to treatment assignment. Was an appropriate blinding procedure used? For example, were identical capsules or syringes used? Were identical devices used? Be aware of different terms used, blinding is sometimes also called masking.

1. **5. Were those delivering treatment blind to treatment assignment?**

If those delivering treatment are aware of participants’ allocation to the treatment group or to the control group there is the risk that they may behave differently with the participants from the treatment group and the participants from the control group, or that they may treat them differently, compared to the situations when they are not aware of treatment allocation and this may influence the implementation of the compared treatments and the results of the study may be distorted. Blinding of those delivering treatment is used in order to minimize this risk. Blinding of those delivering treatment refers to procedures that prevent those delivering treatment from knowing which group they are treating, that is those delivering treatment are not aware if they are treating the group receiving the treatment of interest or if they are treating any other group receiving the control interventions. Check the details reported in the article about the blinding of those delivering treatment with regards to treatment assignment. Is there any information in the article about those delivering the treatment? Were those delivering the treatment unaware of the assignments of participants to the compared groups?

1. **6. Were outcomes assessors blind to treatment assignment?**

If those assessing the outcomes are aware of participants' allocation to the treatment group or to the control group there is the risk that they may behave differently with the participants from the treatment group and the participants from the control group compared to the situations when they are not aware of treatment allocation and therefore there is the risk that the measurement of the outcomes may be distorted and the results of the study may be distorted. Blinding of outcomes assessors is used in order to minimize this risk. Check the details reported in the article about the blinding of outcomes assessors with regards to treatment assignment. Is there any information in the article about outcomes assessors? Were those assessing the treatment's effects on outcomes unaware of the assignments of participants to the compared groups?

1. **7. Were treatment groups treated identically other than the intervention of interest?**

In order to attribute the 'effect' to the 'cause' (the treatment or intervention of interest), assuming that there is no selection bias, there should be no other difference between the groups in terms of treatment or care received, other than the manipulated 'cause' (the treatment or intervention controlled by the researchers). If there are other exposures or treatments occurring at the same time with the 'cause' (the treatment or intervention of interest), other than the 'cause', then potentially the 'effect' cannot be attributed to the examined 'cause' (the investigated treatment), as it is plausible that the 'effect' may be explained by other exposures or treatments occurring at the same time with the 'cause' (the treatment of interest). Check the reported exposures or interventions received by the compared groups. Are there other exposures or treatments occurring at the same time with the 'cause'? Is it plausible that the 'effect' may be explained by other exposures or treatments occurring at the same time with the 'cause'? Is it clear that there is no other difference between the groups in terms of treatment or care received, other than the treatment or intervention of interest?

1.8. Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?

For this question, follow up refers to the time period from the moment of random allocation (random assignment or randomization) to compared groups to the end time of the trial. This critical appraisal question asks if there is complete knowledge (measurements, observations etc.) for the entire duration of the trial as previously defined (that is, from the moment of random allocation to the end time of the trial), for all randomly allocated participants. If there is incomplete follow up, that is incomplete knowledge about all randomly allocated participants, this is known in the methodological literature as the post-assignment attrition. As RCTs are not perfect, there is almost always post-assignment attrition, and the focus of this question is on the appropriate exploration of post-assignment attrition (description of loss to follow up, description of the reasons for loss to follow up, the estimation of the impact of loss to follow up on the effects etc.). If there are differences with regards to the loss to follow up between the compared groups in an RCT, these differences represent a threat to the internal validity of a randomized experimental study exploring causal effects, as these differences may provide a plausible alternative explanation for the observed 'effect' even in the absence of the 'cause' (the treatment or intervention of interest). When appraising an RCT, check if there were differences with regards to the loss to follow up between the compared groups. If follow up was incomplete (that is, there is incomplete information on all participants), examine the reported details about the strategies used in order to address incomplete follow up, such as descriptions of loss to follow up (absolute numbers; proportions; reasons for loss to follow up) and impact analyses (the analyses of the impact of loss to follow up on results). Was there a description of the incomplete follow up (number of participants and the specific reasons for loss to follow up)? It is important to note that with regards to loss to follow up, it is not enough to know the number of participants and the proportions of participants with incomplete data; the reasons for loss to follow up are essential in the analysis of risk of bias; even if the numbers and proportions of participants with incomplete data are similar or identical in compared groups, if the patterns of reasons for loss to follow up are different (for example, side effects caused by the intervention of interest, lost contact etc.), these may impose a risk of bias if not appropriately explored and considered in the analysis. If there are differences between groups with regards to the loss to follow up (numbers/proportions and reasons), was there an analysis of patterns of loss to follow up? If there are differences between the groups with regards to the loss to follow up, was there an analysis of the impact of the loss to follow up on the results? *[No te: Question 8 is NOT about intention-to-treat (ITT) analysis; question 9 is about ITT analysis.]*

1.9. Were participants analyzed in the groups to which they were randomized?

This question is about the intention-to-treat (ITT) analysis. There are different statistical analysis strategies available for the analysis of data from randomized controlled trials, such as intention-to-treat analysis (known also as intent to treat; abbreviated, ITT), per-protocol analysis, and as-treated analysis. In the ITT analysis the participants are analyzed in the groups to which they were randomized, regardless of whether they actually participated or not in those groups for the entire duration of the trial, received the experimental intervention or control intervention as planned or whether they were compliant or not with the planned experimental intervention or control intervention. The ITT analysis compares the outcomes for participants from the initial groups created by the initial

random allocation of participants to those groups. Check if ITT was reported; check the details of the ITT. Were participants analyzed in the groups to which they were initially randomized, regardless of whether they actually participated in those groups, and regardless of whether they actually received the planned interventions? *[Note: The ITT analysis is a type of statistical analysis recommended in the Consolidated Standards of Reporting Trials (CONSORT) statement on best practices in trials reporting, and it is considered a marker of good methodological quality of the analysis of results of a randomized trial. The ITT is estimating the effect of offering the intervention, that is, the effect of instructing the participants to use or take the intervention; the ITT it is not estimating the effect of actually receiving the intervention of interest.]*

10. Were outcomes measured in the same way for treatment groups?

If the outcome (the 'effect') is not measured in the same way in the compared groups there is a threat to the internal validity of a study exploring a causal relationship as the differences in outcome measurements may be confused with an effect of the treatment (the 'cause'). Check if the outcomes were measured in the same way. Same instrument or scale used? Same measurement timing? Same measurement procedures and instructions?

11. Were outcomes measured in a reliable way?

Unreliability of outcome measurements is one threat that weakens the validity of inferences about the statistical relationship between the 'cause' and the 'effect' estimated in a study exploring causal effects. Unreliability of outcome measurements is one of the different plausible explanations for errors of statistical inference with regards to the existence and the magnitude of the effect determined by the treatment ('cause'). Check the details about the reliability of measurement such as the number of raters, training of raters, the intra-rater reliability, and the inter-raters reliability within the study (not as reported in external sources). This question is about the reliability of the measurement performed in the study, it is not about the validity of the measurement instruments /scales used in the study. *[Note: Two other important threats that weaken the validity of inferences about the statistical relationship between the 'cause' and the 'effect' are low statistical power and the violation of the assumptions of statistical tests. These other two threats are explored within Question 12).]*

12. Was appropriate statistical analysis used?

Inappropriate statistical analysis may cause errors of statistical inference with regards to the existence and the magnitude of the effect determined by the treatment ('cause'). Low statistical power and the violation of the assumptions of statistical tests are two important threats that weaken the validity of inferences about the statistical relationship between the 'cause' and the 'effect'. Check the following aspects: if the assumptions of statistical tests were respected; if appropriate statistical power analysis was performed; if appropriate effect sizes were used; if appropriate statistical procedures or methods were used given the number and type of dependent and independent variables, the number of study groups, the nature of the relationship between the groups (independent or dependent groups), and the objectives of statistical analysis (association between variables; prediction; survival analysis etc.).

13. Was the trial design appropriate for the topic, and any deviations from the standard RCT design accounted for in the conduct and analysis?

Certain RCT designs, such as the crossover RCT, should only be conducted when appropriate. Alternative designs may also present additional risks of bias if not accounted for in the design and analysis.

Crossover trials should only be conducted in people with a chronic, stable condition, where the intervention produces a short term effect (i.e. relief in symptoms). Crossover trials should ensure there is an appropriate period of washout between treatments.

Cluster RCTs randomize groups of individuals, forming 'clusters.' When we are assessing outcomes on an individual level in cluster trials, there are unit-of-analysis issues, as individuals within a cluster are correlated. This should be taken into account by the study authors when conducting analysis, and ideally authors will report the intra-cluster correlation coefficient.

Stepped-wedge RCTs may be appropriate when it is expected the intervention will do more good than harm, or due to logistical, practical or financial considerations in the roll out of a new treatment /intervention. Data analysis in these trials should be conducted appropriately, taking into account the effects of time.

Appendix 4.3: JBI Critical appraisal Checklist for Quasi-Experimental Studies (non-randomized experimental studies)

JBI Critical Appraisal Checklist for Quasi-Experimental Studies
(non-randomized experimental studies)

Reviewer_____ Date_____

Author _____ Year_____ Record Number_____

	Yes	No	Unclear	Not applicable
1. Is it clear in the study what is the 'cause' and what is the 'effect' (i.e. there is no confusion about which variable comes first)?				
2. Were the participants included in any comparisons similar?				
3. Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest?				
4. Was there a control group?				
5. Were there multiple measurements of the outcome both pre and post the intervention/exposure?				
6. Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?				
7. Were the outcomes of participants included in any comparisons measured in the same way?				
8. Were outcomes measured in a reliable way?				
9. Was appropriate statistical analysis used?				

Overall appraisal: Include Exclude Seek further info

Comments (Including reason for exclusion)

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Appendix 4.4: Discussion of JBI appraisal criteria for Quasi-Experimental Studies (non-randomized experimental studies)

Explanation for the critical appraisal tool for Quasi-Experimental Studies (experimental studies without random allocation)

Critical Appraisal Tool for Quasi-Experimental Studies (experimental studies without random allocation)

Answers: Yes, No, Unclear or Not Applicable

1. Is it clear in the study what is the 'cause' and what is the 'effect' (i.e. there is no confusion about which variable comes first)?

Ambiguity with regards to the temporal relationship of variables constitutes a threat to the internal validity of a study exploring causal relationships. The 'cause' (the independent variable, that is, the treatment or intervention of interest) should occur in time before the explored 'effect' (the dependent variable, which is the effect or outcome of interest). Check if it is clear which variable is manipulated as a potential cause. Check if it is clear which variable is measured as the effect of the potential cause. Is it clear that the 'cause' was manipulated before the occurrence of the 'effect'?

2. Were the participants included in any comparisons similar?

The differences between participants included in compared groups constitute a threat to the internal validity of a study exploring causal relationships. If there are differences between participants included in compared groups there is a risk of selection bias. If there are differences between participants included in the compared groups maybe the 'effect' cannot be attributed to the potential 'cause', as maybe it is plausible that the 'effect' may be explained by the differences between participants, that is, by selection bias. Check the characteristics reported for participants. Are the participants from the compared groups similar with regards to the characteristics that may explain the effect even in the absence of the 'cause', for example, age, severity of the disease, stage of the disease, co-existing conditions and so on? *[NOTE: In one single group pre-test/post-test studies where the patients are the same (the same one group) in any pre-post comparisons, the answer to this question should be 'yes.']*

3. Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest?

In order to attribute the ‘effect’ to the ‘cause’ (the exposure or intervention of interest), assuming that there is no selection bias, there should be no other difference between the groups in terms of treatments or care received, other than the manipulated ‘cause’ (the intervention of interest). If there are other exposures or treatments occurring in the same time with the ‘cause’, other than the intervention of interest, then potentially the ‘effect’ cannot be attributed to the intervention of interest, as it is plausible that the ‘effect’ may be explained by other exposures or treatments, other than the intervention of interest, occurring in the same time with the intervention of interest. Check the reported exposures or interventions received by the compared groups. Are there other exposures or treatments occurring in the same time with the intervention of interest? Is it plausible that the ‘effect’ may be explained by other exposures or treatments occurring in the same time with the intervention of interest?

4. **Was there a control group?**

Control groups offer the conditions to explore what would have happened with groups exposed to other different treatments, other than to the potential ‘cause’ (the intervention of interest). The comparison of the treated group (the group exposed to the examined ‘cause’, that is, the group receiving the intervention of interest) with such other groups strengthens the examination of the causal plausibility. The validity of causal inferences is strengthened in studies with at least one independent control group compared to studies without an independent control group. Check if there are independent, separate groups, used as control groups in the study. *[Note: The control group should be an independent, separate control group, not the pre-test group in a single group pre-test post-test design.]*

5. Were there multiple measurements of the outcome both pre and post the intervention /exposure?

In order to show that there is a change in the outcome (the ‘effect’) as a result of the intervention /treatment (the ‘cause’) it is necessary to compare the results of measurement before and after the intervention/treatment. If there is no measurement before the treatment and only measurement after the treatment is available it is not known if there is a change after the treatment compared to before the treatment. If multiple measurements are collected before the intervention/treatment is implemented then it is possible to explore the plausibility of alternative explanations other than the proposed ‘cause’ (the intervention of interest) for the observed ‘effect’, such as the naturally occurring changes in the absence of the ‘cause’, and changes of high (or low) scores towards less extreme values even in the absence of the ‘cause’ (sometimes called regression to the mean). If multiple measurements are collected after the intervention/treatment is implemented it is possible to explore the changes of the ‘effect’ in time in each group and to compare these changes across the groups. Check if measurements were collected before the intervention of interest was implemented. Were there multiple pre-test measurements? Check if measurements were collected after the intervention of interest was implemented. Were there multiple post-test measurements?

6. Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?

If there are differences with regards to the loss to follow up between the compared groups these differences represent a threat to the internal validity of a study exploring causal effects as these differences may provide a plausible alternative explanation for the observed ‘effect’ even in the absence of the ‘cause’ (the treatment or exposure of interest). Check if there were differences with regards to the loss to follow up between the compared groups. If follow up was incomplete (that is, there is incomplete information on all participants), examine the reported details about the strategies used in order to address incomplete follow up, such as descriptions of loss to follow up (absolute numbers; proportions; reasons for loss to follow up; patterns of loss to follow up) and impact analyses (the analyses of the impact of loss to follow up on results). Was there a description of the incomplete follow up (number of participants and the specific reasons for loss to follow up)? If there are differences between groups with regards to the loss to follow up, was there an analysis of patterns of loss to follow up? If there are differences between the groups with regards to the loss to follow up, was there an analysis of the impact of the loss to follow up on the results?

7. Were the outcomes of participants included in any comparisons measured in the same way?

If the outcome (the ‘effect’) is not measured in the same way in the compared groups there is a threat to the internal validity of a study exploring a causal relationship as the differences in outcome measurements may be confused with an effect of the treatment or intervention of interest (the ‘cause’). Check if the outcomes were measured in the same way. Same instrument or scale used? Same measurement timing? Same measurement procedures and instructions?

8. Were outcomes measured in a reliable way?

Unreliability of outcome measurements is one threat that weakens the validity of inferences about the statistical relationship between the ‘cause’ and the ‘effect’ estimated in a study exploring causal effects. Unreliability of outcome measurements is one of different plausible explanations for errors of

statistical inference with regards to the existence and the magnitude of the effect determined by the treatment ('cause'). Check the details about the reliability of measurement such as the number of raters, training of raters, the intra-rater reliability, and the inter-raters reliability within the study (not to external sources). This question is about the reliability of the measurement performed in the study, it is not about the validity of the measurement instruments/scales used in the study. *[Note: Two other important threats that weaken the validity of inferences about the statistical relationship between the 'cause' and the 'effect' are low statistical power and the violation of the assumptions of statistical tests. These other threats are not explored within Question 8, these are explored within Question 9.]*

9. Was appropriate statistical analysis used?

Inappropriate statistical analysis may cause errors of statistical inference with regards to the existence and the magnitude of the effect determined by the treatment ('cause'). Low statistical power and the violation of the assumptions of statistical tests are two important threats that weakens the validity of inferences about the statistical relationship between the 'cause' and the 'effect'. Check the following aspects: if the assumptions of statistical tests were respected; if appropriate statistical power analysis was performed; if appropriate effect sizes were used; if appropriate statistical procedures or methods were used given the number and type of dependent and independent variables, the number of study groups, the nature of the relationship between the groups (independent or dependent groups), and the objectives of statistical analysis (association between variables; prediction; survival analysis etc.).

Systematic Reviews of Effectiveness Resources

Digital Resources

Risk of bias assessment: common tool structures and approaches

Lead author Dr Jennifer Stone provides a video abstract of the paper, 'Common tool structures and approaches to risk of bias assessment: implications for systematic reviewers'.

JBI critical appraisal tool for assessing risk of bias in RCTs

This JBI LIVE webinar presented by Dr Timothy Barker breaks down the new JBI critical appraisal tool for assessing risk of bias in randomised controlled trials.

Dr Jennifer St

Publications

The revised JBI critical appraisal tool for the assessment of risk of bias for quasi-experimental studies

Barker et al 2024

This paper presents the revised critical appraisal tool for risk of bias assessment of quasi-experimental studies; offers practical guidance for its use; provides examples for interpreting the results of risk of bias assessment; and discusses major changes from

The revised JBI critical appraisal tool for the assessment of risk of bias for randomized controlled trials

Barker et al 2024

JBI recently began the process of updating and revising its suite of critical appraisal tools to ensure that these tools remain compatible with recent developments within risk of bias science. Following a rigorous development process led by the JBI Effectiveness

Common tool structures and approaches to risk of bias assessment : implications for systematic reviewers

Stone et al 2024

the previous version, along with the justifications for those changes.	Methodology Group, this paper presents the revised critical appraisal tool for the assessment of risk of bias for randomized controlled trials.	There are numerous tools available to assess the risk of bias in individual studies in a systematic review. These tools have different structures, including scales and checklists, which may or may not separate their items by domains.
From critical appraisal to risk of bias assessment: clarifying the terminology for study evaluation in JBI systematic reviews Stone et al 2023 As evidence synthesis methodology has advanced, guidance for the critical appraisal of primary research has emphasized a distinction from the assessment of internal validity required for synthesized research. This assessment is conceptualized and branded in various ways in the literature, such as risk of bias, critical appraisal, study validity, methodological quality, and methodological limitations.	**Revising the JBI quantitative critical appraisal tools to improve their applicability: an overview of methods and the development process** Barker et al 2023 This paper details the methods and rationale that the JBI Effectiveness Methodology Group followed when updating the JBI critical appraisal instruments for quantitative study designs. We detail the key changes made to the tools and highlight how these changes reflect current methodological developments in this field.	**Assessing the risk of bias of quantitative analytical studies: introducing the vision for critical appraisal within JBI systematic reviews** Munn et al 2023 A key step in the systematic review process is the assessment of the methodological quality (or risk of bias) of the included studies. At JBI, we have developed

		several tools to assist with this evaluation.

5. Systematic reviews of textual evidence: narrative, expert opinion or policy

Pearson A, Jordan Z, McArthur A, Florescu S, Cooper A, Yan H, Klugarova J, Stannard D, Edwards D.

We would also like to acknowledge the contribution of our late colleague, Dr Catalin Tufanaru, who was a member of the JBI Textual Evidence Methods group in 2018, and passed away in July 2021.

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Contents

5.1. Introduction to textual evidence and evidence-based practice

5.1.1 Systematic reviews addressing textual evidence

The synthesis of textual evidence within the systematic review process is not well recognized in mainstream evidence-based practice and it is acknowledged that efforts to appraise and synthesize often conflicting opinions, narratives and policies are tentative. However, the use of a transparent systematic process to identify the best available textual evidence can provide practical guidance to practitioners and policy makers. “Textual evidence should be understood as the ... expression of clinical wisdom from health professionals” according to Jordan, Konno & Mu [1 (page 19)] but it may also draw on the expertise of consumers and of consumer representatives aligned with affiliated organizations. Textual evidence, in the form of narrative accounts, expert opinion papers or policy documents, has a role to play in evidence-based health care and can be used to either complement empirical evidence or stand alone as the best available evidence (either in the absence of research studies; or when the question itself is best addressed by systematically reviewing non-research derived evidence).

As evidence-based healthcare focuses on the need to use interventions that are supported by the most up-to-date evidence or *knowledge*, it is appropriate to consider clinicians’ tacit knowledge derived from their clinical experiences or the dominant healthcare discourse at the time of practice as a source of evidence. This is drawn from the extensive work of Patricia Benner who explored clinical wisdom and nursing practice.[2-5] Diverse knowledge/evidence types are required to inform practice, and for this reason comprehensive systematic review methods have been formulated to explore not only the evidence on the effectiveness of interventions (‘knowing what’ type of evidence), but also evidence related to subjective human experiences, culture, values, ethics, health policy, or the accepted discourse at the time of practice (‘knowing how’ type of evidence).[2-5]

Textual evidence often represents the best available evidence where formal research on the specific topic is limited or non-existent. When a particular problem or question is only answered through the perspectives of clinical experience or the consensus of experts (either clinicians or citizens), this evidence becomes vital to practitioners and policy makers and represents the best available evidence to guide their decision-making. Some refer to this as expert evidence. [6,7] This type of evidence can be used to complement empirical evidence or, in the absence of formal research studies, may stand alone as the best available evidence.

Systematic reviews of textual evidence require reviewers to consider the validity of textual data as a source of guidance for practice or policy; to identify and extract the conclusions or recommendations made (messages conveyed) from papers or documents included in the review; and to synthesize these messages into indicative statements that can be used to inform policy and practice. The theoretical basis to the JBI approach to systematic reviews of textual evidence is further outlined in this chapter.

5.1.2 JBI methodological approach to Textual Evidence Systematic Reviews

Of interest to contemporary commentators is the systematic review of policy statements and documents; patient stories/narrative; the opinions of experts and expert bodies; and the varying, competing discourses associated with science, expertise and patient experience. Some commentators [8-10] argue for the conduct of narrative reviews; that is, a review that "….deals in plausible truth. Its goal is an authoritative argument, based on informed wisdom that is convincing to an audience of fellow experts." [10] (page 3)

It is important to differentiate here between the 'narrative synthesis' advocated by these writers and the systematic review, or synthesis, of textual data, which may include data derived from narrative, expert opinion and policy documents or consensus guidelines. Popay et al [8] in their detailed examination of narrative synthesis, describe a process of synthesizing diverse data fields (for example text, quantitative studies, qualitative studies) by:

"…Bringing together evidence in a way that tells a convincing story of why something needs to be done, or needs to be stopped, or why we have no idea whether a long-established policy or practice makes a positive difference is one of the ways in which the gap between research, policy and practice can start to be bridged. Telling a trustworthy story is at the heart of narrative synthesis". [8] (page 5)

While JBI acknowledges the importance of taking an inclusive approach to what counts as evidence, the conceptualization of synthesis as it relates to narrative is quite different to the views expressed above. We contend that a systematic review approach (as opposed to the approach embodied in narrative synthesis) to searching for, appraising, extracting and synthesizing data derived from text (i.e., non-research data) should utilize a structured and pre-determined framework to establish the legitimacy of the evidence included in the review.

Historically, JBI's methodology as it related to this body of evidence (i.e., narrative, opinion and text), was grounded in discourse analysis and the evidence was defined and treated as a relatively homogenous data source.[11] The focus of appraisal was on authenticity and the ability to ascertain the possible motivating factors driving alternate views. It sought to assess the credibility of the expert voice and make decisions as to whether the arguments put forth were logical.

We contend that three related, but distinctive sources of textual evidence exist in the form of narrative, expert opinion and policy. For the purpose of synthesis, we suggest that it is essential to acknowledge the unique nature of these data sources, particularly in relation to critical appraisal because the specific strategies/questions required to effectively interrogate the legitimacy and authenticity of these three data sources is quite different.

The central questions of truth and power as posited by Foucault, [12] remain legitimate in assessing the quality of a textual evidence data set, irrespective of source. Authors' (be they experts expressing an opinion or contributing to the development of policy or narrative) attempts to represent reality may still be prone to being selective about inclusion or exclusion of information in order to serve an agenda. Thus, elements of discourse analysis in this vein remain an important underpinning of this methodological stance. This aligns with the premise that each data source (narrative, expert opinion or policy) is responsible for the presentation of an argument (in some form or another) and thus Toulmin's Model of Argumentation [13] offers some important insight into how such text might be appraised.

Appraising or analyzing an argument, or the process of argumentation, is of much interest to social scientists, philosophers and scholars in the humanities (but historically much less so in the health sciences). There are thus numerous processes and models presented in the literature. In critically appraising textual evidence, assessing the 'quality' and logic of an argument is of some importance. For our purposes, we suggest the use of Toulmin's model.[13] The model conceptualizes an argument as a process that makes a claim based on data. This model breaks arguments into six different components ensuing the argument relates to a warrant (i.e., cause or reason), backing to support the warrant, a qualifier and a reservation or rebuttal. This model describes the beginning of any argument as containing three fundamental elements: the claim, the data or grounds, and the warrant.

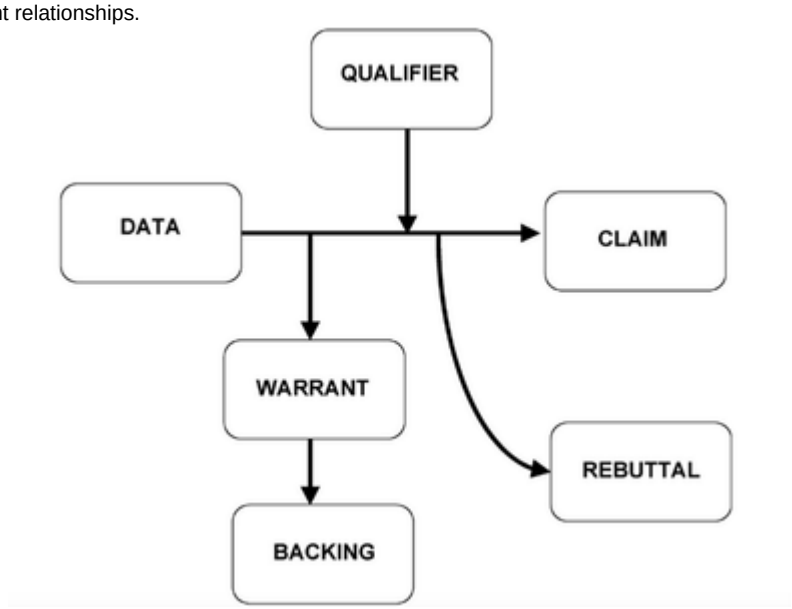
- The **claim** is the conclusion you wish the audience to accept; it's the proposition you want the audience to believe is true or justified or right. For example: Successful emergency management requires both competent on-site and remote healthcare practitioners.[14]

- The **data** (or **grounds)** are the facts and opinions; the evidence used to support your claim. For example: Patient safety and outcomes are related to staffing levels.[15]
- The **warrant** is the connection leading from the data to the claim. The warrant is the principle or the reason why the data justify (or warrant) the claim. For example: When an emergency department lacks either competent on-site or remote staff poor outcomes can result.[14]

In addition to these three elements, there are three other optional elements that may or may not be present depending on the type of argument advanced and the nature of the audience to be persuaded.

- The **backing** is the support for the warrant - the supporting material that backs up the principle or reason expressed in the warrant. Backing is especially important if the warrant is not accepted or believed by the audience. For example: Staffing policies, legislative support for safe staffing levels, staffing ratios.[15]
- The **qualifier** is the degree to which the claim is asserted; it's an attempt to modify the strength or certainty of the claim. The qualifier is used only when the claim is presented with less than total certainty. For example: There should be more support for emergency management staffing to prevent some unintended poor outcomes.[14]
- The **reservation** (or rebuttal) specifies those situations under which the claim might not be true. For example: Although many institutions having severe staffing challenges, supporting a staffing model that includes both competent on-site and remote healthcare practitioners can improve outcomes.[14]

Usually, these six parts of an argument are laid out in diagrammatic form to further illustrate the important relationships.



5.1.3 Sources of textual evidence

JBI conceptualizes textual evidence as documented communication sources (other than research) that inform decision making in healthcare. The question of what constitutes a 'text' can differ due to highly variable theoretical approaches to textual linguistics and discourse analysis where even the concepts of text and discourse are used in a multitude of ways and are grounded in differing research traditions. Similarly, social scientists' understandings and utilization of methods and the act of analysing text are variable.

Text can be defined as a 'communicative event' that may correspond with a particular genre - in this case we are talking about sources of knowledge for the purpose of systematic reviews relating to health care research, inquiry, discussion, debate or opinion. Different genres have particular linguistic features, fulfil particular functions and are bound to specific rules of production and response. Contextual expectations, therefore, are also fundamental to understanding the role of text in different settings.

Non-research text within health care is, generally speaking, found in published narratives or 'stories' from health care consumers or health care providers; expert opinion-based pieces; government or institutional policies and/or reports; unpublished (or grey/gray) literature; discussion papers; white /position papers from professional organizations, media sources, or consensus guidelines. Clinicians

often refer to these texts as sources of knowledge to inform practice, particularly where no research-based information exists.

The overarching term ‘text’ therefore, for our purpose, refers specifically to documented communication other than research that inform decision making in healthcare embodied in the following sources: narrative, expert opinion, and policy.

5.1.3.1 Evidence from narrative

5.1.2.1.1 Definition

Narrative: A spoken (recorded) or written account of connected events [16]

Narrative generally refers to the recounting of real events in healthcare or the telling of a story. [1] From a systematic review perspective, this type of data is likely to be related to accounts of experience from the perspective of patients, health professionals or other stakeholders in enterprises related to the phenomenon of interest of the review. The narrator puts forward an account of a series of events or actions that may involve one or more people; and the account may be a ‘real’ or fictional story. Paley and Eva [17] distinguish between the term’s narrative and story, arguing that a ‘story’:

“…Is an interweaving of plot and character, whose organization is designed to elicit a certain emotional response from the reader, while ‘narrative’ refers to the sequence of events and the (claimed) causal connections between them. We suggest that it is important not to confuse the emotional persuasiveness of the ‘story’ with the objective accuracy of the ‘narrative’.” [17 (page 1)]

They argue that narrative is best defined as a reported sequence of events rather than a broad term for non-medical discourse. For them, narrative is the recounting of one or more real or fictitious events that relates this sequence of events and makes causal claims about them. These claims may be true or false, and they can certainly be tested. The authors propose that narrative is different to a story - a story is also a recounting of a sequence of events, but a story also organizes its various constituents in such a way as to elicit a particular effect, and this can sometimes detract attention from, or even be mistaken for, the implicit claims about causation. [17]

Important sources of narrative data in evidence-based healthcare include (but are not limited to): patient stories or classic illness narratives; clinicians’ stories; narratives about clinician-patient encounters; recollections captured through written (eg. diaries) or other media; and grand stories or metanarratives.[18] They argue that both evidence of cause and effect and other relationships generated through primary research on groups and populations (focusing on generalities) and the evidence generated through the description of the ‘specific, unique and singular’ (focusing on particularities) are important in evidence-based healthcare. This is referred to as the “…tensions between the known and the unknown (or at least the knowable and the unknowable), the universal and the particular, and the body and the self.” [19(page 296)] Greenhalgh [18] concurs with this, asserting “…appreciating the narrative nature of illness experience and the intuitive and subjective aspects of clinical method does not require us to reject the principles of evidence-based medicine.” [18(page 325)]

Narrative has always played an important role in our understandings of health and illness and in the health professions. Narratives and stories about patients, the experience of caring for them, and their recovery from illness have always been shared both in the community and across the health professions. Narratives have been, and continue to be, a source of knowledge or evidence, alongside the gold standard of randomized controlled trials. They provide meaning, context and perspective and can act as a bridge between the evidence of large-scale randomized-controlled studies and the art of applying this knowledge to a single patient.

The insights of Paley and Eva [17] are useful in examining narrative as evidence and in considering its appraisal. Of importance is the distinction they draw between ‘story’ as “an interweaving of plot and character, whose organization is designed to elicit a certain emotional response from the reader” and ‘narrative’ as an account of a “sequence of events and the (claimed) causal connections between them.”[17 (page 1)] They stress the importance of not confusing “…the emotional persuasiveness of the ‘story’ with the objective accuracy of the ‘narrative’” and they “…recommend what might be called ‘narrative vigilance’”[17 (page 1)] when considering narrative as evidence. Central to ‘narrative vigilance’ is the concept of narrativity. Narrativity is something that a text has degrees of. It is constituted by a series of elements whose presence is associated with ‘high’ narrativity, and whose absence is associated with ‘low’ narrativity. They present a ‘narrativity ladder’ (see Figure 1 below), which ranges from a simple recounting of one or two events to a more complex account:

8 ... and presented in a way that is likely to elicit an emotional reaction from the audience

7 ... the explanation being related to the problem they confront

6 ... characters who are confronted by some kind of difficulty or problematic issue

5 ... there being one or more characters centrally involved in the events described

4 ... causally related in such a way that a certain event is explained

3 ... two or more events, some of which must be causally related

2 … The recounting of at least two events

1 … The recounting of one or more events

Figure 1: Narrativity Ladder/ Degrees of narrativity [17] (page 87)

Paley and Eva [17] argue that a story sits at the 'high' narrativity end of a continuum and that an account that incorporates features 4–8 on the narrativity ladder should be regarded as a story. While all stories are narratives, not all narratives are stories.

Sources of this type of data may be found in the grey literature and located from printed publications or on the websites of patient groups, professional associations or industry/provider groups. It may also include spoken accounts (video or audio with transcripts), or blogs. Narratives are increasingly a common data source, but are collected outside the frame of formal research.

5.1.3.2 Evidence from expert opinion

5.1.2.2.1 Definition

Expert Opinion: A view or judgement formed about something, not necessarily based on fact or knowledge; a statement of advice by an expert on a professional matter. [16]

Expert opinion refers to a view or judgement formed about something, not necessarily based on fact from formal empirical evidence; or a statement of advice by an expert on a healthcare matter. In healthcare, common sources of expert opinion will be the repositories of learned colleges/bodies and opinion pieces in professional journals.

Proponents of evidence-based healthcare have, since the earliest days of its emergence, been brutally explicit in their rejection of opinion as a sound basis for decision-making. Sackett [19] is vehement in his rejection of the use of expert opinion in evidence-based healthcare and argues that 'experts' are often regarded as having a great deal of prestige and that their opinions possess a much:

"...greater persuasive power than they deserve on scientific grounds alone. Whether through deference, fear, or respect, others tend not to challenge them, and progress towards the truth is impaired in the presence of an expert."[19] (page 1283)

Generally speaking, this view (or 'opinion') of Sackett is shared by a majority of those who are involved in the evidence-based healthcare movement. Holmes [20] argues that the emergence of the evidence-based medicine movement in the 1990s ranked randomized controlled trials "atop a hierarchy of scientific methods, with expert opinion situated at the bottom."[20] (page 11) This rejection of expert opinion is seen as a source of evidence because expertise is difficult to define, and experts do not always agree with one another. He suggests that expert clinicians are often constrained by cognitive biases that cannot be overcome. Additionally it is asserted that reliance on expert opinion in decision-making "is not an unfortunate consequence of an underdeveloped Evidence Based Medicine (EBM) but a necessary requirement for optimal practice of clinical medicine." [21](page 1188)

Evidence from expert opinion differs in kind instead of in degree from evidence from randomized controlled trials[22] and in contemporary practice, the now promoted ideal being an evidence-based practitioner rejects any deference to the clinical expert because expert opinion is seen as the last remnant of the 'authoritarian' model of clinical practice that EBM seeks to replace.[23]

Accordingly, knowledge derived from reasoning related to pathophysiologic principles or unsystematic clinical experience is regarded as suspect. Whilst proponents of EBM assert that evidence-based practice includes the integration of the best available evidence with clinical judgement or experience and the patient's goals and values, they do not explicitly acknowledge the value of pathophysiologic reasoning or of expert opinion as evidence in and of itself. Whilst an opinion is not a product of 'good' science it is, however, largely empirically derived and mediated through the cognitive processes of practitioners who have been typically trained in scientific method (and often draws on evidence from research). This is not to say that the superior quality of evidence derived from rigorous research is to be denied, but rather that in its absence it is not appropriate to discount expert opinion as non-evidence.

Opinion as Evidence

Evidence of generalities versus evidence of particularities

Proponents of the evidence-based practice movement originally envisioned a future when most, if not all, clinical decisions would be based on external, objective, and empirically derived evidence that supports particular courses of action.[2] However, expert opinion (based on accumulated knowledge from a wide range of sources including research) probably still constitutes the basis of many healthcare practices. [24]

The reality that there is often no solid evidence for much of the care delivered by healthcare professionals. [25] Furthermore, there are few examples of evidence-based healthcare groups developing concrete plans for remedying this problem. This contemporary lack of serious thought and research into the substantive nature of expert knowledge/expertise and the role it plays in evidence-based healthcare, with its focus only on external evidence, represents a recognizable gap in knowledge nationally and internationally.[2] Although the importance of clinical expertise and judgment is acknowledged in mainstream evidence-based healthcare, it is not well understood in terms of the extent to which external, research-derived wisdom outweighs expertise in everyday clinical decision making from both a practitioner perspective and a patient/client perspective. Whilst patients/clients value the technically, scientifically informed practitioner who is also clinically wise, health professionals of all persuasions recognize that using evidence without clinical judgment, clinical reasoning or critical thinking falls far short of best practice. Thus, marrying the generalized evidence derived from research to the particular and singular evidence derived from individual patients/clients is anecdotally supported by patients/clients and health professionals, yet it is rarely discussed in evidence-based practice circles, and understandings of it are, as yet, poorly developed.

Expert opinion arises out of: "...the expert's personal assessment of the validity of published reports, new knowledge learned at meetings and symposia, awareness of unpublished studies with "negative" results, and knowledge of the (often unreported) practice styles of colleagues in their field of expertise. The breadth and depth of such knowledge are often difficult to capture and may not be appreciated by those outside the field of expertise but are typically recognized by other domain experts. As in any human endeavour, fundamental conflicts often exist between the opinions of experts due to differences of interpretation. In healthy organizations, these conflicts lead to more in-depth exploration, hopefully including efforts to seek objective data to support one contention over another."[24] (page 356)

Expert opinion as a legitimate source of evidence

There is a growing literature that argues for the recognition of opinion as a form of knowledge that should be afforded some legitimacy as evidence for policy and practice to either complement empirical evidence or, in the absence of research studies, stand alone as the best available evidence. Expert opinion arises out of expertise. Expertise is an important phenomenon amongst health care practitioners and the possession of expertise is highly regarded in all of the health professions. Essentially linked to the ability of a practitioner to 'have to hand' relevant information in a given area of practice, it is generally associated with the possession of large amounts of knowledge and fluency in applying this knowledge. Expertise is difficult to quantify and even more difficult to rank in terms of its reliability. However, a large proportion of health care practice relies on expertise. Practitioners who have expertise are titled experts, and the opinions of experts often represent the best available evidence in areas where research is limited, or where research on a specific question is difficult to conduct.

Adequately addressing the potential role of opinion as legitimate evidence for decision-making requires an exploration of the nature of knowing and of knowledge. Two broad types of knowledge have been identified; propositional knowledge and non-propositional. [26] Propositional knowledge has been described as "...formal, explicit, derived from research and scholarship and concerned with generalizability."[26] (page 83) Non-propositional knowledge is described as "...informal, implicit and derived primarily through practice. It forms part of professional craft knowledge (the tacit knowledge of professionals) and personal knowledge linked to the life experience and cognitive resources that a person brings to the situation to enable them to think and perform."[26] (page 83) It is asserted that evidence-based healthcare requires an integration of both propositional and non-propositional knowledge drawn from evidence bases that have been critically and publicly scrutinized.[26]

Capturing expert opinion through consensus meetings (eg. the Delphi method) or conferences seeks to reduce bias by replacing individual expert judgments with those of groups of experts who develop an aggregate judgment. However, consensus conferences and other mechanisms for reaching group judgments may also be problematic. It is argued that consensus conferences often take place after the medical community have already settled an issue.[27] Considering the collective of experts' experience is important when published literature is lacking.

5.1.3.3 Evidence from policy/consensus guidelines

5.1.2.3.1 Definition

Policy: A course or principle of action adopted or proposed by an organization or individual [16]

Policy refers to policy documents or communication artefacts that generally, in healthcare, give direction for action. It relates to policies (guidelines, standard procedures or statements) at public, organizational or clinical levels, usually developed by an expert or group of experts or a government department on a healthcare matter. Sources of this type of data may come from the websites of government departments, consumer groups, professional associations or industry/provider groups.

Policy refers to a deliberate set of principles designed to guide decisions and achieve rational outcomes, in the form of consensus guidelines or policy statements. In healthcare, a policy or consensus guideline is essentially a statement of intent that is often then implemented as a procedure or protocol.

The term is used in many different ways, varying from country to country, institution to institution, organization to organization and sometimes within institutions and organisations, but there are some central features common to all good policy:

- It states matters of principle;
- It is focused on action, stating what is to be done and by whom; and
- It is an authoritative statement, made by a person, group, organization or body with the power to do so.

Evidence-based policy making has been advocated across policy making systems at all levels since the emergence of the evidence-based healthcare movement, and policies at the operational level (i.e., within health units) is frequently evidence based. However, policy making at the national, state, regional and local levels is often strongly associated with political, professional and fiscal issues and a reliance on evidence is not always apparent. Policy and guideline documents at all levels generally involve key stakeholders in their development, including patients/clients, clinical experts and health service managers, and represent an investment of time, experience and expertise. Some policies and guidelines are rigorous in their reference to the evidence but many, although taking existing external evidence into account, focus on reaching, if not total consensus, at least a majority view of those involved in the policy development process. Whilst policy and guideline developers may commission rigorous systematic reviews and draw on them to formulate policy, many focus on policy or guidelines developed and published in other jurisdictions, or health units; thus, conducting a synthesis of consensus guidelines or of policy statements or documents is increasing.

Policies and guidelines are complex and may apply to entire populations in varied contexts and they need to consider issues related to implementation. Thus, the concept of evidence generally focuses on the best available data, and not the best possible data. Mays et al [28], in a methodological article on systematic reviews aimed at informing decision makers and managers, argue that the more the authors of a knowledge review seek to support decision making, the more the review must consider context and the more open it must be to different forms of ‘evidence.’ [28] This openness implies including quantitative and qualitative data, research data and other types of data.

The JBI method for synthesizing knowledge from policies and guidelines adopts openness toward data, going beyond the exploration of the scientific literature, to include exploration of the ‘grey’ literature (documents produced by governments or non-profit organizations, statements by professional associations, opinion polls, etc.).

Policies and Consensus Guidelines as Evidence

Although most policy documents and guidelines draw on formal external evidence, the synthesis of evidence embedded in them usually takes an essentially textual approach. That is, each policy piece retrieved for synthesis is regarded as textual data (much like expert opinion) that can be synthesized using a process of meta-aggregation. However, given the likelihood that a policy or guideline has referred to external evidence, the degree to which the text is supported by evidence is of some importance and can be accounted for in the critical appraisal stage of the synthesis.

The classical policy/guideline development process generally involves (but is not limited to):

- Identifying the need for the policy/guideline;
- Identifying existing local, national or international policies/guidelines and determining if they can be adopted without change or with some change;
- Establishing a policy/guideline development team or group, often including policy experts, subject experts, interested practitioners and appropriate consumers/service users;
- Conducting research and analysis and literature reviews to identify, evaluate and summarize the external evidence on the topic. The degree to which this occurs is variable, with some policies and guidelines relying entirely on the input of the development team or group and others focusing strongly on the external evidence. Some policies and guidelines consider external evidence but allow the expert opinion of development group members or political or financial imperatives to overrule the external evidence;
- Drafting the policy/guideline;
- Consultation with stakeholders, other experts and opinion leaders; and
- Finalizing the policy/guideline.

Thus, policies and guidelines are complex and variable in their content, rigour of development and intended influence (e.g. a whole country or a single health unit such as a hospital, ward or clinic). At one end of a continuum, they can be explicitly based on a thorough examination of the evidence whilst at the other, be focused entirely on the views and opinion of the policy's/guideline's developers and may in some cases be in conflict with the extant external evidence.

Kopp[29] posits that public policies and organizational policies pursue either a 'top-down' strategy or a 'bottom-up' strategy. Top-down policy occurs when policy-makers seek to introduce a new policy or modify existing policy, often because a problem requires a response. Although consultation and evidence gathering may or may not occur, policy-makers decide to change existing policy or introduce new policy because they want to address a problem they consider important in health or healthcare. Bottom-up policy is usually a response to campaigns or requests from clinicians, patients or others. These campaigns may be welcomed by policy-makers or resisted strongly, in which case the campaigners may have to invest a lot of time and energy. In addition, bottom-up campaigns may involve a variety of groups with different views or agendas, and the debate may become a competition between these groups, or the differences may lead to internal disputes.

Guidelines are usually systematically developed statements designed to inform, and sometimes direct, decision making in health service settings. Guidelines can also be used for public policy. Policies and guidelines play an important role in healthcare delivery and the practices of healthcare professionals and, for our purposes as reviewers, are best categorized as:

- Public policies;
- Organizational policies; and
- Clinical/Practice guidelines.

Public policy

Public policy is a strategic action carried out by a public authority with an overall aim of promoting a particular phenomena. Examples of well-publicised public policy include policies on obesity, smoking, the role of the nurse practitioner in primary health care or the organization of maternity services. [30]

Organizational policy

Health services (national, regional and local) are responsible for providing policy and procedural guidelines that both reflect legislation and the ethical standards of the community and support the delivery of services and the practices of clinicians. Indeed, the quality-of-service delivery is dependent on the responsibility of both the organization and the worker in following the policies that guide service delivery. Organizational policies are influenced by the values and beliefs that the organization holds, and problems experienced by an organization, such as an increasing number of incidents where people with disabilities are discriminated against in the workplace.

Clinical/Practice Guidelines

A clinical practice guideline is a systematically developed statement to inform or direct clinical decision-making. Such guidelines are developed at a number of levels:

- At a national or State level, to inform or direct practices and services across the systems of the jurisdiction.
- At an organizational level, such as a health district, a hospital or a local health system.
- At the local, service level such as a ward or a clinic.

Many clinical guidelines are explicitly based on the evidence, with some commissioning rigorous systematic reviews and others relying heavily on existing syntheses and systematic reviews. Clinical guidelines are defined as: "…statements that include recommendations intended to optimize patient care that are informed by a systematic review of the evidence and an assessment of the benefits and harms of alternative care options." [31 (page 3)]

This is not as widely accepted as the National Academy of Medicine may think, with many guidelines developed by professional organizations and health services focusing much more on local data and the consensus of experts, and sometimes with no reference to the external evidence.[32] Evidence-based clinical guidelines, though often robust in their development, do have limitations in that they are often based on low levels of evidence, they may be influenced by the guideline development team or group members and they may lack of information on new treatments.[33] The beliefs of guideline development team members, often clinical experts may, in spite of the evidence, draw on misconceptions and personal recollections that misrepresent reality and practices that are not in the best interests of the patient perspective may be recommended to help control costs, serve societal needs, or protect special interests.

5.1.3.4 Selecting the appropriate type of text to answer your question

There are two options for inclusion of evidence sources within JBI systematic reviews of textual evidence. The first option is to clearly indicate in the protocol which types of text will be included in

the review, and then only include those textual evidence types during selection. This approach is transparent in that you are only including textual evidence that is either narrative, expert opinion or policy.

The second option is to consider the question you are trying to answer and include evidence from all three textual evidence types. This will depend on the question, as there may not be all three types of evidence available. Where feasible, JBI prefers this option, as it is the most inclusive approach. If reviewers have decided to combine the results from all three types of textual evidence, then clear reporting must be provided regarding the inclusion process.

Whichever option is taken, authors need to justify their decision.

5.2 JBI Systematic reviews of textual evidence

It is important that systematic reviews are reported in a transparent, complete and accurate way to allow users to be able to assess the trustworthiness and applicability of the results. The Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) 2020 statement is an evidence-based minimum set of items for reporting in systematic reviews and meta-analyses, which has recently been updated.[34] It is important that reviewers follow this reporting guidance.

5.2.1 Selecting a title for your systematic review

A clear, descriptive title is important to allow readers and users to readily identify the scope and relevance of the review. The clearer and more specific a title is, the more readily a reader will be able to make decisions about the potential relevance of the systematic review and the readily they will be able to locate it in indexing databases using relevant key terms.

The systematic review title should accurately describe and reflect the content of the manuscript and include relevant information with regards the participants, the types of interventions or phenomena of interest, and the context considered in the review. The title should be concise and ideally, should not be phrased as a question.

The title of the relevant manuscript should explicitly identify the publication as either a protocol for a systematic review, or the review proper. The following convention is recommended: '...:a systematic review (or protocol)'. An example:

'The use of physical restraint in acute care settings: a textual evidence systematic review.'

5.2.2 Determining your review question

The review question should consist of clear and explicit statement(s) that are directly linked to the focus of the systematic review. The review question may be posed as an actual question or as a statement. For textual evidence reviews, the review question is commonly developed using the PICo mnemonic (**P**opulation, the Types of **I**nterventions / Phenomena of **I**nterest and the **Co**ntext). The review questions should specify the focus of the review (textual evidence), the types of participants, types of interventions or phenomena of interest, and the context considered. There should be consistency between the review title and the review questions in terms of the focus of the review. Review authors are encouraged to read the article by Stern, et al. [35] regarding the review questions and the inclusion criteria.

The review question can provide readers with a significant amount of information about the focus, scope and applicability of a review to their needs. It should be apparent if the review is examining narrative, expert opinion or policy or if all three are to be considered. Similarly, including the context in the question assists readers to situate the review.

A textual evidence review will have a primary question. If that question sufficiently addresses the review objectives, there is no need for secondary or sub questions. However, some questions benefit from one or more sub questions that delve into particular attributes of context, population or phenomena of interest.

For example:

What is the textual, non-research evidence relating to the use of physical restraint in acute care settings?

- What are the narratives, expert opinions or policies from either healthcare consumers or healthcare providers in relation to the use of physical restraint in the acute care setting?

5.2.3 Introduction

Every systematic review requires a clear and meaningful introductory section. Given the international circulation of systematic reviews, it is important to state variations in local understandings of clinical practice (including 'usual practice'), health service management and client or patient experiences. The introduction should describe and situate the phenomena of interest under review, as well as the

population and context. The introduction should cover the main elements of the topic under review. The purpose of the introduction is to:

- Situate the PICo and put the inclusion criteria into context;
- Provide context to the review;
- Define key terms and list operational definitions;
- Refer to existing international literature to support and inform the inclusion criteria;
- Provide indication that the review question has not been addressed previously; and
- Justify the rationale and conduct of the review.

The introduction should avoid synthesizing findings from multiple authors given this is exactly what your review will aim to achieve. It should, however, provide some indication that there is evidence available that will be included in your review and inform your question. The introduction should also include a statement that a preliminary search for existing systematic reviews on the topic has been conducted (state the sources searched e.g. JBI Evidence Synthesis, Cochrane Database, CINAHL, PubMed, PROSPERO where relevant). If there is an existing systematic review, it should be specified how the proposed review will differ.

5.2.3.1 Identifying your eligibility criteria / PICO framework

Inclusion criteria:

Eligibility criteria should be reasonable, sound (based on scientific arguments), and based on the PICo framework. These criteria will be used in the selection process when it is decided if an evidence source will be included or not in the review. Inclusion criteria for a review are not intended to be considered in isolation; in this regard they should be articulated to be as mutually exclusive as possible and not repeat information relevant to other aspects of the PICo.

Two categories of eligibility criteria should be considered: eligibility criteria based on the PICo characteristics, and eligibility criteria based on publication characteristics. Eligibility criteria based on PICo characteristics are those related to the types of participants and settings, types of interventions or phenomena of interest, and types of textual papers (narrative, expert opinion or policy). Eligibility criteria based on publication characteristics are those related to publication date, and type of publication, etc. Usually, reviewers use the PICo framework (participants, intervention or phenomena of interest, and context) to construct a clear and meaningful review objective/question regarding the textual evidence. The reviewer uses the same PICo framework to develop eligibility criteria based on textual characteristics. The eligibility criteria must provide adequate details about the conceptual and operational definitions of each element to enable reviewers to make reliable decisions when making decisions to include studies.

Population/Type of participants

Describe the population, giving attention to whether specific characteristics of interest, such as age, sex and gender, and level of education or professional qualification are important to the question. These specific characteristics should be stated. Specific reference to population characteristics, either for inclusion or exclusion should be based on a clear justification rather than personal reasoning. The term population is used but is considered from a different perspective in textual reviews. Aspects of population pertinent to quantitative reviews such as sampling methods, sample sizes or homogeneity are may not be significant or appropriate in a review of textual evidence.

Types of interventions / Phenomena of interest

Is there a specific intervention or phenomenon of interest? As with other types of reviews, phenomena may include broad areas of health care, or specific experiences. However, reviews of textual data may also reflect an interest in opinions around power, politics or other aspects of health care other than direct interventions, in which case, these should be described in detail.

Context

In a textual review, context will vary depending on the objective and question(s) of the review. Context may include but is not limited to consideration of:

- Cultural or sub-cultural factors;
- Geographic location;
- Specific racial or gender-based interests; or
- Detail about the specific setting (such as acute care, primary health care, or the community).

It is important to consider the context, or the consequences (impact) that will be the focus of the review.

Types of publications/evidence sources

The type of text that is being extracted, for example, a narrative paper/piece, an expert opinion, a consensus guideline, policy reports or reports accessed from web pages of professional organizations.

5.2.4 Search strategy

5.2.4.1 Finding and using the appropriate resources

A JBI review of textual evidence should consider both published and unpublished material. The aim of the search strategy is to identify all relevant papers suitable for answering the research question posed by the systematic review that are eligible. The literature encompasses several types of published and unpublished material, including articles published in refereed journals and grey literature. Grey literature refers to materials that are unpublished, or have been published by sources that are neither commercial nor academic (e.g. magazine articles, trade press articles, academic dissertation, institutional reports, consultant reports, conference proceedings, fact sheets, websites, policy documents and blogs). Rather than compete with the published literature, inclusion of grey literature has the potential to complement and communicate findings to a wider audience, as well as to reduce publication bias. It is important that any sources searched should be tailored to the particular review topic.[36,37]

In addition to databases of commercially published research and conference proceedings, there are several online sources of grey literature that should be considered alongside hand searching journals, checking reference lists of relevant publications, tracking citations of relevant studies and contacting experts.

As reviews of textual evidence do not draw on published research as the principal designs of interest, the reference is to types of ‘papers’ or ‘publications’ rather than types of ‘studies.’ The timeframe chosen for the search should be justified, and any language restrictions stated and also justified.

Part of the search strategy is to not only define what type of textual evidence is being included (narrative, opinion, policy) but also to provide details if a more specific search is being conducted. The specificity may include limiting to particular types of evidence (e.g. white papers, policy documents, editorials). This specificity should include a description as to why limiting the search to these forms of evidence is warranted based upon the initial review question(s).

Narrative

Related to accounts of experience from the perspective of patients, health professionals, or other stakeholders in enterprises related to the topic of interest. Primarily grey literature found in the websites of patient groups, professional associations, or industry/provider groups.

Opinion

Refers to a view or judgement formed about something, not necessarily based on fact on formal empirical evidence; or a statement of advice by an expert on a healthcare matter. Common sources are repositories of learned colleges/bodies and opinion pieces in the professional journals.

Policy

Refers to policy documents or communication artefacts that give direction for action. Relates to policies and the documentation of such things as meetings, discussions, and group communication vehicles such as position papers and newsletters and guidelines or statements of advice by an expert or group of experts or a government department on a healthcare matter. Sources may be websites of government departments, patient groups, professional associations or industry/provider groups.

5.2.4.2 Searching for published material

The search strategy for a JBI systematic review for narrative, opinion or policy should be conducted in three phases.

Searching stage 1: Identification of keywords and search terms

A limited search should be undertaken in major databases (such as MEDLINE) using preliminary search terms. The aim of this stage is to locate some papers relevant to the review and determine whether those papers can provide any additional keywords, indexing terms, or subject headings that may help in the search for similar papers. This is done by analysing words contained in the title, keywords, abstract and indexing list and looking for similarity of key terms across relevant/eligible studies.

Searching stage 2: Conducting the search across the specified databases

The second phase is to construct database-specific searches for each included database.

This may involve making slight modifications in the index terms entered, as each database may have differences in their index terms and subject headings. Appropriate bibliographic citation databases should be searched, the most common include major databases such as MEDLINE (PubMed), CINAHL and EMBASE. Details should include specification from the outset of the platform used to search a particular database. The final search strategy should use both keywords and subject headings searches. Initial search terms should be updated after searching the reference lists of relevant articles.

Searching stage 3: Reference list searching

The final phase of searching involves the review of the reference lists of all identified papers, either at full-text assessment or at appraisal stage. Additionally, researchers who are experts in the field of interest may also be considered as a potential source of articles and/or unpublished data.

5.2.4.3 Searching for grey literature

The first step is search grey literature databases relevant to the subject and focus of the review and could include:

- Conference abstracts or proceedings (e.g. BIOSIS citation index, Web of Science , Scopus Proquest Conference Papers Index)
- PhD Theses and Dissertations (e.g EtHOS, WorldCat Dissertations and Theses (OCLC, Open Access These and Dissertations,
- Grey literature databases: (e.g . OpenGrey, Grey Literature Report (1999 – 2016), TRIP Pro)

As well as using the above sources grey literature searching also involves customised google searches, targeted websites and consultations with topic experts. The Google search can be used to locate webpages and/or documents (narrative, opinion or policy) published on the internet. It is recommended that the first 5-10 pages of each search's hits are reviewed, and any potentially relevant results are retained for further screening. The number of results retrieved and/or screened then need to be recorded for each search strategy used. The Google search can also be used to identify any relevant third sector and government organisations/authorities who have published on the topic of interest. The next step would then involve browsing/searching targeted websites of the identified organisations for any potentially webpages and/or documents and to record the date of each search, the name of the website and how the search was conducted (i.e., browsing through the publications list or using a search feature). Any potentially relevant records retrieved from any of these methods will continue through to the next stage of screening. The final step in searching for grey literature is through contacting experts in the field. Content experts may be able to recommended specific documents relevant to the research question or suggest relevant third sector and government organisations/authorities. It is important to keep a track of the records retrieved from each source of grey literature so that this information can be recorded in the PRISMA flow chart.

5.2.5 Selection of evidence sources/texts

5.2.5.1 Process of determining eligibility

Selection is performed based on eligibility criteria developed earlier in the review process. Selection (both at title/abstract screening and full text screening) should be performed by two or more reviewers, independently. Any disagreements are solved by consensus or by the decision of a third reviewer. JBI reviewers are encouraged to read the article by Porritt, et al.[38] regarding study selection and critical appraisal.

5.2.5.2 Details of how to screen studies at the title and abstract level

When selecting texts, aim to select only those that are specific to your review question. If your question relates to adults with mucositis, a paper detailing the effects of a mucositis therapy for children is not applicable. The results may be interesting, but not relevant. Aim to be inclusive and selective, but the decision of whether to retrieve must be made with the review question in mind. The inclusion and exclusion criteria described in the review protocol provide this information. Like searching, textual selection should be transparent and reproducible. Also be aware that many policy documents will not necessarily have an abstract, but may have an executive summary.

While it might seem worthwhile to retrieve all texts, there are considerable resource implications with this. For example, they may need to be photocopied or requested from other libraries at considerable expense. There is also the impact of the time required for these activities to occur. There may be some issues that arise during selection that require discussion/clarification between assessors; it may be that this process identifies gaps in your eligibility criteria such as not factoring in a particular subgroup of the population. Since selection is a judgement, assessors might disagree, so it is important to consider how disagreements will be resolved. Will a third reviewer be used or will disagreements be resolved through discussion? It is important for assessors to pilot some texts initially before undertaking full selection.

When conducting your selection, you will come across some common problems in regards to the identification of possible texts. Most reference management software have an option to ‘remove duplicates’ however there may be some circumstances where you may need to do this yourself, particularly when details of a reference are incomplete or slightly different (e.g. information for a particular field is in the wrong spot or missing for one of the records).

Ideally the title of a text will provide sufficient information to the reader and you can determine instantly if it is of interest to your review question. This is rarely the case. Some authors take pride in developing catchy titles that have little to do with the actual topic. In these circumstances you will need to look further to the abstract (or executive summary) in order to determine if the text may be suitable for inclusion. This is not always possible however as some references do not provide an abstract. This means you need to make a decision as to whether to retrieve the full text or not. In these circumstances we suggest erring on the side of caution and if uncertain retrieve the full text for further information.

5.2.5.3 Details of how to screen papers at the full text stage

If you have to retrieve the full text to make your decision, then the decision to include or exclude is still required to be made by two independent reviewers. It is important to provide reasons for decisions to exclude, as this will appear in the Appendices, ensuring a transparent and reproducible review.

5.2.5.4 Current tools and software available to support the selection process

Tools such as JBI SUMARI, as well as other software is available to facilitate selection and screening, including Endnote, Excel and Covidence. Systematic reviewers should choose the software that works for them and is feasible and available in their setting. This should be reported in your systematic review.

For example:

Following the search, all identified citations were collated and uploaded into #insert bibliographic software or citation management system (e.g. EndNote version/year (Clarivate Analytics, PA, USA))# and duplicates removed. Titles and abstracts were then screened by two reviewers for assessment against the inclusion criteria for the review. Papers that met the inclusion criteria were retrieved in full and their details imported into the JBI System for the Unified Management Assessment and Review of Information package (JBI SUMARI). The full text of selected papers were retrieved and assessed in detail against the inclusion criteria by two independent reviewers. Full text papers that did not meet the inclusion criteria were excluded and reasons for exclusion are provided in #insert Appendix number#. Any disagreements that arose between the reviewers were resolved through discussion (OR There were no disagreements that arose between reviewers).

5.2.6 Assessment of quality

The goal of critical appraisal is to assess the methodological quality of a study and to determine the extent to which a study has excluded or minimized the possibility of bias in its design, conduct and analysis. The focus on limiting bias to establish validity in the appraisal of quantitative studies is not possible when dealing with textual evidence. In appraisal of text, the opinions being raised are vetted, the credibility of the source investigated, the motives for the opinion examined, and the global context in terms of alternate or complementary views are considered. Validity in this context therefore relates to what is being said, the source and its credibility and logic; and consideration of the overt and covert motives at play.

There are JBI standardized appraisal tools based on textual type appropriate for JBI reviews of textual evidence. JBI systematic reviews are required to use these JBI standardized appraisal tools. Reviewers should refer in the review protocol to the JBI standardized critical appraisal checklists and provide references for these checklists. It is not necessary to provide these checklists in appendices of the review protocol. If non-JBI appraisal tools are proposed, then these tools should be briefly described and correctly referenced. In this case, an explicit justification for the use of non-JBI appraisal tools should be provided in the review protocol.

Two reviewers should perform independent assessment of retrieved papers using the standardized checklists developed by JBI. Any disagreements are solved by consensus or by the decision of a third reviewer. Reviewers should specify that they plan to report in narrative form and in tables the results of quality assessments, for each aspect of quality for each individual paper and the overall quality of the entire set of included papers. This phase of the review should not be treated as a rapid ‘box ticking exercise’ on checklists, but rather as a complex, profound, critical, systematic, thorough examination of the quality of each included text, a solid foundation for an appropriate synthesis of the results.

The review (and protocol) should specify if and how the results will be used for the exclusion of papers from the review. For example, if papers judged of low quality will be excluded from the review, the details of the circumstances under which such decisions will be made and the explicit criteria or decision rules should be explicitly provided, including explanations for what is considered

low quality by reviewers. It is the decision of the review team if they want to exclude from the review papers judged of low quality. Reviewers should explain and justify their criteria and decision rules. The decision as to whether or not to include a text can be made based on meeting a predetermined proportion of all criteria, or on certain criteria being met. It is also possible to weight the different criteria differently. The decisions about the scoring system and the cut-off for inclusion of a paper in the review should be made in advance and be agreed upon by all participating reviewers before assessments commence. The review protocol should specify if and how the results of critical appraisal will be used in the synthesis of the results. JBI reviewers are encouraged to read the article by Porritt et al[38] regarding study selection and critical appraisal.

This section of the review should include the results with the three different JBI textual evidence critical appraisal checklists, embedded in the JBI SUMARI software, whether it is narrative, expert opinion or policy (or consensus guideline). The primary and secondary reviewer should discuss each item of assessment for each textual type included in their review. In particular, discussions should focus on what is considered acceptable to the needs of the review in terms of the characteristics of the textual evidence. The reviewers should be clear on what constitutes acceptable levels of information to allocate a positive appraisal compared with a negative, or response of ‘unclear’ or ‘not applicable.’ This discussion should take place before conducting the assessment, as each paper should be assessed independently by both reviewers. The quality assessment tool should be referenced accordingly.

The explanation for the JBI SUMARI text and expert opinion critical appraisal tool is detailed below. Ongoing consideration by the methodology group is to have three separate critical appraisal tools for the different types of text; narrative, expert opinion and policy.

Important note: These critical appraisal tools are presented separately according to the textual source (narrative, expert opinion or policy), but please be aware that these are not currently available in the JBI SUMARI software. However, if you plan to use the separate critical appraisal tools, please cite as detailed. Currently in JBI SUMARI is the Text and Expert Opinion critical appraisal tool.[11]

5.2.6.2 Assessment of quality: Narrative evidence

Narrative refers to first-hand accounts (or, in some cases, third person accounts by legitimate stakeholders or advocates) of experience, perspective or views of patients, health professionals or other stakeholders. Thus, the validity of the evidence retrieved in this context relates to the authenticity of the source of the data, the relationship of the account to a particular/specific context, the adequate representation of those involved in the event and the degree of narrativity embodied in the narrative. When critically appraising evidence from narrative it is important to be able to distinguish between narrative and story. Criteria to assess these elements are incorporated into the Textual Evidence module of SUMARI and consist of a series of questions to be addressed for each type of evidence retrieved.

5.2.6.2.1 JBI Critical Appraisal Checklist: Narrative Evidence

	Yes	No	Unclear	Not applicable
1. Is the generator of the narrative a credible or appropriate source?				
1. Is the relationship between the text and its context explained? (where, when, who with, how)				
1. Does the narrative present the events using a logical sequence so the reader or listener can understand how it unfolds?				
1. Do you, as reader or listener of the narrative, arrive at similar conclusions to those drawn by the narrator?				
1. Do the conclusions flow from the narrative account?				
1. Do you consider this account to be a narrative?				

Overall appraisal:	Include	Exclude	Seek further info
Comments (Including reason for exclusion):			

5.2.6.2.2 Explanation of Narrative tool

1. **Is the generator of the narrative a credible or appropriate source?**

It is important to establish the legitimacy of the narrator as part of assessing the degree to which the narrative is authentic. ***Ask:***

– Is this a first- hand account of an event?

– Do you sense that the author is both a credible and appropriate narrator?

1. **Is the relationship between the text and its context explained?**

   Narrative always describes an event that occurs within a specific time and space; within a context. The relationship between the characters and the place in which the event occurs needs to be described. ***Ask:***

   – Where does the event take place?

   – Who does it involve?

   – What occurs?

1. **Does the narrative present the events using a logical sequence so the reader or listener can understand how it unfolds?**

   A narrative seeks to convince a reader; this, in assessing this narrative, the reviewer should 'follow' the narrative and its meanings. **Ask:**

   – Can I 'imagine' the event, the characters involved and what happened?

   – Does the 'story' or the account flow in a logical way?

1. **Do you, as reader or listener of the narrative, arrive at similar conclusions to those drawn by the narrator?**

   Again, note the purpose of narrative to persuade or convince. **Ask:**

   – Are the conclusions drawn from the description of the event?

   – Are any seemingly causal relationships explained?

   – Do you draw similar conclusion from the narrative as the narrator?

1. **Do the conclusions flow from the narrative account?**

   Again, note the purpose of narrative to persuade or convince. **Ask:**

   – Are the conclusions drawn from the description of the event?

1. **Do you consider this account to be a narrative?**

   In appraising the authenticity of the narrative, can you differentiate between the emotional persuasiveness of the 'story' with the objective accuracy of the narrative? **Ask:**

   – What is the degree of narrativity in this piece?

5.2.6.3: Assessment of quality: Evidence from expert opinion

Expert opinion draws on the knowledge and experience of experts (both practitioners and consumers); and frequently, extant external evidence informs the opinion. Thus, validity in this context relates to those involved in the development of the opinion and their motives; the degree to which extant evidence is sourced and used in the process; and the soundness of the opinion in terms of its logic and its ability to convince.

Burrows and Walker[39] describe a tool designed to critique expert opinion. They argue that expert opinion should be subject to the same critical scrutiny as research studies in order to make a judgement about quality and reliability. They developed a framework for critiquing expert opinion by

analysing published frameworks and exploring the considerations that academics are expected to pursue when publishing expert opinion.[39] This has many similarities with the JBI Text and Expert Opinion critical appraisal tool. [1,11]

The focus of appraisal is on authenticity: specifically, authenticity of the opinion, its source, and the possible motivating factors and how alternate opinions are addressed. It is also focused on the assessment of credibility of the expert voice, and decision as to whether the arguments are logical. Criteria to assess these elements are incorporated into the Textual Evidence module of SUMARI[40] and consist of a series of questions to be addressed for each type of evidence retrieved.

5.2.6.3.1 JBI Critical Appraisal Checklist: Expert Opinion Evidence

	Yes	No	Unclear	Not applicable
1. Is the source of the opinion clearly identified?				
1. Does the source of the opinion have standing in the field of expertise?				
1. Are the interests of the relevant population the central focus of the opinion?				
1. Does the opinion demonstrate a logically defended argument to support the conclusions drawn?				
1. Is there reference to the extant literature?				
1. Is any incongruence with the literature/sources logically defended?				

Overall appraisal:	Include	Exclude	Seek further info
Comments (Including reason for exclusion):			

5.2.6.3.2 Explanation of expert opinion tool

1. **Is the source of the opinion clearly identified?**

   To assess an opinion, it is important to locate its source. ***Ask:***

   – Are the authors clearly identified (Including their name, their role/ experience /qualifications)?

1. **Does the source of the opinion have standing in the field of expertise?**

   Determining whether the author is informed or possesses knowledge about a specific subject is a key stage in assessing the credibility of the opinion. ***Ask***:

   – For health professionals or health researchers, what are their qualifications, current role and other indicators such as fellowships or licensures? Are any allegiances or affiliations with specific organisations or groups known?

   – For patients/consumers/advocates, what are their experiences and role?

1. **Are the interests of the relevant population the central focus of the opinion?**

   The expert opinion should focus on improving outcomes and it is important to determine that the opinion has such a focus. ***Ask:***

   – Does the paper take a position that advantages a profession or a specific institution or body; or financial or political objectives, rather than patients, clients, communities or health gain?

1. **Does the opinion demonstrate a logically defended argument to support the conclusions drawn?**

An opinion without a logical argument behind it is difficult to accept as a legitimate guide for practice/action. It is therefore important to look at the degree to which a logical argument to defend the conclusions drawn in the opinion is evident. ***Ask:***

– Does the opinion 'make sense' and demonstrate an attempt to justify the stance it takes?

– Is the opinion the result of an analytical process drawing on experience or the literature?

– Does the argument comply with Toulmin's model for argumentation?

1. **Is there reference to the extant literature?**

It is important to determine whether or not the opinion expressed comes from a position of awareness of extant evidence. ***Ask:***

– What extant literature does the author present to support the arguments?

1. **Is any incongruence with the literature/sources logically defended?**

Is there any reference provided in the text to ascertain if the opinion expressed has wider support? **Ask:**

– Has the author demonstrated awareness of alternate or dominant opinions in the literature?

– Have they provided an informed defence of their position as it relates to other or similar discourses?

5.2.6.4 Assessment of quality: Evidence from policy/consensus guidelines

Policy, for our purposes, refers to a deliberate set of principles designed to guide decisions and achieve rational outcomes. In health care, a policy or consensus guideline is essentially a statement of intent that is often then implemented as a procedure or protocol. Critical appraisal of policy and consensus guidelines draws on features of discourse analysis that seek to identify the degree to which the text being reviewed has 'authority' in-so-far as its purpose and its focus on serving the best interests of health care recipients; and the quality of the policy or guideline.

Discourse analysis is characterized by a wide range of approaches stemming from a number of theoretical bases. The term discourse itself refers to expressing oneself using words and discourse analysis attempts to describe, interpret, analyse and critique positions reflected in text. Critical discourse analysis more particularly studies written texts to uncover discursive sources of power, dominance, inequality, and bias. The JBI approach to critically appraising evidence from policy merely draws on the techniques of discourse analysis, rather than subscribing to, or committing to, its philosophical bases.

In terms of the quality of guidance, an international team of guideline developers and researchers, known as the AGREE Collaboration (Appraisal of Guidelines, Research and Evaluation) established the AGREE II Instrument [41] which provides a framework to assess the quality of guidelines. Evidence-based guidelines require a strict methodological approach for development, but there is also a need for consensus guidelines, drawn from expert opinion and nominal group processes (eg Delphi methods) in reaching consensus.

It is important to take heed of Sutcliffe and Court, [30] who assert the importance of acknowledging that evidence is not the only factor which influences policymaking and guideline development. Each stage of the development cycle, a number of different factors will also affect the outcome including a policymaker's or guideline developer's own experience, expertise and judgement; at an institutional level, institutional capacity; and the pressure to process information quickly. They argue that policymaking and guideline development is neither objective nor neutral; it is an inherently political process.

The validity of evidence from policy and consensus guidelines in this context therefore relates to what is being said, the source and its credibility and logic; a consideration of the overt and covert motives at play; the processes of policy/guideline development; and the degree to which external evidence is considered.

5.2.6.4.1 JBI Critical Appraisal Checklist for Policy / Consensus Guidelines Evidence

	Yes	No	Unclear	

				Not applicable
1. Are the developers of the policy/ consensus guideline (and any allegiences/affiliations) clearly identified?				
1. Do the developers of the policy/ consensus guideline have standing in the field of expertise?				
1. Are appropriate stakeholders involved in developing the policy/guideline and do the conclusions drawn represent the views of their intended users?				
1. Are biases due to competing interests acknowledged and responded to?				
1. Are the processes of gathering and summarizing the evidence described?				
1. Is any incongruence with the extant literature/evidence logically defended?				
1. Are the methods used to develop recommendations described?				

Overall appraisal:	Include	Exclude	Seek further info
Comments (Including reason for exclusion):			

5.2.6.4.2 Explanation of policy statements/consensus guidelines tool

1. **Are the developers of the policy/consensus guideline (and any allegiances/affiliations) clearly identified?**

   To assess a policy or guideline that seeks to direct action, it is important to be aware of who was involved in its development. ***Ask:***

   – Are the authors clearly identified (Including their name, their role/experience /qualifications?).

   – Are any allegiances or affiliations with specific organisations or groups known?

1. **Do the developers of the policy/consensus guideline have standing in the field of expertise?**

   Determining whether the developers are informed or possess knowledge about a specific subject is a key stage in assessing the credibility of a policy or guideline. ***Ask***:

   – For health professionals or health researchers, what are their qualifications, current role and other indicators such as fellowships or licensures? (Reviewers may wish to follow up the standing of the source by consulting with experts in the field of expertise; checking accreditation rolls; or contacting the source for further information.)

   – For patients/consumers/advocates, what are their experiences and role?

1. **Are appropriate stakeholders involved in developing the policy/consensus guideline and do the conclusions drawn represent the views of their intended users?**

   Guideline and policy development requires involvement of (or at least consultation with) both health care providers who will be expected to implement them and the receivers of healthcare (patients/clients/consumers). ***Ask:***

   – Who are the central stakeholders that might be impacted by this policy/guideline?

   – Are these stakeholders either part of the development group; or is there evidence that they have been consulted?

1. **Are biases due to competing interests acknowledged and responded to?**

   All policy/guideline development groups are likely to include competing interests and to be subject to a range of biases. The quality of the development process is improved if competing interests and potential biases are identified and addressed. ***Ask:***

   – Are potential competing interests identified in the policy/guideline document?

– Are potential biases identified in the policy/guideline document?

– Are any strategies to acknowledge and address competing interests and biases presented in the policy/guideline document?

1. **Are the processes of gathering and summarizing the evidence described?**

   Some policy/guideline developers search for and use published evidence reviews (systematic reviews etc.), published and unpublished papers; and local clinical and activity data. Others commission a full evidence review. For our purpose, it is important to assess the quality of gathering and summarizing data. ***Ask:***

   – Are the processes involved in gathering and analysing extant evidence detailed?

   – Are the approaches taken rigorous?

1. **Is any incongruence with the extant literature/evidence logically defended?**

   Whilst policy/guideline developers may search for and refer to synthesized evidence and because of possible competing interests and local biases, the external evidence may not concur with the conclusions or recommendations embodied in the resulting policy or guideline. ***Ask:***

   – Is there any incongruence between the conclusions/recommendations and the extant literature?

   – If there is, is this acknowledged in the paper/document?

   – Is there a logical defence of any position taken that is in conflict with the extant literature?

1. **Are the methods used to develop recommendations described?**

   Policy and guideline developers usually spend a great deal of time and exert much effort on developing final conclusions or recommendations and seek to balance the evidence with the expertise of the development group and the views of other stakeholders (frequently seeking a consensus view). Thus, a description of how recommendations or conclusions are developed is of importance. ***Ask:***

   – Is the process of developing recommendations or conclusions documented?

   – Do these processes suggest that a balance between opinion and evidence was sought?

Standardized appraisal criteria for all three of these textual evidence sources require the primary and secondary reviewer to meet or electronically discuss the criteria to ensure a common understanding, then to apply them individually to each type of evidence. Once both primary and secondary reviewers have conducted their appraisal, any discrepancies are discussed and a mutual decision agreed upon.

5.2.7 Data extraction

This section of the review should include details of the types of data extracted for inclusion in the review. Data extraction begins with recording the type of text. Once data extraction of the background details is complete, the extraction becomes highly specific to the nature of the data of interest and the question being asked in the review. Elements of data extraction are undertaken through JBI SUMARI[40], when you have selected that you are undertaking a textual evidence systematic review.

It is recommended that double textual data extraction is performed independently by two reviewers, outlining procedures for solving disagreements between reviewers. Selecting a tool, or modifying an existing tool for data extraction may be considered by the systematic review team, or the standard tool within JBI SUMARI may be utilized. This may need to be customised depending on the type of textual data. Cite the tool used, or append the data extraction tool if an existing tool was modified or a new tool developed. Authors may need to be contacted for further information or additional data.

5.2.7.1 Phase one of data extraction

This section of the review should include details of the types of data extracted for inclusion in the review. An extraction in JBI SUMARI includes fields relating to the type of text, its authors and participants, and the content of the paper. Textual data (conclusions) are extracted from papers included in the review using the standardized data extraction tool for textual evidence reviews. The

data extracted will include specific details about the phenomena of interest, populations, and any outcomes of significance to the review question and specific objectives.

The specific fields and types of text to extract are as follows:

1. **Types of text**
   The type of textual evidence that is being extracted, for example, from narrative, an expert opinion, a consensus guideline, conference proceedings, policy reports or reports accessed from web pages of professional organizations.
2. **Population represented**
   To whom the paper refers or relates.
3. **Setting / Context (may be clinical, cultural or geographical)**
   Setting is the specific location where the opinion was written, for example, a nursing home, a hospital or a dementia specific ward in a sub-acute hospital. Some papers will have no setting at all.

   The geographical context is the location of the author(s) – be as specific as possible, for example Poland, Austria, or rural New Zealand.

   The cultural context is the cultural features in the publication setting, such as, but not limited to, time period (16th Century); ethnic groupings (indigenous Australians); age groupings (e.g. older people living in the community); or socio-economic groups (e.g. working class). When entering information it is important to be as specific as possible. This data should identify cultural features such as time period, employment, lifestyle, ethnicity, age, gender, and socio-economic class or context.
4. **Stated allegiance/position**
   A short statement from the expert voice summarizing the main thrust of the publication.
5. **Conclusion (with illustration from text and page number)**
   Use this field to describe the main finding/s of the publication. This includes an assessment of the clarity of the argument's presentation and logic. Is other evidence provided to support assumptions and conclusions? Is it based on clinical or life experience?
   Levels of credibility (Unequivocal/Credible/Not Supported) can be assigned in this section (see further detail in data synthesis section)
6. **Reviewer's conclusion**
   Use this field to summarize the strengths and weaknesses of the paper.
7. **Notes**
   This section of the report should include any other notes the reviewer wants to make. It may also include techniques that have been used to analyze the data, e.g. named software program.

5.2.7.2 Phase two of data extraction

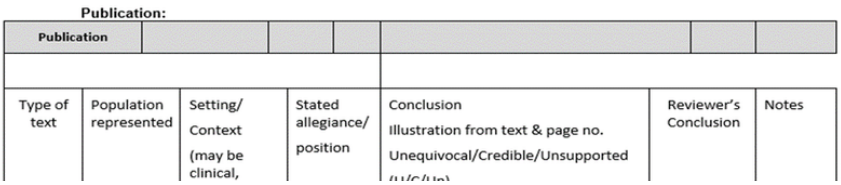
Phase two of data extraction is the extraction of author's conclusions from full text articles and rating each according to its assessed validity (unequivocal, credible, not supported) drawn from all of the included texts. The units of extraction in this process are specific conclusions stated by the author /speaker and the text that demonstrate the argument or basis of the conclusion. Conclusions are principal opinion statements embedded in the paper and are identified by the reviewer after examining the text in the paper. It is for this reason that reviewers are required to read and re-read the paper closely to identify the conclusions to be entered into JBI SUMARI. Conclusions should be extracted as verbatim statements from the author.

Example:

Conclusion: To ensure safe, quality care for all patients in the least restrictive environment, American Nurses Association supports nursing efforts to reduce patient restraint and seclusion.

Illustration (and page number): "Developmentally appropriate methods of restraint must be used in the least restrictive manner with the ultimate goal of a safe, restraint-free environment."[42] (p 5) (Unequivocal)

Following data extraction of the three various types of text: narrative, expert opinion or policy /consensus guideline, conclusions will be synthesized together, depending on the nature of the clinical question. If the three various types of text are included in the systematic review, a decision will need to be made by the review team whether these are presented in their separate textual types, or synthesized together. This should be outlined transparently in the a priori protocol.



Publication:

Publication						
Type of text	Population represented	Setting/ Context (may be clinical,	Stated allegiance/ position	Conclusion Illustration from text & page no. Unequivocal/Credible/Unsupported (U/C/Up)	Reviewer's Conclusion	Notes

		cultural, or geographical)				

5.2.8 Textual evidence synthesis

The JBI approach to the synthesis of textual evidence derived from sources other than research follows the qualitative evidence approach based on pragmatic and transcendental thought. This process of textual synthesis replicates the JBI approach to the synthesis of qualitative evidence as articulated by Lockwood and colleagues.[43] Following critical appraisal and data extraction of the three various types of text: narrative, expert opinion or policy, conclusions will be synthesized together, depending on the nature of the clinical question. If the three various types of text are included in the systematic review, a decision will be made by the review team whether these are presented in their separate textual types, or synthesized together. This should be outlined transparently in the a priori protocol. As the process relates to textual findings rather than numeric data, the need for methodological homogeneity, so important in the meta-analysis of the results of quantitative studies, is not a consideration.

The aim of textual evidence synthesis is to: firstly, assemble conclusions; secondly, categorize these conclusions into categories based on similarity in meaning; and thirdly, to aggregate these to generate a set of statements that adequately represent that aggregation. These statements are referred to as synthesized findings and they can be used as a basis for evidence-based practice. In order to facilitate this process, as with ensuring a common understanding of the appraisal criteria and how they will be applied, reviewers need to discuss synthesis and work to common understandings on the assignment of categories, and assignment to synthesized findings.

This section of the report should include how the findings were synthesized. Where evidence synthesis is possible, textual conclusions should be pooled using JBI SUMARI. The units of extraction in this process are specific conclusions stated by the author/speaker and the text that demonstrate the argument or basis of the conclusion. Conclusions are principal opinion statements embedded in the paper and are identified by the reviewer after examining the text in the paper; the conclusion is the claim or assertion of the author. It is for this reason that reviewers are required to read and re-read the paper closely to identify the conclusions to be entered into JBI SUMARI. Conclusions should be extracted as verbatim statements from the author.

The processes for categorization and formulating synthesized ndings mirror that of the JBI SUMARI qualitative approach of synthesis. For a more detailed discussion of synthesis, reviewers are encouraged to read the section on data synthesis for qualitative studies. [43]

Data synthesis should involve the synthesis of conclusions to generate a set of statements that represent that aggregation, through assembling the conclusions rated according to their credibility, and categorizing them on the basis of similarity in meaning. These categories should then be subjected to a meta-synthesis in order to produce a single comprehensive set of synthesized findings that can be used as a basis for evidence-based practice. Where textual pooling is not possible the findings can be presented in narrative form.

Prior to carrying out data synthesis, reviewers first need to establish, and then document:

- their own rules for setting up categories
- how to assign conclusions to categories
- how to aggregate categories into synthesized findings.

In JBI SUMARI, a reviewer can add conclusions to a study after an extraction is completed on that paper. The JBI approach to synthesizing the conclusions of textual or non-research studies requires reviewers to consider the credibility (logic, authenticity) of each report as a source of guidance for practice; identify and extract the conclusions from papers included in the review; and to aggregate these conclusions as synthesized findings.

The most complex problem in synthesizing textual data is agreeing on and communicating techniques to compare the conclusions of each publication. The JBI approach uses the SUMARI software, which involves categorizing and re-categorizing the conclusions of two or more studies to develop synthesized ndings. Reviewers should also document these decisions and their rationale in the systematic review report. Many textual based reports do not state conclusions explicitly. It is for this reason that reviewers are required to read and re-read each paper closely to identify the conclusions to be generated into JBI SUMARI.

Each conclusion should be assigned a level of credibility, based on the congruency of the conclusion with supporting data from the paper where the finding was found. Textual evidence has three levels of credibility; thus, the reviewer is required to determine if, when comparing the conclusion with the argument the conclusion represents evidence that is:

- **Unequivocal (U) -** relates to evidence beyond reasonable doubt which may include conclusions that are matter of fact, directly reported/observed and not open to challenge.

- **Credible (C) -** relates to those conclusions that are, albeit interpretations, plausible in light of the textual data and theoretical framework. As the conclusions are interpretive they can be challenged.
- **Not Supported (NS) -** is when the conclusions are not supported by the textual data.

In the systematic review report, it may be set out in the following way.

Papers were pooled using JBI SUMARI. This involved a three stage process: [11]

1. Extraction of Level 1 author's conclusions from full text articles and rating each according to its assessed validity (unequivocal, credible, not supported).
2. Categories were developed and assigned (Level 2 conclusions) based on similarity of meaning of Level 1 conclusions.
3. A set of synthesized conclusions were developed (Level 3 conclusions) after subjecting the categories to meta-synthesis. This represents the synthesis of Level 1 and Level 2 conclusions.

Please note: For JBI textual evidence reviews, not supported findings should not be included in the synthesis process. They may be presented separately in the extraction table, or in the Appendices.

5.2.9 Assessing certainty or confidence in the evidence

Further consideration is required to assess the certainty of the evidence, or confidence in the final synthesized finding being used to make recommendations for clinical practice and policy. For systematic reviews of textual evidence, the GRADE approach[7] (assessing certainty) or the ConQual approach[44] (assessing confidence), presented in a 'Summary of Findings' table may not be appropriate, especially when the certainty of the evidence is very low to begin with.

It may be more appropriate to consider issuing a recommendation as a Good Practice Statement (GPS), that is clearly articulated as separate to GRADEd recommendations.[45] The JBI Textual Evidence methodology group is planning to do some ongoing work in this area.

5.2.10 Presenting your review results

5.2.10.1 Description of included papers

The presentation of results should identify how many textual evidence texts were identified and selected. There should be a narrative description of the search decision process accompanied by the search decision flowchart. This section should include the type and number of papers identified by the search and the number of papers that were included and excluded from the review. This should also highlight the type of textual evidence; whether narrative, expert opinion or policy. A flowchart should be displayed according to the PRISMA 2020 approach outline by Page et al.[34]

The results section should be framed in such a way that as a minimum, the following fields are described or given consideration by the reviewers in preparing their systematic review report: number of textual evidence texts identified, number retrieved, number appraised, number excluded and overview of reasons for exclusion, and the final number of included textual evidence papers.

The results section then focuses on providing a detailed description of the results of the review. Where a systematic review has several foci, the results should be presented in a logical, structured way, relevant to the specific questions. The role of tables and appendices should not be overlooked. Adding extensive detail on studies in the results section may 'crowd' the findings, making them less accessible to readers, hence the use of tables, graphs and in text reference to specific appendices is encouraged.

5.2.10.2 Assessment of quality

This section should focus on the quality as determined by the JBI SUMARI textual evidence critical appraisal checklist.[11] There should be a narrative summary of the overall quality of the included texts, which can be supported by a table showing the overall results of the quality assessment. This should be presented separately for each type of textual evidence; narrative, expert opinion or policy. The example below is the final critical appraisal checklist table for textual evidence: expert opinion. As discussed previously, the decision as to whether to exclude based on the quality assessment must be determined by the review team, prior to the conduct of the quality assessment, and reported in a transparent manner.

Table: JBI critical appraisal checklist for textual evidence: expert opinion

Citation	Q1	Q2	Q3	Q4	Q5	Q6
Wright, K., Bauer, C., 2005	Y	Y	Y	Y	N	N
McIntyre, T., Jones, D.B., 2005	Y	Y	N	Y	Y	Y
Marzen-Groller, K.D., Cheever, K.H., 2010	Y	U	N	Y	N	N

N: No, N/A: Not applicable, U: Unclear, Y: Yes. Values are indicative of Y (Yes) responses.
Q1: Is the source of the opinion clearly identified?
Q2: Does the source of the opinion have standing in the field of expertise?
Q3: Are the interests of the relevant population the central focus of the opinion?
Q4: Does the opinion demonstrate a logically defended argument to support the conclusions drawn?
Q5: Is there reference to the extant literature? Q6. Is any incongruence with the literature/sources logically defended?

5.2.10.3 Interpreting the results from your systematic review

There is no standardized international approach to structuring how the findings of systematic reviews of textual or non-research evidence should be reported. The audience for the review should be considered when structuring and writing up the findings. Textual evidence synthesis flowcharts represent a specific item of analysis that can be incorporated into the results section of a review. However, the results are more than the flowcharts, and whether it is structured based on the intervention of interest, or some other structure, the content of this section needs to present the results with clarity using the available tools supported by textual descriptions.

Given there is no clear international standard or agreement on the structure or key components of this section of a review report, and the level of variation evident in published systematic reviews, the parameters described in this section should be considered as guidance for consideration rather than a prescription.

The results section then focuses on providing a detailed description of the results of the review. For clarity and consistency of presentation, JBI recommends that the reviewers, in discussion with their review panel (which may comprise content or methodology experts) give consideration to whether the ndings can be reported under the outcomes/phenomenon of interest specified in the protocol.

Where a systematic review seeks to address multiple questions, the results may be structured in such a way that particular outcomes are presented under specific questions. When all conclusions and supporting illustrative data have been identified, the reviewer needs to read all of the conclusions and identify similarities that can then be used to create categories of more than one conclusion. JBI SUMARI sorts the textual data into an evidence synthesis flowchart, when allocation of categories to synthesized findings (a set of statements that adequately represent the data) is completed (see SUMARI Figure above). These statements can be used as a basis for evidence-based practice.

5.2.10.4 Discussion

This section should provide a detailed discussion of issues arising from the conduct of the review, as well as a discussion of the findings of the review, and to demonstrate the significance of the review findings in relation to practice and research. Areas that may be addressed include:

- A summary of the major findings of the review;
- Issues related to the quality of the data within the area of interest (such as poor indexing);
- Other issues of relevance;
- Implications for practice and research, including recommendations for the future; and
- Potential limitations of the systematic review (such as a narrow search timeframe or other restrictions).

The discussion does not bring in new literature or findings that have not been reported in the results section but does seek to establish a line of argument based on the findings regarding the phenomenon of interest, or its impact on the outcomes identified in the protocol.

5.2.10.5 Conclusions

This section should begin with an overall conclusion based on the results. The conclusions drawn should match the review objective/question.

Recommendations for practice or policy

This subsection of the Conclusion section should include the recommendations for practice inferred from the results of the review, and also based on the discussion of the generalizability of the results, and the potential factors that may affect the applicability of the results. The recommendations must be based on the documented results, not reviewer opinion. Recommendations must be clear, concise and unambiguous. Refer to the editorial[46] for further discussion regarding the appropriateness of making recommendations in systematic reviews.

Recommendations for research

All recommendations for research must be derived from the results of the review, based on identified gaps, or on areas of weakness in the literature such as professional credibility of the authors. Recommendations for research should avoid generalized statements calling for further research but should be linked to specific issues. Recommendations must be clear, concise and unambiguous.

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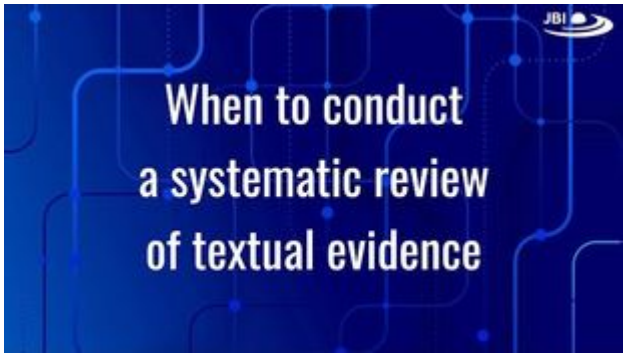
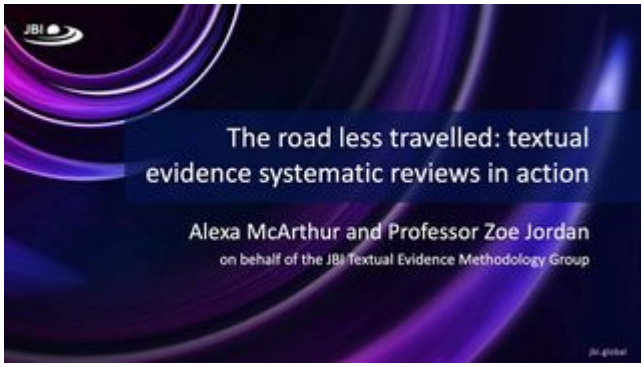
Systematic Reviews of Textual Evidence Resources

Digital Resources



When to conduct a systematic review of textual evidence

Prof Zoe Jordan outlines three indications for when it is appropriate to review textual evidence.



Textual Evidence Systematic Reviews in Action

Prof Zoe Jordan and Alexa McArthur present on textual evidence systematic reviews, on behalf of the JBI Textual Evidence Methodology Group

Critical

Prof Zoe
Evidenc
textual e

6. Systematic reviews of economic evidence

This chapter is currently being updated. In the meantime, please refer to the following pdf: https://drive.google.com/file/d/12OkTDHvZ9mGxGHKfsaIIOT563Bffom-t/view?usp=sharing

https://doi.org/10.46658/JBIMES-24-05

7. Systematic reviews of etiology and risk

Sandeep Moola, Zachary Munn, Catalin Tufanaru, Edoardo Aromataris, Kim Sears, Raluca Sfetc, Marian Currie, Karolina Lisy, Rubab Qureshi, Patrick Mattis, Pei-Fan Mu

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Contents

7.1 Introduction to etiological evidence and systematic reviews

In the epidemiological literature, terms such as risk, risk factors, and cause are inconsistently and imprecisely used, and as a result are often misinterpreted leading to incorrect research and policy recommendations (Kraemer, Kazdin et al. 1997). Risk refers to the probability of an outcome within a population of subjects (e.g. risk of lung cancer among people exposed to asbestos) and etiology refers to the cause or the causes (origin) of a certain disease (Kraemer, Kazdin et al. 1997). It is important to distinguish between etiology and risk factors. A risk factor refers to an individual characteristic or exposure that is associated with an increased likelihood of an outcome occurring. For example, are children in sub-Saharan Africa who are exposed to Plasmodium falciparum malaria at an increased risk of developing mental disorders (Akpalu, Ae-Ngibise et al. 2012)? Whereas a protective factor refers to a characteristic or exposure that is associated with the reduced likelihood of an adverse outcome. For example, are people who perform regular higher levels of physical activity less likely to develop lung cancer than those who perform little or no physical activity (Cancer Australia 2014)?

Risk factors are commonly referred to as modifiable, which means they may be controlled or modified in some way, or they may represent a characteristic over which an individual has no control, and therefore categorized as non-modifiable. Exposure to cigarette smoke (either actively or passively), elevated arsenic concentrations, or asbestos in the work or home environment are examples of exposure to modifiable factors – all can ultimately be avoided in most circumstances. Conversely, having a family history of the disease is also known to increase the likelihood of lung cancer development in an individual, and despite any efforts, these non-modifiable risk factors, though less common, are difficult to control or modify (Cancer Australia 2014).

Systematic reviews of etiology and risk factors assess the relationship (association) between certain factors (whether genetic or environmental for example) and the development of a disease or condition or other health outcome. Systematic reviews underpin evidence-based healthcare. The process of conducting a systematic review is a scientific exercise, and as the results will influence healthcare decisions, it is required to have the same rigor expected of all research. The quality of a systematic review depends on the extent to which the methods minimize the risk of error and bias. There is currently no universally accepted methodology for conducting systematic reviews of etiology and risk. Systematic review and meta-analysis of studies related to etiology and risk can provide useful information for healthcare professionals and policymakers on the risk factors (and preventive or protective factors) of disease and where factors, other than direct intervention with therapy and treatment, may influence or impact on health outcomes. Systematic review of etiological studies is important in the public health domain for informing health care planning, resource allocation and strategies for disease prevention.

This chapter outlines and describes JBI's approach and guidance for synthesizing evidence related to etiology and risk and contributes to the emerging field of systematic review methodologies. The systematic review of studies to answer questions of etiology and risk still adheres to the same basic principles of systematic review of other types of data. An *a priori* protocol must precede and inform the conduct of the systematic review, comprehensive searching must be performed, and critical appraisal of retrieved studies must be carried out followed by data abstraction, analysis and

synthesis. These steps will be further discussed in the following sections of this chapter. Additionally, reviewers should refer to two statements/checklists: one for transparent reporting of a systematic review of various research study designs, the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Page et al. 2021), and one for Meta-Analyses Of Observational Studies in Epidemiology (MOOSE), which provides a checklist or guidance to report meta-analyses of observational studies in epidemiology, including background, search strategy, methods, results, discussion, and conclusion (Stroup, Berlin et al. 2000).

A note on causation

British epidemiologist Sir Austin Bradford Hill proposed in 1965 a list of nine “viewpoints”, “circumstances” or “aspects” that should be considered when exploring the likelihood of inferring causation from examined associations: strength of the association; consistency of the observed association; specificity of the association; temporal relationship of the association; biological gradient (dose-response); biological plausibility; coherence (cause-effect interpretation of data should not conflict with generally known facts regarding natural history and biology of the disease; experimental evidence; analogy) (Hill 1965). Sir Bradford Hill explicitly stated that none of the nine viewpoints can be used as “indisputable evidence” for or against the causal hypothesis and that these aspects are used to explore more or less likely alternative explanations to the proposed causal explanation for the observed association.

A comprehensive modern discussion about causality (including a critical examination of Hill’s viewpoints) was provided by Rothman et al (2008). It was contended that temporality is a *sine qua non* for causal explanations of observed associations; however, there is no other criterion other than temporality that is necessary or sufficient criterion for determining whether an observed association is causal (Rothman, Greenland et al. 2008).

7.2 Study designs for etiology and risk

Commonly, epidemiological or observational studies are utilized to investigate etiology and risk. Observational studies aid in studying causal associations between an exposure and disease/health outcome (for example associations between occupational risk factors and lung cancer, or the adverse effects of a treatment in healthcare), although distinguishing true causality generally requires experimental research. Observational studies do not involve manipulation on the part of the researcher. These studies rely on the natural or “ecological” events of exposures and disease, where the researcher simply observes certain characteristics of the sample population as they occur “naturally”, and records the relevant data (The Joanna Briggs Institute b 2014). In this way they can be distinguished from experimental or quasi-experimental studies (such as RCTs and controlled clinical trials) where there is researcher manipulation of the independent variable (the potential cause or the exposure) (The Joanna Briggs Institute b 2014).

7.2.1 Observational Study Designs

Observational study designs include prospective and retrospective cohort studies, case-control studies, cross-sectional studies, case series and case reports, and can be broken down into the broad categories of analytical studies and descriptive studies. Generally, descriptive studies describe the occurrence/presence of an outcome or exposure, whereas analytical studies describe the relationship between the exposure and an outcome. Due to the nature of observational study designs compared with experimental designs, they are more at risk of the influence of confounding factors and different sources of bias that are unavoidable, which will be discussed further below. Similar to the MOOSE statement (Stroup, Berlin et al. 2000), reviewers should also refer to the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) statement, which is a checklist of items that need to be addressed in studies reporting on cohort, case-control, and cross sectional study designs and provides guidance on how to report observational research (von Elm, Altman et al. 2007).

7.2.1.1 Cohort Studies

Cohort studies are the “gold standard” of observational study designs and prospective cohort studies appear the highest on evidence hierarchies of observational study designs (Thiese 2014). These longitudinal studies are typically used to analyse relationships between exposures and disease by comparing the outcomes between two groups over time, where individuals in one group are exposed to a common event or characteristic, such as a risk factor, and the other group are not. Sampling in cohort studies is based on the presence or absence of an exposure or characteristic, and participants are followed over time to observe development of any disease or health outcomes. A prospective cohort study begins with the exposure of interest, and participants are followed forward through time to observe any outcomes that may occur. Conversely, a retrospective cohort study generally begins after the outcomes of interest have already been recorded; a researcher may sift through patient records or data that is already available and groups patients according to exposures, and identifies any differences in outcomes. Cohort studies enable observations of a large number of people over a long period of time.

7.2.1.2 Case-control studies

Case-control studies select participants based on presence of disease or a specific condition, and look for prior exposures that may have led to the disease or outcome developing. In this study design, those with the disease/outcome (cases) are matched with comparable individuals who do not have the disease (controls), and both groups are studied to determine if any differences in characteristics or past exposures exist. Case control studies have an advantage over cohort studies, particularly when investigating rare diseases, because of fewer costs associated with recruiting participants (usually less). In addition, the issue of “drop out” or “loss to follow up” of participants as seen in cohort studies does not arise in case-control studies.

7.2.1.3 Cross-sectional studies (Analytical)

Cross-sectional studies are used to provide a snapshot of disease and other variables in a defined population at one point in time. Data can be used to infer relationships between a disease and other variables, however, as the data is gathered simultaneously, chronological sequences of exposures and outcomes cannot be determined. Some cross-sectional studies are purely descriptive, in that they just describe the number of cases or number of events in a particular population at a point in time or over a period of time.

7.2.2. Descriptive study designs

Descriptive studies aim to collect information about a given individual or group and can be used to provide data on the distribution of disease. Examples of descriptive study designs are case reports and case series. In health care, these types of studies are typically used to describe the occurrence of disease or a risk factor. Case reports and case series are often used to report novel occurrences of a disease or a unique finding, and they can be particularly informative for rare or emerging diseases. There are guidelines to report case reports in terms of completeness, transparency and data analysis (The CARE Guidelines: Consensus-based Clinical Case Reporting Guideline Development), which the reviewers should refer to when including and reporting case reports in their systematic review reports (Gagnier, Kienle et al. 2014).

7.3 The systematic review protocol and report

This section outlines the requirements and methods for systematic review protocols and systematic review reports addressing etiology and risk.

7.3.1 Title of the systematic review

The title should be clear, explicit and reflect the core elements of the question. It should be as informative and descriptive as is reasonable, reflecting the scope and type of systematic review to be undertaken. The title should not be phrased as a question or conclusion and there should be congruency between the title, review objectives/questions and inclusion criteria. The title should include the phrase “…: a systematic review protocol” in a review protocol and “…: a systematic review” in a review report.

Although a range of mnemonics have been described for different types of review (and research) questions, if, for example the review aims to examine etiology of disease or risk of a health outcome, this should, as much as possible, be stated clearly in the title of the document. If specific exposure/s and/or patient outcomes are to be examined these should also be included in the title. For example: “Long-term topical corticosteroid use and risk of skin cancer: a systematic review protocol” (Ratib, Burden-Teh et al. 2016). This example provides potential readers of the review with a clear indication of the population, the exposure (corticosteroid use), and the outcome (incidence of skin cancer) of interest, as well as that it is a systematic review protocol.

7.3.2 Abstract

This section forms a structured abstract of the main features of the systematic review. It must be no longer than 500 words and should contain no abbreviations or references. The abstract must accurately reflect and summarize the systematic review with the main focus on the results of the review.

The abstract should report the essential elements of the review using the following sub-headings in this order:

- **Objective**: State an overarching review objective structured using the key components of the inclusion criteria (approximately one to two sentences).
- **Background**: Briefly describe what is already known on the topic and what this review will add to the evidence-base (approximately two to three sentences).
- **Inclusion criteria:** Summarize the inclusion criteria as it relates to the type of review being conducted. Present the information in one or two sentences – **NOT** under individual subheadings.
- **Methods:** List the key information sources searched (those that provided the majority of included studies), any limits placed on the scope of the search (e.g. language), and the date range, or the date of the last search. If the recommended JBI approach to critical appraisal, study selection, data extraction and data synthesis was used, simply state it as such (without naming the actual tool). Otherwise, briefly describe any notable deviations to the methodological approach taken (e. g. criteria used to exclude studies on the basis of methodological quality etc.).

- **Results**: The bulk of the abstract should be reserved to convey the main results of the review. As a general rule, report the number and type of included studies and participants, as well as any pertinent study characteristics. Summarize the overall quality of the included studies and notable aspects of rigor for qualitative reviews.
  Report the number of findings and categories and final synthesized findings. Depending how many are presented in the review, the synthesized findings may be presented here or abridged summarized statements.
- **Conclusions**: Provide a conclusion based on a general interpretation of the results considering, for example, the methodological quality of the included studies and any limitations of the review. Briefly convey key implications for practice and/or research.

7.3.3 Objective and review question

The objective(s) of the review should be clearly stated. This should be followed by the specific review question(s). The overarching objectives of reviews of etiology and risk are to determine whether and to what degree a relationship exists between two or more quantifiable variables. Accordingly, the review question should outline the exposure, the population or groups at risk and the disease, symptom or health outcome of interest. The specific context/location (which may include any contextual factors such as geographical, or cultural elements relevant to the topic), and the duration of the exposure (e.g. pregnancy) may also be important to articulate if relevant.

An example of an objective for a systematic review of etiology and risk is:

- The objective of this review is to assess the epidemiological association between consumption of alcohol (as exposure of interest or risk factor) and lung cancer (as the outcome of interest).

A question that will align with this review objective is:

- Does the consumption of alcohol increase the incidence of lung cancer?

The exposure and outcome may be positively associated or the relationship may be negative e.g. as one increases the other decreases.

7.3.4 Background

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The background section of the review protocol and systematic review should be comprehensive and consider the main elements of the topic under review. Many reviewers will find that the background provided with the protocol needs modification or extension following the conduct of the review proper. The background should detail any definitions important to the review. The information in the background section must be sufficient to put the review inclusion criteria into context and also highlight the importance and relevance of the topic for the reader and a clear basis for the rationale to pursue the review topic. The background section should conclude with a statement that a preliminary search for previous systematic reviews on the topic was conducted (state the sources searched e.g. *JBI Evidence Synthesis*, Cochrane Library, CINAHL, PubMed, PROSPERO). If there is a previous systematic review on the topic, it should be specified how the proposed review differs. All JBI systematic reviews should contain a sentence clearly stating:

"The objectives, inclusion criteria and methods of analysis for this review were specified in advance and documented in an a priori protocol. Ref" (Reference should be to the appropriate citation in the *JBI Evidence Synthesis*, and provide registration number in PROSPERO where applicable).

This sentence should appear as the final line of the background/introduction section of the review report and complies with the recommendations for reporting of systematic reviews detailed in the PRISMA guidelines.

7.3.5 Inclusion criteria

Specific inclusion criteria ensure that the included studies will meet these criteria and they represent an important and transparent plan for to the selection of studies for the review. The inclusion criteria are also critical when formulating a comprehensive search strategy to locate studies.

Authors will realize that the traditional PICO format (Population, Intervention, Comparator, Outcomes) commonly encountered and well aligned to systematic reviews assessing the effectiveness of interventions or therapies in health care does not readily align with questions relating to etiology and risk (The Joanna Briggs Institute a, 2014). Rather, a systematic review of etiology should include the following components, easily referred to as PEO:

- Population (types of participants)
- Exposure of interest (independent variable)
- Outcome (dependent variable)

7.3.5.1 Population (types of participants)

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The types of participants should be appropriate for the review objective and question(s). The reasons for the inclusion of a participant group should be supported by information in the background and the rational for the review. Specific criteria for inclusion or exclusion of participants should be explained in this section. The inclusion and exclusion criteria need to reflect sound clinical and scientific reasoning and the need for an adequate degree of homogeneity amongst the samples in the studies.

7.3.5.2 Exposure of interest (Independent variable)

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This refers to a particular risk factor or several risk factors (or protective factors) of interest. It should be clearly reported in this section what the exposure or risk factor (or protective factor) is, and how it may be measured/identified including the nature of the exposure and its intensity and/or the duration of exposure, if relevant. The exposure of interest may be modifiable, and relate to lifestyle habits such as alcohol consumption, smoking or may relate to the environment and occupation such as asbestos and air pollution or conversely, may be non-modifiable, such as family history of the disease.

7.3.5.3 Outcome (dependent variable)

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It should be clearly reported in this section what the outcome (disease or condition) is, and how it may be measured/identified. Commonly, the outcome of reviews of etiology and risk is often the incidence or observed rate of a disease or condition. Outcomes should be presented in a non-directional expression; for example, the outcome should simply be stated as the incidence of lung cancer, not an increase in lung cancer, as the evidence may suggest that the exposure has no effect and does not increase risk (neutral factor) or may decrease the risk (protective factors). The review protocol should specify the important outcomes of interest relevant to the health issue and relevant to key stakeholders like the knowledge users, consumers, policy makers, consumers and the like.

7.3.5.4 Types of studies

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Epidemiological observational studies of etiology relate individual characteristics, personal behaviours, environmental conditions, and treatments as ‘exposures’ that may modify risk of disease. These reviews will predominantly include observational studies such as prospective and retrospective cohort studies, case control studies and analytical cross-sectional studies. Randomized controlled trials may also report on the risk associated with an exposure and can be included. Prospective cohort studies usually provide stronger evidence than case-control studies when addressing etiological questions or issues.

7.3.6 Methods

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This section of the review report is reserved for the methods used to conduct the review and should be presented under the relevant subheadings, including any deviations from the method outlined in the *a priori* protocol. In empty reviews for example, this section should not refer to methods that were not performed.

Directly below the Methods heading provide the following information:

- State and appropriately cite the JBI methodology that was employed in the conduct of the review and synthesis.
- Refer to and cite the *a priori* protocol that was published, or accepted for publication (e.g. ‘in press’), in *JBI Evidence Synthesis*.
- If the protocol has been registered with PROSPERO, provide registration information including registration number (e.g. PROSPERO CRD42015425226).

7.3.6.2 Sources to search

Appropriate databases to search should be included, the most common being Medline (PubMed) and EMBASE. Details should include specification from the outset of the platform used to search a particular database. Etiology and risk data are commonly reported within the published, peer-reviewed literature and accordingly the standard JBI three-step search strategy can be applied to locating this type of evidence. The search strategy should use both subject heading and text word searches. Initial search terms should be updated after searching the reference lists of relevant articles. The timeframe chosen for the search should be justified and any language restrictions stated (e.g. only studies published in English will be considered for inclusion).

A JBI review should consider papers both published and unpublished (grey) literature. Grey literature can often provide useful studies and estimates for reviews of etiology and risk factors.

Some examples include:

- Disease and health association websites (e.g. American Diabetes Association)
- Bibliographic databases: Disease and allied health research database (e.g. Medline, EMBASE, PsycINFO, CINAHL, British Nursing Index (BNI), Web of Science, Cochrane library, PhD theses etc)
- Conference abstracts or proceedings (e.g. BIOSIS databases, American Society of Clinical Oncology (ASCO), Biological Abstracts/RRM, British Library Inside, British Library Direct Plus, ISI Proceedings)
- Web searching (e.g. Google Scholar, Science.gov)
- Administrative sources (clinical records, insurance data)
- Vital statistics data, government reports, centres for disease control and prevention data, population consensus and surveys
- Medical books, grey literature and reports from experts.

7.3.6.3 Assessment of methodological quality

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Assessment of methodological quality, or critical appraisal, is a process conducted in systematic reviews to establish the internal validity and risk of bias of studies that meet the review inclusion criteria. JBI has developed a number of tools for assessing the quality of various quantitative study designs that are appropriate to use in systematic reviews assessing questions of etiology & risk (see Appendix II).

The protocol should indicate which tool is going to be used that match the included study designs when determining methodological quality of papers to include in the review. JBI appraisal tools should be used preferentially; if not clear reasoning should be provided. Critical appraisal tools should be cited in the protocol and should be appended if the tools are modified in any way. Critical appraisal must be conducted by two reviewers independently of each other. The reviewers should then meet to discuss the results of their critical appraisal for their final appraisal. If the two reviewers disagree on the final critical appraisal and this cannot be resolved through discussion, a third reviewer may be required.

When detailing the methods of the review report, the section on appraisal should detail the approach to critical appraisal, not the assessment results, and should be consistent with the protocol. The approach to critical appraisal process should include information on what constitutes acceptable levels of information for appraisal and whether the decision to include or exclude studies following critical appraisal is based on meeting a predetermined proportion of criteria or weighing criteria differently. The authors of the review should state *a priori* in the review protocol the criteria used to determine the inclusion or exclusion of poor quality studies. The authors have to make explicit and agree on criteria to determine whether a study is of good, moderate or poor quality, and based on these criteria or a combination of criteria, the authors can decide whether to include only good quality studies or all studies irrespective of the quality. However, the importance of these criteria (e.g. selection, measurement bias, confounding) will vary with study type and problems specific to the review question.

The report should detail the criteria that were considered when determining the methodological quality of papers considered for inclusion in the review. In the systematic review, appraisal questions should be presented with the results, or appended.

7.3.6.3.1 Confounding and confounders

Confounding occurs when another factor other than primary factor of interest or being investigated, can directly influence the outcome being measured. To be classed as a confounding factor, it should not be a factor that appears in the casual pathway between and exposure and the outcome. Confounding bias is defined as “bias of the estimated effect of an exposure on an outcome due to the presence of common causes of the exposure and the outcome” (Miquel 2014) [(p.55)]. A confounder or confounding variable is a variable that can be used to decrease confounding bias when properly adjusted for (Miquel 2014) [(p.55)].

Criteria for confounders are (Rothman, Greenland et al. 2008) [p.132-134]:

1. A confounding factor must be an extraneous risk factor for the disease; i.e. the confounder is a risk factor for the disease and the factor's association with disease arises from a causal pathway other than the one under study.
2. A confounding factor must be associated with the exposure under study in the source population (the population at risk from which the cases are derived).
3. A confounding factor must not be affected by the exposure or the disease. In particular, it cannot be an intermediate step in the causal path between the exposure and the disease. For example, in the case of increased risk of lung cancer from high levels of red meat consumption, the confounding factor could possibly be the ‘cooking method’ (Cancer Australia 2014).

Confounding can be controlled in the design and analysis phases in the case of observational studies. The two approaches used for the control of confounding in the analysis of data are stratification and statistical modelling. In stratification, study participants are split into strata that are different groups based on levels of the potential confounding variable, for example age. Although this approach is a simple method, this approach is limited by the fact that only a certain a number of potential factors could be stratified. Hence, it is not a common approach to control for confounding in observational studies in the analysis phase (Kahlert, Gribsholt et al. 2017). Statistical modelling (such as multiple logistic regression, conditional logistic regression, Cox proportional hazards regression, multivariable regression analysis) is used to estimate the strength of the relationship of interest while controlling for all of the potential confounders (Webb and Bain 2011).

7.3.6.3.2 Types of bias in studies of etiology and risk

Bias is a particular concern when assessing the methodological quality of studies of etiology and risk. Bias refers to systematic errors in any type of study that result in an incorrect estimate of the association between putative risk or predictive factors and the study outcome(s). The taxonomy of bias is well covered in the Cochrane Handbook (Higgins and Green 2011) and in the Agency for Healthcare Research and Quality Methods Guide for Comparative Effectiveness Reviews (Viswanathan, Ansari et al. 2008). If bias is suspected or reported, it is important to try and detect the direction of the bias, i.e. is it towards a change in the effect estimate of risk or not. Table 1 below shows the common types of bias that affect studies of etiology and risk.

Table 1: Common types of bias affecting studies of etiology and risk

Type of bias	**Definition**	**Check for**
Selection Bias	Systematic errors that result from procedures used to select study participants, from factors that influence participation in the study, or the ways in which data are collected or analyzed	**Sample** e.g. inappropriate definition of the eligible population or use of an inappropriate sampling frame; oversampling of healthy volunteers; exclusion of those who cannot or do not access health care services/those from a CALD background/those who are illiterate; changes to population over time; attrition (general or greater in one group than another)/non-response related to survivorship and severity of illness or length of illness; institutional bias e.g. hospital patients are different form community living patients. **Classification** e.g. uneven diagnostic procedures; changes in procedures over time; observer bias; competing risks (e.g. attribution of cause of death); changes in guidelines/institutional policy outside the researchers’ control and publication bias.
Information bias	Flawed measuring of independent and /or dependent variables/s that results in differential quality of information.	Inadequate detection; missing variables; misclassification; Hawthorne effect ; ecological fallacy; prestige/social desirability bias; recall bias; interviewer bias; reporting bias and missing data.

7.3.6.4 Data extraction

This section in the review report should include details of the types of data extracted from the included studies. Standardized data extraction tools allow the extraction of the same types of data across the included studies and are required for JBI systematic reviews. The protocol should detail what data the reviewers plan to extract from the included studies and the data extraction tool should be appended to the protocol.

The data extracted should include specific details about the participants, exposure of interest and outcomes of significance to the review question. Irrespective of the focus of the systematic review, additional data should be extracted, such as study methods, covariates and the sample size for each study included in the review. The methods of collection of exposure and outcome data (i.e. number of cigarettes or ppm of asbestos fibres or dust), which commonly include questionnaires, registries or interviews should also be stated.

Relative risk and other measures of association should be extracted, preferably those adjusted for the maximum number of covariates. Unadjusted results should be included only where no other data is provided. Epidemiological studies investigating the same association between an exposure and disease/condition provide different effect measures that may be too dissimilar to combine, which presents a challenge when combining studies in a meta-analysis. Each different study may report different measures of association, or estimates of effect, which most commonly include relative risks (RR), odds ratios (OR), hazard ratios (HR), standardized incidence ratios (SIR) or a standardized mortality ratios (SMR). An absolute risk reflects the observed or calculated probability of an outcome (disease) in a population exposed to a specific risk factor. A relative risk, which is the most common metric of risk, is simply the ratio of absolute risk in the group exposed to the risk factor of interest, to the absolute risk in a group (control) that is not exposed to the risk factor. An OR uses the odds of developing a disease in both groups to calculate a relative measure between two groups rather than the risk.

Where an absolute risk of the exposed group is presented relative to available existing data for a population group, this is referred to as a standardized ratio. Depending on whether incidence or mortality data is used will depend on whether the SIR or SMR is reported. Standardized mortality ratio refers to the ratio of observed and expected mortality, based on the age-sex-calendar period specific rates. Usually SMR greater than 1 implies higher than expected deaths and SMR less than 1 implies lower than expected deaths. Standardized incidence ratio is the ratio of the observed number of cases to the expected number of cases, based on the age-sex specific rates. A range of corrections, transformations and assumptions can be used to account for difference in the different types of data presented.

The following details are suggested at a minimum for extraction.

Study details
Author – this is an alphabetic or character code which is usually the first few characters of the primary study author's name. This serves as an easy way to identify the study in the bibliography
Year – the year of publication
Journal – the journal in which the article was published

Study method/characteristics
Study design – briefly describing the type of study design. For e.g. if it is a cohort study or a cross-sectional study.
Setting – may refer to hospital or community. May also refer to rural/urban etc.
Participants – includes age, sex, country/location, sample size, diagnosis and other relevant characteristics
Recruitment procedures utilized
Follow-up or study duration – any details on the duration of the study or follow-up of the participants
Exposure(s) of interest (Independent variable) – type, frequency, intensity, duration

Dependent variable (outcome)
Outcomes – the primary outcome measured and where relevant includes associated secondary outcomes.
Outcome measurements – describe the scales or tools used to measure the outcomes, e.g. a standardized pain scale to measure pain.

Data analysis methods including statistical technique (e.g. regression), adjustment for confounding factors, etc.
Study results
Appropriate measures for effect size such as:

- Risk ratio
- Relative risk ratio
- Odds ratio

P value & 95% Confidence Intervals

Reviewer comments

7.3.6.5 Data synthesis

The protocol should detail how the reviewers plan to synthesize data extracted from included studies. The types of data it is anticipated will be synthesized should be consistent with the methods used for data collection and the included study designs. The review report should detail how the reviewers synthesized the data extracted from included studies and how it was applied consistently across all included studies.

As with all systematic reviews, there are various approaches to present the results, including a narrative, graphical or tabular summary, or meta-analysis (refer to the appropriate section below) (Munn, Tufanaru et al. 2014). There are some special considerations when conducting meta-analysis for questions related to etiology & risk.

7.3.6.5.1 Meta-analysis of observational research

A meta-analysis is a statistical procedure that combines the findings from multiple primary studies into a single overall summary estimate. A meta-analysis can be conducted to improve statistical power to detect a treatment effect, to estimate a summary average effect, to identify sub-groups associated with a negative outcome or a beneficial effect, and to explore differences in the size or direction of the treatment effect associated with study-specific variables. Interpretation of summary effect sizes from meta-analyses of epidemiological studies addressing etiological issues is difficult because of the differences in the factors controlled for in multivariate analyses from individual studies, and also because of poor reporting in the original studies with lack of adequate or complete details. For more information and guidance on meta-analysis, refer to Chapter 3 of this manual.

An overall effect size is reported in a meta-analysis. It is computed for each study and the findings are pooled together to draw overall inferences. There are many different types of effect size and it is possible to convert one effect size into another, so each really just offers a differently scaled measure of the strength of an effect or a relationship. Reviewers should be aware that there are different guidelines for the interpretation of practical significance of the effect sizes such as ORs and RRs (Tufanaru C, Huang WJ et al. 2012). One proposed guide for interpretation of effect sizes suggests that a value of 2 for a risk estimate (such as a relative risk RR or an odds ratio OR) is considered the minimum significant value from a practical point of view; a value of 3 is considered moderate significant; a value of 4 is considered to indicate strong significance from a practical point of view (Tufanaru C, Huang WJ et al. 2012).

Frequently primary published studies investigating risk of an exposure will design the study and present the available data at different levels of the exposure, or in different categories to reflect a ‘dose-response’ relationship between the exposure and outcome variable. Difficulties will naturally arise if different studies have used different exposure categories and have presented this data in a variety of different ways. A dose response relationship between an exposure and the outcome is most commonly investigated to strengthen the support for causal inference or causation (Greenland and Longnecker 1992, Bekkering, Harris et al. 2008). Individual studies may present results in a stratified manner, either across different exposure groups or in different quantiles. For example, considering the risk of alcohol intake and lung cancer, the data may be presented as different exposure groups such as in glasses/week or in grams of alcohol. Irrespective of this, methods are available to combine the results of individual studies presenting such ‘trend’ data. Dependent on the type of data presented from such a dose response investigation, accepted methods exist to summarize the data to a consistent risk estimate which can then be subsequently used in meta-analysis.

Bekkering et al in a study on the usability of results in a meta-analysis reported that majority of usable results reported were odds, risk, or hazard ratios that compared one or more exposure categories with a baseline category (Bekkering, Harris et al. 2008). They further suggest some advantages in reporting results in ORs, RRs and HRs, which include checking informally for nonlinear exposure effects, and easier interpretation of the magnitude of the association (Bekkering, Harris et al. 2008). In case of nonlinear associations, there is a risk for conclusions from dose-response meta-analysis being misleading and it is suggested that linearity assumptions be checked for each study, when conducting dose-response meta-analysis (Greenland and Longnecker 1992, Bekkering, Harris et al. 2008). Bekkering et al, Chene and Thompson, Greenland and Longnecker, Hamling et al, and Orsini et al describe methods for conducting linear and non-linear dose-response meta-analyses. Essentially, for linear dose-response meta-analysis, the method involves estimation of a linear dose-response curve for each study when combining studies with different exposure category definitions. Further, it requires the numbers of cases and noncases (outcomes) and persons /person-years (person-time) and the effect estimates (RR or OR) with confidence intervals for at least three quantitative exposure categories (Aromataris, Hopp L et al. 2011).

A note on heterogeneity (refer to Chapter 3 for more details)

Despite the impediment to meta-analysis that heterogeneity of the published data presents, be it for methodological, clinical or statistical reasons, meta-analysis of observational studies to inform etiology and risk is almost always possible and can offer a valid means to explore heterogeneity and its impact within a data set. A combined analysis of individual studies, beyond the outright aim of increased precision due to increased sample size, may be desirable as it allows the exploration of

potential confounders and interactions and other modifying effects that may explain the heterogeneity among the included studies. It is suggested that the decision to conduct meta-analysis should not be just based on statistical considerations regarding heterogeneity but should be based on the review question, the characteristics of the studies, and the interpretability of the results.

7.3.6.5.2 The narrative synthesis of data

The results of all systematic reviews require some degree of narrative. Where a meta-analysis has been performed, that narrative may focus on synthesis of the characteristics of studies and their quality to explain and interpret the calculated effect estimates. In instances where meta-analysis has not been possible, the review authors will have to resort to narrative synthesis of the results of the included studies also. Narrative synthesis relies primarily on the use of words and text (tables are often included also, see Section 2.8.3) to summarise and explain the findings of a synthesis process. Its form may vary from the simple recounting and description of study characteristics, context, quality, and findings. The textual description of studies (individual or group of studies) and the thematic analysis methods are briefly presented below. Further exploration as well as worked examples for these approaches is provided by Lucas & co (Lucas, Baird et al. 2007).

- Textual descriptions of individual studies. Summaries of individual studies can be structured to provide details of the setting, participants, exposure, and outcomes, along with any other factors of interest (e.g. the income level of the users, age of users, previous experiences, attrition, length of follow-up, sample size);
- Textual descriptions of groups of studies. Based on relevant criteria (e.g. types of participants) included studies can be sub-grouped. Subsequently, commentaries summarizing key aspects of the studies in relation to the sub-group within which they were included are produced. In a final step, the scope, differences and similarities among studies are used to draw conclusions across the studies.

Where a narrative synthesis is undertaken to describe the included studies and their conclusions, it is important to discern how the evidence was weighted and whether conclusions were biased. It is recommended that the characteristics of the studies and the data extracted are emphasised and tables, graphs, and other diagrams are made use of to compare data (Lockwood and White 2012). The narrative summary will present quantitative data extracted from individual studies, as well as, where available, point estimates (a value that represents a best estimate of effects) and interval estimates (an estimated range of effects, presented as a 95% confidence interval).

Because a potentially large amount of data can be conveyed in a narrative summary, consistency can be ensured in the results section if all reviewers agree beforehand on a structure for the reporting of results. If a structure is not followed, the report of results may appear incomplete or unreliable (Lockwood and White 2012). However, if included studies do not provide the relevant information to comply with a structure, it should be made clear in the summary. A textual combination of data is often used when the included studies are dissimilar in terms of patients, methods, or data.

7.3.6.5.3 The tabular synthesis of data

Tabulating the data begins with grouping the studies in discrete categories (e.g. based on types of participants, exposures, outcomes, country of origin, duration of the exposure, number of participants in each group, context, results and comments). When the analysis of the tables reveals the presence of dominant groups or clusters of characteristics groups of studies can be formed by which the subsequent synthesis can be organized; this technique is particularly useful when there are larger number of papers. Based on the type of data reported, a common results rubric can be tabulated as well (e.g. absolute difference, relative risk, odds ratio, favours exposure vs. favours no exposure column); this approach can serve as a first step in comparing the effects observed across the included studies.

Bellow you will find some suggested steps for tabulating information from studies included in a systematic review (Khan, Kunz et al. 2003).

Suggested steps:

- Place features related to populations, exposures and outcomes in columns.
- Consider what subgroups of populations there are among included studies.
- Consider what subtypes of exposures there are.
- Consider the outcomes and their importance.
- Consider if studies need to be sub-classified according to study designs and quality.
- Populate the cells in the table with information from studies along rows in subgroups.
- Sort studies according to a feature that helps to understand their results (e.g. a characteristic of a population or exposure, rank order of quality, year of publication, etc.).

7.3.6.1 Search strategy

This section should state how the reviewers plan to search for relevant papers in a protocol and how they conducted the final search in a review report, clearly detailing how the review authors located the studies included in their review. Details of the databases and sources searched must be provided along with search strategies and the search dates. Databases and sources searched should be

appropriate for the review question and include specification from the outset of the platform used to search a particular database. A JBI review should search for studies published by commercial and academic publishers as well as non-commercially published studies (grey literature). Any limits applied to the search, for example limiting the range of years searched, should be justified and any language restrictions stated (e.g. only studies published in English will be considered for inclusion).

In the JBI review report, a detailed search strategy for all of the major databases searched should be appended and relevant details and dates of searching through other sources. The documentation of search strategies is a key element of the scientific validity of a systematic review. It enables readers to look at and evaluate the steps taken, decisions made to consider the comprehensiveness and exhaustiveness of the search strategy for each included database.

7.3.7 Results

The findings of the review should flow logically from the review objective/question i.e. they must ultimately answer the question! Findings should be extracted using JBI SUMARI and a narrative, tabular, graphical or meta-analysis should constitute part of this section. Reporting of results, as suggested by previous research, can include graphical summaries of study estimates and any combined estimate, a table listing descriptive information for each study, results of sensitivity testing and any subgroup analysis, and an indication of statistical uncertainty of findings.

This section should allow the reader to clearly follow how the included studies were identified and selected for inclusion in the review. In addition, the number of papers excluded should also be stated. There should be a narrative description of the process accompanied by a flowchart of the review process (from the PRISMA statement) detailing the flow from the search, through study selection, duplicates, full text retrieval, and any additions from 3rd search, appraisal, extraction and synthesis.

7.3.7.1 Description of studies

This section of the results should include an overall description of the included studies (with reference to the table in the appendices), with the main aim to provide some context to the results section and sufficient detail for the reader to determine if the included studies are similar enough to combine in meta-analysis. Specific items/points of interest from individual studies may also be highlighted here. Additional details may include the assessment of methodological quality, characteristics of the participants, location and types of exposures and outcomes. These can be presented in a narrative form, in a table or in both formats when studies vary in orientation and focus.

7.3.7.2 Methodological quality

This section should focus on methodological quality as determined by the relevant critical appraisal checklist. There should be a narrative summary of the overall methodological quality of the included studies, which can be supported (optional) by a table showing the results of the critical appraisal. Where only few studies are identified, or there are specific items of interest from included studies, these should be addressed in the narrative also, particularly where studies were deficient, or particularly good, i.e. with clear narrative regarding risk of bias/rigor of included studies. Use of N/A should also be justified in the text.

7.3.7.3 Findings of the review

This section should be organized in a meaningful way based on the review objectives and questions and types of exposures and outcomes and types of studies. This section should provide comprehensive information regarding the results of all performed meta-analyses and additional analyses such as sensitivity analysis and sub-group analysis. Point estimates and interval estimates (confidence intervals) should be reported. Before presenting any meta-analysis results, the conduct of meta-analyses should be justified; reviewers should explicitly provide commentaries regarding the clinical, methodological, and statistical heterogeneity of the studies included in meta-analyses and the appropriateness of conducting meta-analyses. Summary results from meta-analyses should be reported as summary point estimates and interval estimates. The meta-analysis forest plots for all performed meta-analyses should be presented in this section. A narrative summary should complement the forest plots and provide additional commentaries and explanations for all performed meta-analyses (Munn et al 2014).

Reviewers should report the funnel plot for publication bias if such assessment was appropriate and performed. Reviewers should include the results of assessment of risk of publication bias, including the results of statistical tests for publication bias, if such tests were used.

Even if meta-analysis is performed, a narrative summary should be included to supplement the technical details provided on the process and results of meta-analysis and to provide synthesis of data not captured in statistical meta-analysis.

If meta-analysis is not performed, a narrative summary should be included. The narrative summary should provide an overall summary of the findings of the included studies and their biases, strengths and limitations. The essence of narrative summary is that the results are summarized in words and in tables without any statistical meta-analysis. Textual commentaries and tables are used in order to

summarize the results from the included studies and to provide context information for these results, thus facilitating understanding of the summarized results.

7.3.8 Discussion

This section should discuss the results of the synthesis as well as any limitations of the primary studies included in the review and of the review itself (i.e. language, access, timeframe, study design, etc.). The results should be discussed in the context of current literature, practice and policy.

The aim of this section is to explain and discuss the main findings – including the strength of the evidence, for each main outcome. It should address the issues arising from the conduct of the review including limitations and issues arising from the findings of the review (such as search limitations). The discussion does seek to establish a line of argument based on the findings regarding the exposure and its association with the outcomes identified in the protocol. The application and relevance of the findings to relevant stakeholders (e.g. healthcare providers, patients and policy makers) should also be discussed in this section.

Points to consider this section include:

- Where any problems identified undertaking the search (perhaps there is little primary research on this topic or perhaps it is poorly indexed by the databases that were searched or perhaps the search was insufficient)?
- What limitations were found in the included primary research (e.g. were there inconsistencies or errors in reporting)?
- How do the review findings fit with what is currently known on the topic (from issues highlighted in the Background section)?
- Are the findings generalizable to other populations of participants/healthcare settings etc.?

Suggested layout of Discussion section:

Paragraph 1 – Begin your discussion with the:

- Amount and weight of available evidence
- Any particular feature/s associated with future risk of disease/harm/outcome
- Limitations to establish the reliability of results of the included studies (e.g. biases, data issues)

Paragraph 2 – set in context.

- Set the results in context of other knowledge on the topic, i.e. compare your work with previous systematic reviews or current opinions and guidelines.

Paragraph 3 – outline strengths and weaknesses of the meta-analytic methods used.

- Strengths: e.g. multiple reviewers reduced inclusion bias; which moderating variables were identified and how they were managed e.g. study design; determined that the effect estimate was sufficiently large in practical as well as statistical terms; determined precision of the effect; determined heterogeneity of the participants to enable generalisation of findings; conducted sensitivity analyses to assess any changes in the pooled effect estimator.
- Weaknesses: bias e.g. included only English language publications, unable to access suitable grey literature; possibility of missing (explanatory) variable/s, some issues with interpretation of findings.

Paragraph 4 – discuss limitations to establish the reliability of result/s.

- Of your review (bias)

7.3.9 Conclusion and Recommendations

This section should begin with an overall conclusion based on the results. The conclusions drawn should match with the review objective/question.

The conclusion section of a systematic review should provide a general interpretation of the findings in the context of other evidence and provide a detailed discussion of issues arising from the findings of the review and demonstrate the significance of the review findings to practice and research. Areas that may be addressed include:

- A summary of the major findings of the review;
- Issues related to the quality of the research within the area of interest;
- Other issues of relevance; and
- Potential limitations of the systematic review.

Recommendations for practice

It should be stated how the findings of the review impact on public health issues and clinical practice in the area. If there is sufficient evidence to make specific recommendations for practice, then the appropriate JBI Grades of Recommendation should be assigned to each recommendation based on the study design that led to the recommendation.

Recommendations for research

This section should include clear, specific recommendations for future research based on gaps in knowledge identified from the results of the review. Recommendations for research should avoid generalised statements calling for further research, but should be linked to specific issues.

7.3.10 Appendices

Here are several required appendices for a JBI review:

- Appendix I: Search strategy
  - A detailed and complete search strategy for all of the major databases and other sites and sources searched must be appended. Major databases that were searched must be identified, including the search platform used where necessary. All search filters with logic employed should be displayed, including the number of records returned.
- Appendix II: Table of included studies
  - A table of included studies is crucial to allow a snapshot of the studies included in the review.
- Appendix III: List of excluded studies
  - At a minimum, a list of studies excluded at the full text selection stage, if any, must be appended and reasons for exclusion should be provided for each study.

7.4 Chapter references

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Appendix 7.1 Critical appraisal checklist for cohort studies

JBI Critical Appraisal Checklist for Cohort Studies

Reviewer_____ Date_____

Author _____ Year_____ Record Number _____

	JBI Critical Appraisal Checklist for Cohort Studies	Yes	No	Unclear	Not applicable
1	Were the two groups similar and recruited from the same population?				
2	Were the exposures measured similarly to assign people to both exposed and unexposed groups?				
3	Was the exposure measured in a valid and reliable way?				
4	Were confounding factors identified?				
5	Were strategies to deal with confounding factors stated?				
6	Were the groups/participants free of the outcome at the start of the study (or at the moment of exposure)?				
7	Were the outcomes measured in a valid and reliable way?				
8	Was the follow up time reported and sufficient to be long enough for outcomes to occur?				
9	Was follow up complete, and if not, were the reasons to loss to follow up described and explored?				
10	Were strategies to address incomplete follow up utilized?				
11	Was appropriate statistical analysis used?				

Overall appraisal: Include Exclude Seek further info

Comments (Including reason for exclusion)

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Explanation of cohort studies critical appraisal

How to cite: Moola S, Munn Z, Tufanaru C, Aromataris E, Sears K, Sfetcu R, Currie M, Lisy K, Qureshi R, Mattis P, Mu P. Chapter 7: Systematic reviews of etiology and risk. In: Aromataris E, Munn Z (Editors). JBI Manual for Evidence Synthesis. JBI, 2020. Available from https://synthesismanual.jbi.global. https://doi.org/10.46658/JBIMES-20-08

Cohort studies Critical Appraisal Tool

Answers: Yes, No, Unclear or Not/Applicable

1. **Were the two groups similar and recruited from the same population?**

Check the paper carefully for descriptions of participants to determine if patients within and across groups have similar characteristics in relation to exposure (e.g. risk factor under investigation). The two groups selected for comparison should be as similar as possible in all characteristics except for their exposure status, relevant to the study in question. The authors should provide clear inclusion and exclusion criteria that they developed prior to recruitment of the study participants.

2. Were the exposures measured similarly to assign people to both exposed and unexposed groups?

A high quality study at the level of cohort design should mention or describe how the exposures were measured. The exposure measures should be clearly defined and described in detail. This will enable reviewers to assess whether or not the participants received the exposure of interest.

3. Was the exposure measured in a valid and reliable way?

The study should clearly describe the method of measurement of exposure. Assessing validity requires that a 'gold standard' is available to which the measure can be compared. The validity of exposure measurement usually relates to whether a current measure is appropriate or whether a measure of past exposure is needed.

Reliability refers to the processes included in an epidemiological study to check repeatability of measurements of the exposures. These usually include intra-observer reliability and inter-observer reliability.

4. Were confounding factors identified?

Confounding has occurred where the estimated intervention exposure effect is biased by the presence of some difference between the comparison groups (apart from the exposure investigated /of interest). Typical confounders include baseline characteristics, prognostic factors, or concomitant exposures (e.g. smoking). A confounder is a difference between the comparison groups and it influences the direction of the study results. A high quality study at the level of cohort design will identify the potential confounders and measure them (where possible). This is difficult for studies where behavioral, attitudinal or lifestyle factors may impact on the results.

5. Were strategies to deal with confounding factors stated?

Strategies to deal with effects of confounding factors may be dealt within the study design or in data analysis. By matching or stratifying sampling of participants, effects of confounding factors can be adjusted for. When dealing with adjustment in data analysis, assess the statistics used in the study. Most will be some form of multivariate regression analysis to account for the confounding factors measured. Look out for a description of statistical methods as regression methods such as logistic regression are usually employed to deal with confounding factors/variables of interest.

6. Were the groups/participants free of the outcome at the start of the study (or at the moment of exposure)?

The participants should be free of the outcomes of interest at the start of the study. Refer to the ‘methods’ section in the paper for this information, which is usually found in descriptions of participant /sample recruitment, definitions of variables, and/or inclusion/exclusion criteria.

7. Were the outcomes measured in a valid and reliable way?

Read the methods section of the paper. If for e.g. lung cancer is assessed based on existing definitions or diagnostic criteria, then the answer to this question is likely to be yes. If lung cancer is assessed using observer reported, or self-reported scales, the risk of over- or under-reporting is increased, and objectivity is compromised. Importantly, determine if the measurement tools used were validated instruments as this has a significant impact on outcome assessment validity.

Having established the objectivity of the outcome measurement (e.g. lung cancer) instrument, it’s important to establish how the measurement was conducted. Were those involved in collecting data trained or educated in the use of the instrument/s? (e.g. radiographers). If there was more than one data collector, were they similar in terms of level of education, clinical or research experience, or level of responsibility in the piece of research being appraised?

8. Was the follow up time reported and sufficient to be long enough for outcomes to occur?

The appropriate length of time for follow up will vary with the nature and characteristics of the population of interest and/or the intervention, disease or exposure. To estimate an appropriate duration of follow up, read across multiple papers and take note of the range for duration of follow up. The opinions of experts in clinical practice or clinical research may also assist in determining an appropriate duration of follow up. For example, a longer timeframe may be needed to examine the association between occupational exposure to asbestos and the risk of lung cancer. It is important, particularly in cohort studies that follow up is long enough to enable the outcomes. However, it should be remembered that the research question and outcomes being examined would probably dictate the follow up time

9. Was follow up complete, and if not, were the reasons to loss to follow up described and explored?

It is important in a cohort study that a greater percentage of people are followed up. As a general guideline, at least 80% of patients should be followed up. Generally a dropout rate of 5% or less is

considered insignificant. A rate of 20% or greater is considered to significantly impact on the validity of the study. However, in observational studies conducted over a lengthy period of time a higher dropout rate is to be expected. A decision on whether to include or exclude a study because of a high dropout rate is a matter of judgement based on the reasons why people dropped out, and whether dropout rates were comparable in the exposed and unexposed groups.

Reporting of efforts to follow up participants that dropped out may be regarded as an indicator of a well conducted study. Look for clear and justifiable description of why people were left out, excluded, dropped out etc. If there is no clear description or a statement in this regards, this will be a 'No'.

10. Were strategies to address incomplete follow up utilized?

Some people may withdraw due to change in employment or some may die; however, it is important that their outcomes are assessed. Selection bias may occur as a result of incomplete follow up. Therefore, participants with unequal follow up periods must be taken into account in the analysis, which should be adjusted to allow for differences in length of follow up periods. This is usually done by calculating rates which use person-years at risk, i.e. considering time in the denominator.

11. Was appropriate statistical analysis used?

As with any consideration of statistical analysis, consideration should be given to whether there was a more appropriate alternate statistical method that could have been used. The methods section of cohort studies should be detailed enough for reviewers to identify which analytical techniques were used (in particular, regression or stratification) and how specific confounders were measured.

For studies utilizing regression analysis, it is useful to identify if the study identified which variables were included and how they related to the outcome. If stratification was the analytical approach used, were the strata of analysis defined by the specified variables? Additionally, it is also important to assess the appropriateness of the analytical strategy in terms of the assumptions associated with the approach as differing methods of analysis are based on differing assumptions about the data and how it will respond.

Appendix 7.2 Critical appraisal checklist for case-control studies

JBI Critical Appraisal Checklist for Case Control Studies

Reviewer_____ Date_____

Author _____ Year_____ Record Number_____

	JBI Critical Appraisal Checklist for Case Control Studies	Yes	No	Unclear	Not applicable
1	Were the groups comparable other than the presence of disease in cases or the absence of disease in controls?				
2	Were cases and controls matched appropriately?				
3	Were the same criteria used for identification of cases and controls?				
4	Was exposure measured in a standard, valid and reliable way?				
5	Was exposure measured in the same way for cases and controls?				
6	Were confounding factors identified?				
7	Were strategies to deal with confounding factors stated?				
8	Were outcomes assessed in a standard, valid and reliable way for cases and controls?				
9	Was the exposure period of interest long enough to be meaningful?				
10	Was appropriate statistical analysis used?				

Overall appraisal: Include Exclude Seek further info

Comments (Including reason for exclusion)

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Explanation of case control studies critical appraisal

How to cite: Moola S, Munn Z, Tufanaru C, Aromataris E, Sears K, Sfetcu R, Currie M, Lisy K, Qureshi R, Mattis P, Mu P. Chapter 7: Systematic reviews of etiology and risk. In: Aromataris E, Munn Z (Editors). *JBI Manual for Evidence Synthesis.* JBI, 2020. Available from https://synthesismanual.jbi.global. https://doi.org/10.46658/JBIMES-20-08

Case Control Studies Critical Appraisal Tool

Answers: Yes, No, Unclear or Not/Applicable

1. Were the groups comparable other than presence of disease in cases or absence of disease in controls?

The control group should be representative of the source population that produced the cases. This is usually done by individual matching; wherein controls are selected for each case on the basis of similarity with respect to certain characteristics other than the exposure of interest. Frequency or group matching is an alternative method. Selection bias may result if the groups are not comparable.

2. Were cases and controls matched appropriately?

As in item 1, the study should include clear definitions of the source population. Sources from which cases and controls were recruited should be carefully looked at. For example, cancer registries may be used to recruit participants in a study examining risk factors for lung cancer, which typify population-based case control studies. Study participants may be selected from the target population, the source population, or from a pool of eligible participants (such as in hospital-based case control studies).

3. Were the same criteria used for identification of cases and controls?

It is useful to determine if patients were included in the study based on either a specified diagnosis or definition. This is more likely to decrease the risk of bias. Characteristics are another useful approach to matching groups, and studies that did not use specified diagnostic methods or definitions should provide evidence on matching by key characteristics. A case should be defined clearly. It is also important that controls must fulfil all the eligibility criteria defined for the cases except for those relating to diagnosis of the disease.

4. Was exposure measured in a standard, valid and reliable way?

The study should clearly describe the method of measurement of exposure. Assessing validity requires that a 'gold standard' is available to which the measure can be compared. The validity of exposure measurement usually relates to whether a current measure is appropriate or whether a measure of past exposure is needed.

Case control studies may investigate many different ‘exposures’ that may or may not be associated with the condition. In these cases, reviewers should use the main exposure of interest for their review to answer this question when using this tool at the study level.

Reliability refers to the processes included in an epidemiological study to check repeatability of measurements of the exposures. These usually include intra-observer reliability and inter-observer reliability.

5. Was exposure measured in the same way for cases and controls?

As in item 4, the study should clearly describe the method of measurement of exposure. The exposure measures should be clearly defined and described in detail. Assessment of exposure or risk factors should have been carried out according to same procedures or protocols for both cases and controls.

6. Were confounding factors identified?

Confounding has occurred where the estimated intervention exposure effect is biased by the presence of some difference between the comparison groups (apart from the exposure investigated /of interest). Typical confounders include baseline characteristics, prognostic factors, or concomitant exposures (e.g. smoking). A confounder is a difference between the comparison groups and it influences the direction of the study results. A high quality study at the level of case control design will identify the potential confounders and measure them (where possible). This is difficult for studies where behavioral, attitudinal or lifestyle factors may impact on the results.

7. Were strategies to deal with confounding factors stated?

Strategies to deal with effects of confounding factors may be dealt within the study design or in data analysis. By matching or stratifying sampling of participants, effects of confounding factors can be

adjusted for. When dealing with adjustment in data analysis, assess the statistics used in the study. Most will be some form of multivariate regression analysis to account for the confounding factors measured. Look out for a description of statistical methods as regression methods such as logistic regression are usually employed to deal with confounding factors/ variables of interest.

8. Were outcomes assessed in a standard, valid and reliable way for cases and controls?

Read the methods section of the paper. If for e.g. lung cancer is assessed based on existing definitions or diagnostic criteria, then the answer to this question is likely to be yes. If lung cancer is assessed using observer reported, or self-reported scales, the risk of over- or under-reporting is increased, and objectivity is compromised. Importantly, determine if the measurement tools used were validated instruments as this has a significant impact on outcome assessment validity.

Having established the objectivity of the outcome measurement (e.g. lung cancer) instrument, it's important to establish how the measurement was conducted. Were those involved in collecting data trained or educated in the use of the instrument/s? (e.g. radiographers). If there was more than one data collector, were they similar in terms of level of education, clinical or research experience, or level of responsibility in the piece of research being appraised?

9. Was the exposure period of interest long enough to be meaningful?

It is particularly important in a case control study that the exposure time was sufficient enough to show an association between the exposure and the outcome. It may be that the exposure period may be too short or too long to influence the outcome.

10. Was appropriate statistical analysis used?

As with any consideration of statistical analysis, consideration should be given to whether there was a more appropriate alternate statistical method that could have been used. The methods section should be detailed enough for reviewers to identify which analytical techniques were used (in particular, regression or stratification) and how specific confounders were measured.

For studies utilizing regression analysis, it is useful to identify if the study identified which variables were included and how they related to the outcome. If stratification was the analytical approach used, were the strata of analysis defined by the specified variables? Additionally, it is also important to assess the appropriateness of the analytical strategy in terms of the assumptions associated with the approach as differing methods of analysis are based on differing assumptions about the data and how it will respond.

Appendix 7.3 Critical appraisal checklists for case series

JBI Critical Appraisal Checklist for Case Series

Reviewer _____ Date _____

Author _____ Year _____ Record Number _____

	JBI Critical Appraisal Checklist for Case Series	Yes	No	Unclear	Not applicable
1	Were there clear criteria for inclusion in the case series?				
2	Was the condition measured in a standard, reliable way for all participants included in the case series?				
3	Were valid methods used for identification of the condition for all participants included in the case series?				
4	Did the case series have consecutive inclusion of participants?				
5	Did the case series have complete inclusion of participants?				
6	Was there clear reporting of the demographics of the participants in the study?				
7	Was there clear reporting of clinical information of the participants?				
8	Were the outcomes or follow up results of cases clearly reported?				
9	Was there clear reporting of the presenting site(s)/clinic(s) demographic information?				
10	Was statistical analysis appropriate?				

Overall appraisal: Include Exclude Seek further info

Comments (Including reason for exclusion)

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Introduction to the Case Series Critical Appraisal Tool

How to cite: Moola S, Munn Z, Tufanaru C, Aromataris E, Sears K, Sfetcu R, Currie M, Lisy K, Qureshi R, Mattis P, Mu P. Chapter 7: Systematic reviews of etiology and risk. In: Aromataris E, Munn Z (Editors). *JBI Manual for Evidence Synthesis.* JBI, 2020. Available from https://synthesismanual.jbi.global. https://doi.org/10.46658/JBIMES-20-08

The definition of a case series varies across the medical literature, which has resulted in inconsistent use of this term (Appendix 1).[1-3] The gamut of case studies is wide, with some studies claiming to be a case series realistically being nothing more than a collection of case reports, with others more akin to cohort studies or even quasi-experimental before and after studies. This has created difficulty in assigning 'case series' a position in the hierarchy of evidence and identifying and appropriate critical appraisal tool.[1, 2]

Dekkers et al. define a case series as a study in which 'only patients with the outcome are sampled (either those who have an exposure or those who are selected without regard to exposure), which does not permit calculation of an absolute risk.'[1p.39] The outcome could be a disease or a disease related outcome. This is contrasted to cohort studies where sampling is based on exposure (or characteristic), and case- control studies where there is a comparison group without the disease.

The completeness of a case series contributes to its reliability.[1] Studies that indicate a consecutive and complete inclusion are more reliable than those that do not. For example, a case series that states 'we included all patients (24) with osteosarcoma who presented to our clinic between March 2005 and June 2006' is more reliable than a study that simply states 'we report a case series of 24 people with osteosarcoma.'

For the purposes of this checklist, we agree with the principles outlined in the Dekker et al. paper, and define case series as studies where only patients with a certain disease or disease-related outcome are sampled. Some of the items below relate to risk of bias, whilst others relate to ensuring adequate reporting and statistical analysis. A response of 'no' to any of the questions below negatively impacts the quality of a case series.

Tool Guidance

Answers: Yes, No, Unclear or Not/Applicable

1. Were there clear criteria for inclusion in the case series?

The authors should provide clear inclusion (and exclusion criteria where appropriate) for the study participants. The inclusion/exclusion criteria should be specified (e.g., risk, stage of disease progression) with sufficient detail and all the necessary information critical to the study.

2. Was the condition measured in a standard, reliable way for all participants included in the case series?

The study should clearly describe the method of measurement of the condition. This should be done in a standard (i.e. same way for all patients) and reliable (i.e. repeatable and reproducible results) way.

3. Were valid methods used for identification of the condition for all participants included in the case series?

Many health problems are not easily diagnosed or defined and some measures may not be capable of including or excluding appropriate levels or stages of the health problem. If the outcomes were assessed based on existing definitions or diagnostic criteria, then the answer to this question is likely to be yes. If the outcomes were assessed using observer reported, or self-reported scales, the risk of over- or under-reporting is increased, and objectivity is compromised. Importantly, determine if the measurement tools used were validated instruments as this has a significant impact on outcome assessment validity.

4. Did the case series have consecutive inclusion of participants?

Studies that indicate a consecutive inclusion are more reliable than those that do not. For example, a case series that states ‘we included all patients (24) with osteosarcoma who presented to our clinic between March 2005 and June 2006’ is more reliable than a study that simply states ‘we report a case series of 24 people with osteosarcoma.’

5. Did the case series have complete inclusion of participants?

The completeness of a case series contributes to its reliability (1). Studies that indicate a complete inclusion are more reliable than those that do not. A stated above, a case series that states ‘we included all patients (24) with osteosarcoma who presented to our clinic between March 2005 and June 2006’ is more reliable than a study that simply states ‘we report a case series of 24 people with osteosarcoma.’

6. Was there clear reporting of the demographics of the participants in the study?

The case series should clearly describe relevant participant’s demographics such as the following information where relevant: participant’s age, sex, education, geographic region, ethnicity, time period, education.

7. Was there clear reporting of clinical information of the participants?

There should be clear reporting of clinical information of the participants such as the following information where relevant: disease status, comorbidities, stage of disease, previous interventions /treatment, results of diagnostic tests, etc.

8. Were the outcomes or follow-up results of cases clearly reported?

The results of any intervention or treatment should be clearly reported in the case series. A good case study should clearly describe the clinical condition post-intervention in terms of the presence or lack of symptoms. The outcomes of management/treatment when presented as images or figures can help in conveying the information to the reader/clinician. It is important that adverse events are clearly documented and described, particularly a new or unique condition is being treated or when a new drug or treatment is used. In addition, unanticipated events, if any that may yield new or useful information should be identified and clearly described.

9. Was there clear reporting of the presenting site(s)/clinic(s) demographic information?

Certain diseases or conditions vary in prevalence across different geographic regions and populations (e.g. women vs. men, sociodemographic variables between countries). The study sample should be described in sufficient detail so that other researchers can determine if it is comparable to the population of interest to them.

10. Was statistical analysis appropriate?

As with any consideration of statistical analysis, consideration should be given to whether there was a more appropriate alternate statistical method that could have been used. The methods section of studies should be detailed enough for reviewers to identify which analytical techniques were used and whether these were suitable.

References

1 Dekkers OM, Egger M, Altman DG, Vandenbroucke JP. Distinguishing case series from cohort studies. Annals of Internal Medicine. 2012;156(1 Part 1):37-40.

2 Esene IN, Ngu J, El Zoghby M, Solaroglu I, Sikod AM, Kotb A et al. Case series and descriptive cohort studies in neurosurgery: the confusion and solution. Child's Nervous System. 2014; 30(8):1321-32.

3 Abu-Zidan FM, Abbas AK, Hefny AF. Clinical “case series”: a concept analysis. African Health Sciences. 2012;12(4):557-62.

4 Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-based medicine: How to practice and teach EBM. 3rd Edition ed: Elsevier 2005.

Appendix 1: Case series definitions:

‘A report on a series of patients with an outcome of interest. No control group is involved.’(4) (p 279)

‘A case series is a descriptive study involving a group of patients who all have the same disease or condition: the aim is to describe common and differing characteristics of a particular group of individuals’ (Oxford Handbook of medical statistics)

‘A group or series of case reports involving patients who were given similar treatment. Reports of case series usually contain detailed information about the individual patients. This includes demographic information (for example, age, gender, ethnic origin) and information on diagnosis,

treatment, response to treatment, and follow-up after treatment.' Law K, Howick J. OCEBM Table of Evidence Glossary. 2013 [cited 2014 10th January]; Available from: http://www.cebm.net/index.aspx?o=1116

'A **case series** (also known as a clinical **series**) is a type of medical research study that tracks subjects with a known exposure, such as patients who have received a similar treatment, or examines their medical records for exposure and outcome.' Wikipedia

'A study which makes observations on a series of individuals, usually all receiving the same intervention, with no control group. Comments: At this stage it is unclear whether case series should be included in Cochrane systematic reviews, but we have left them in the list so that working groups can consider whether there are circumstances in which it would be appropriate to include them, and to assess risk of bias. A particular reason for including case series might be where they provide evidence relating to adverse effects of an intervention. Potential examples of risk of bias might be that if a case series does not [attempt to] recruit consecutive participants, this might introduce a risk of selection bias, while some case series could be at risk of detection bias, if the circumstances in which adverse effects are reported (or elicited) are not standardised.' http://bmg.cochrane.org/research-projectscochrane-risk-bias-tool

Appendix 7.4 Critical appraisal checklist for case reports

JBI Critical Appraisal Checklist for Case Reports

Reviewer_____Date_____

Author_____ Year_____ Record Number _____

	JBI Critical Appraisal Checklist for Case Reports	Yes	No	Unclear	Not applicable
1	Were patient's demographic characteristics clearly described?				
2	Was the patient's history clearly described and presented as a timeline?				
3	Was the current clinical condition of the patient on presentation clearly described?				
4	Were diagnostic tests or assessment methods and the results clearly described?				
5	Was the intervention(s) or treatment procedure(s) clearly described?				
6	Was the post-intervention clinical condition clearly described?				
7	Were adverse events (harms) or unanticipated events identified and described?				
8	Does the case report provide takeaway lessons?				

Overall appraisal: Include Exclude Seek further info

Comments (Including reason for exclusion)

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Explanation of case reports critical appraisal

How to cite: Moola S, Munn Z, Tufanaru C, Aromataris E, Sears K, Sfetcu R, Currie M, Lisy K, Qureshi R, Mattis P, Mu P. Chapter 7: Systematic reviews of etiology and risk. In: Aromataris E, Munn Z (Editors). *JBI Manual for Evidence Synthesis.* JBI, 2020. Available from https://synthesismanual.jbi.global. https://doi.org/10.46658/JBIMES-20-08

Case Reports Critical Appraisal Tool

Answers: Yes, No, Unclear or Not/Applicable

1. Were patient's demographic characteristics clearly described?

Does the case report clearly describe patient's age, sex, race, medical history, diagnosis, prognosis, previous treatments, past and current diagnostic test results, and medications? The setting and context may also be described.

2. Was the patient's history clearly described and presented as a timeline?

A good case report will clearly describe the history of the patient, their medical, family and psychosocial history including relevant genetic information, as well as relevant past interventions and their outcomes. (CARE Checklist 2013)

3. Was the current clinical condition of the patient on presentation clearly described?

The current clinical condition of the patient should be described in detail including the uniqueness of the condition/disease, symptoms, frequency and severity. The case report should also be able to present whether differential diagnoses was considered.

4. Were diagnostic tests or methods and the results clearly described?

A reader of the case report should be provided sufficient information to understand how the patient was assessed. It is important that all appropriate tests are ordered to confirm a diagnosis and therefore the case report should provide a clear description of various diagnostic tests used (whether a gold standard or alternative diagnostic tests). Photographs or illustrations of diagnostic procedures, radiographs, or treatment procedures are usually presented when appropriate to convey a clear message to readers.

5. Was the intervention(s) or treatment procedure(s) clearly described?

It is important to clearly describe treatment or intervention procedures as other clinicians will be reading the paper and therefore may enable clear understanding of the treatment protocol. The report should describe the treatment/intervention protocol in detail; for e.g. in pharmacological management of dental anxiety - the type of drug, route of administration, drug dosage and frequency, and any side effects.

6. Was the post-intervention clinical condition clearly described?

A good case report should clearly describe the clinical condition post-intervention in terms of the presence or lack thereof symptoms. The outcomes of management/treatment when presented as images or figures would help in conveying the information to the reader/clinician.

7. Were adverse events (harms) or unanticipated events identified and described?

With any treatment/intervention/drug, there are bound to be some adverse events and in some cases, they may be severe. It is important that adverse events are clearly documented and described, particularly when a new or unique condition is being treated or when a new drug or treatment is used. In addition, unanticipated events, if any that may yield new or useful information should be identified and clearly described.

8. Does the case report provide takeaway lessons?

Case reports should summarize key lessons learned from a case in terms of the background of the condition/disease and clinical practice guidance for clinicians when presented with similar cases.

References:

Gagnier JJ, Kienle G, Altman DG, Moher D, Sox H, Riley D, CARE Group. The CARE Guidelines: ConsensusBased Clinical Case Reporting Guideline Development. Headache: The Journal of Head and Face Pain, 2013;53(10):1541-1547.

Appendix 7.5 Critical appraisal checklist for analytical cross-sectional studies

JBI Critical Appraisal Checklist for Analytical Cross Sectional Studies

Reviewer_____ Date_____

Author_____ Year_____ Record Number_____

	JBI Critical Appraisal Checklist for Analytical Cross Sectional Studies	Yes	No	Unclear	Not applicable
1	Were the criteria for inclusion in the sample clearly defined?				
2	Were the study subjects and the setting described in detail?				
3	Was the exposure measured in a valid and reliable way?				
4					

	Were objective, standard criteria used for measurement of the condition?				
5	Were confounding factors identified?				
6	Were strategies to deal with confounding factors stated?				
7	Were the outcomes measured in a valid and reliable way?				
8	Was appropriate statistical analysis used?				

Overall appraisal: Include Exclude Seek further info

Comments (Including reason for exclusion)

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Explanation of analytical cross sectional studies critical appraisal

How to cite: Moola S, Munn Z, Tufanaru C, Aromataris E, Sears K, Sfetcu R, Currie M, Lisy K, Qureshi R, Mattis P, Mu P. Chapter 7: Systematic reviews of etiology and risk. In: Aromataris E, Munn Z (Editors). *JBI Manual for Evidence Synthesis.* JBI, 2020. Available from https://synthesismanual.jbi.global. https://doi.org/10.46658/JBIMES-20-08

Analytical cross sectional studies Critical Appraisal Tool

Answers: Yes, No, Unclear or Not/Applicable

1. Were the criteria for inclusion in the sample clearly defined?

The authors should provide clear inclusion and exclusion criteria that they developed prior to recruitment of the study participants. The inclusion/exclusion criteria should be specified (e.g., risk, stage of disease progression) with sufficient detail and all the necessary information critical to the study.

2. Were the study subjects and the setting described in detail?

The study sample should be described in sufficient detail so that other researchers can determine if it is comparable to the population of interest to them. The authors should provide a clear description of the population from which the study participants were selected or recruited, including demographics, location, and time period.

3. Was the exposure measured in a valid and reliable way?

The study should clearly describe the method of measurement of exposure. Assessing validity requires that a 'gold standard' is available to which the measure can be compared. The validity of exposure measurement usually relates to whether a current measure is appropriate or whether a measure of past exposure is needed.

Reliability refers to the processes included in an epidemiological study to check repeatability of measurements of the exposures. These usually include intra-observer reliability and inter-observer reliability.

4. Were objective, standard criteria used for measurement of the condition?

It is useful to determine if patients were included in the study based on either a specified diagnosis or definition. This is more likely to decrease the risk of bias. Characteristics are another useful approach to matching groups, and studies that did not use specified diagnostic methods or definitions should provide evidence on matching by key characteristics.

5. Were confounding factors identified?

Confounding has occurred where the estimated intervention exposure effect is biased by the presence of some difference between the comparison groups (apart from the exposure investigated /of interest). Typical confounders include baseline characteristics, prognostic factors, or concomitant exposures (e.g. smoking). A confounder is a difference between the comparison groups and it influences the direction of the study results. A high quality study at the level of cohort design will identify the potential confounders and measure them (where possible). This is difficult for studies where behavioral, attitudinal or lifestyle factors may impact on the results.

6. Were strategies to deal with confounding factors stated?

Strategies to deal with effects of confounding factors may be dealt within the study design or in data analysis. By matching or stratifying sampling of participants, effects of confounding factors can be adjusted for. When dealing with adjustment in data analysis, assess the statistics used in the study. Most will be some form of multivariate regression analysis to account for the confounding factors measured.

7. Were the outcomes measured in a valid and reliable way?

Read the methods section of the paper. If for e.g. lung cancer is assessed based on existing definitions or diagnostic criteria, then the answer to this question is likely to be yes. If lung cancer is assessed using observer reported, or self-reported scales, the risk of over- or under-reporting is increased, and objectivity is compromised. Importantly, determine if the measurement tools used were validated instruments as this has a significant impact on outcome assessment validity.

Having established the objectivity of the outcome measurement (e.g. lung cancer) instrument, it's important to establish how the measurement was conducted. Were those involved in collecting data trained or educated in the use of the instrument/s? (e.g. radiographers). If there was more than one data collector, were they similar in terms of level of education, clinical or research experience, or level of responsibility in the piece of research being appraised?

8. Was appropriate statistical analysis used?

As with any consideration of statistical analysis, consideration should be given to whether there was a more appropriate alternate statistical method that could have been used. The methods section should be detailed enough for reviewers to identify which analytical techniques were used (in particular, regression or stratification) and how specific confounders were measured.

For studies utilizing regression analysis, it is useful to identify if the study identified which variables were included and how they related to the outcome. If stratification was the analytical approach used, were the strata of analysis defined by the specified variables? Additionally, it is also important to assess the appropriateness of the analytical strategy in terms of the assumptions associated with the approach as differing methods of analysis are based on differing assumptions about the data and how it will respond.

Systematic Reviews of Etiology and Risk Resources

Digital Resources

Innovations in Systematic Reviews of Aetiology and Risk

Dr Jennifer Stone presents at JBI iGNITE on the innovations in systematic reviews of aetiology and risk.

What is aetiology and risk?

In this short podcast Dr Jennifer Stone briefly summarises what aetiology and risk mean in systematic reviews.

8. Mixed methods systematic reviews

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[1] Co-first authors

How to cite:

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https://doi.org/10.46658/JBIMES-24-07

Contents

8.1 Introduction to mixed methods systematic reviews

Decision-makers who use systematic reviews increasingly argue for a more comprehensive synthesis of the evidence than that currently offered by single method reviews (Dixon-Woods et al., 2005). This is particularly evident in the areas of public health and social policy that deal with complex interventions. A range of methodologies are available that incorporate multiple study designs /types of data including integrative literature reviews (which can include both empirical and theoretical studies with limited formal methods on combining data) (Broome, 2000), comprehensive literature reviews/systematic reviews (where no formal combination or integration of data is undertaken) and mixed methods reviews (where data is combined and integrated together in a more formalized manner). Systematic reviews aim to provide unbiased syntheses of studies/evidence using rigorous and transparent methods as opposed to literature reviews that are largely subjective and unreproducible. Mixed methods systematic reviews (MMSR) can bring together the findings of effectiveness (quantitative evidence) and patient, family, staff or other's experience (qualitative evidence) to enhance their usefulness to decision-makers (Bressan et al., 2016). In addition to this movement for MMSR, there is an increasing focus on the different types of information that guideline developers need when making a decision, such as feasibility, priority, cost effectiveness, impact on equity, acceptability (Alonso-Coello et al., 2016) and patient values and preferences (Zhang et al., 2018). Integrating data in response to these different types of questions into a single synthesis would be incredibly useful for guideline development groups and decision makers.

Systematic reviews addressing questions of experience, (qualitative) and effectiveness (quantitative) have specific purposes but increasingly both perspectives are required to inform clinical, policy or organizational decisions. For example, although quantitative evidence suggests that the use of larval therapy is both clinically effective and cost effective for the debridement of wounds (Adela, 2017; Arabloo et al., 2016; Sun et al., 2014; Tian et al., 2013; Wilasrusmee et al., 2014), evidence from qualitative studies indicates that negative experiences and perceptions impact on the acceptability of the therapy. Some studies indicate feelings of distaste and disgust associated with maggots influence patients' decisions to reject the therapy or impact negatively on their experience of the therapy (McCaughan et al., 2015; Menon, 2012).

Mixed method systematic review methodology is an emerging field of enquiry; MMSR are also referred to as mixed methods research syntheses (Heyvaert et al., 2013), mixed studies reviews (Pluye & Hong, 2014) and mixed research syntheses (Sandelowski et al., 2006). While there is a degree of complexity in conducting MMSR, the core intention is to combine quantitative and qualitative data (from primary studies) or integrate quantitative evidence and qualitative evidence to create a breadth and depth of understanding that can confirm or dispute evidence and ultimately answer the review question/s posed.

Mixed methods reviews represent an important development for individuals engaged in evidence synthesis for healthcare as they attempt to increase the usefulness of their findings and the ability of those findings to inform policy and practice. Similarly, Sandelowski et al. 2013 suggest that the methodological inclusiveness characteristic of MMSR is particularly relevant to international organizations as this broad conceptualization of evidence increases accessibility and utility by a wider range of end users.

Through the development of a well-structured MMSR, the numerical data inherent in the positivist paradigm can support or endorse the equally important opinions and perspectives presented in interpretive and critical paradigms and vice versa. This has the potential to produce more informative conclusions than those derived from evidence presented in autonomous modes of synthesis, i.e. effectiveness systematic reviews and experiential systematic reviews.

Dependent on the nature of the review question (discussed in more depth in Section 8.3) MMSRs allow for:

- an examination of the degree of agreement between quantitative and qualitative data to validate or triangulate results/findings,
- identification of discrepancies within the available evidence,
- determination of whether the quantitative and qualitative data address different aspects of a phenomenon of interest, and
- one type of data that can explore, contextualize or explain the findings of the other type of data.

Although MMSR are gaining traction among healthcare professionals due to their usefulness and practicality, guidance regarding the methodology of combining quantitative and qualitative data is limited and largely at the theoretical stage (Hong et al., 2017).

8.2 Concepts and considerations for mixed methods systematic reviews

The universal steps involved in a systematic review (e.g. formulation of review question/s, establishing eligibility criteria, development of a search strategy, searching and retrieval of relevant studies, critical appraisal of included studies, data extraction, and synthesis) also apply to a MMSR. However, unique aspects regarding how data is combined and the overall integration of the evidence are additional factors that need to be considered.

To avoid confusion in describing a MMSR, it is important to firstly outline a number of core concepts related to this type of systematic review (Table 8.1). A review of the literature conducted by the authors informed the development of core concepts and the subsequent JBI MMSR approach that is detailed in Section 8.3.

Table 8.1: Summary of concepts related to MMSR

Data	Refers to the primary data obtained from quantitative studies, qualitative studies or mixed methods studies.
Data transformation	Refers to the process of transforming qualitative data into a quantitative format (‘quantitizing’) or quantitative data into a qualitative format (‘qualitizing’).
Integration	Refers to the combining of quantitative data with qualitative data following transformation OR of combining quantitative evidence and qualitative evidence without transformation.
Synthesis	Can either be a quantitative synthesis or a qualitative synthesis. Quantitative synthesis refers to the process of combining extracted data from quantitative studies (including data from the quantitative component of a mixed methods study), resulting in the generation of quantitative evidence. Qualitative synthesis refers to the process of combining extracted data from qualitative studies (including data from the qualitative component of a mixed methods study), resulting in the generation of qualitative evidence.
Sequence of synthesis	Refers to whether the quantitative synthesis and qualitative synthesis occurs *si multaneously* (i.e. convergent) or *consecutively* (i.e. sequential, where the results/findings from a synthesis of one type of evidence inform the synthesis of the other type of evidence).

A systematic review examining the different methods available to synthesize quantitative and qualitative data or integrate quantitative and qualitative evidence was undertaken by Hong et al 2017. The review included 459 reviews utilizing a number of different frameworks for integration; however, it identified two predominant frameworks to MMSR: the convergent design (where syntheses occur at the same time) and the sequential design (where syntheses occur one after another). The two frameworks identified in Hong et al.’s (2017) review concur with the seminal work undertaken by Sandelowski and colleagues (2006) who developed three basic designs for MMSR which were adapted from the primary mixed methods literature. They include the: (1) integrated design, (2) segregated design and (3) contingent design (Sandelowski et al., 2006).

1. The integrated design involves integration of transformed data referred to as *direct assimilation* , which rests on the assumption that quantitative and qualitative data can both address the same research question. As such they can be combined once data have been transformed in the same format (i.e. ‘quantitized’ or ‘qualitized’) (Sandelowski et al., 2006).
2. The segregated design involves integration of evidence through a method referred to as *config uration,* which is the arrangement of complementary evidence into a line of argument. Complementarity rests on the assumption that quantitative and qualitative evidence address different research questions that are related to the same phenomenon of interest. In other words, quantitative and qualitative evidence address different aspects or dimensions of a phenomenon of interest and therefore they can neither confirm nor refute each other but

rather only complement each other. As such, the quantitative evidence and qualitative evidence cannot be directly combined and can only be organized into a coherent whole (Sandelowski et al., 2006).
3. The contingent design takes a cyclic approach in which synthesis is conducted in order to answer questions raised from the previous synthesis i.e. the results of each synthesis determines the next question to undertake until a comprehensive research synthesis that addresses the reviewers objectives is complete (Sandelowski et al., 2006). Table 8.2 provides a comparison of these frameworks.

Table 8.2: Comparison of frameworks identified by Hong et al. (2017) and Sandelowski et al. (2006).

Hong et al. (2017)	What is involved?	Sandelowski et al. (2006)
Convergent data-based	• Typically involves a broad review question that can be addressed by both quantitative studies and qualitative studies • **Requires data transformation** • Involves integration of transformed data	**Integrated**
Convergent results-based: results are presented in the results section of the systematic review **Convergent parallel-results: results are presented in the discussion section of the systematic review**	• Typically involves an overall review question with sub-questions (some that can only be addressed by quantitative studies and others that can only be addressed by qualitative studies) • Separate and simultaneous synthesis of quantitative data and qualitative data • Involves integration of quantitative evidence and qualitative evidence • **No data transformation**	**Segregated**
Sequential	• Synthesis of quantitative data and qualitative data are conducted sequentially based on results from the previous synthesis	**Contingent**

The three main considerations in undertaking an MMSR relate to:

1. the sequence in which the synthesis occurs,
2. how data is transformed, and
3. how transformed data or quantitative and qualitative evidence are integrated together.

Sequence of synthesis

As described above, the order of synthesis can be either convergent or sequential. The convergent design is the dominant approach used in MMSR (95% of reviews), with the sequential design only applied in a very small proportion of reviews (5%) (Hong et al., 2017). Consequently, this current MMSR guidance will focus exclusively on convergent approaches.

In the convergent approach the synthesis occurs simultaneously. This can occur at two different stages within the review; dependent on the type of convergent design utilized. In the first instance, synthesis occurs at the data level when quantitative, qualitative and mixed methods studies are extracted concurrently, data is transformed and then analyzed in a parallel manner.

In the second instance, quantitative evidence (from quantitative studies and data from the quantitative component of mixed methods studies) is synthesized separately as is qualitative evidence (from qualitative studies and data from the qualitative component of mixed methods studies) which are then integrated together.

Data transformation

In order for qualitative and quantitative data to be integrated and fully inform the topic, one approach is for the data to be transformed into a mutually compatible format (Voils et al., 2009). Data transformation can occur either by converting qualitative data into quantitative data (i.e. quantitizing)

or by converting quantitative data into qualitative data (i.e. qualitizing). Quantitizing is a process in which qualitative data are assigned numerical values. Approaches described in the literature include content analysis, Bayesian analysis and Boolean analysis (Frantzen & Fetters, 2016). Qualitizing refers to quantitative data being converted into themes, categories, typologies or narratives (Frantzen & Fetters, 2016; Heyvaert et al., 2013; Sandelowski et al., 2006). This can be undertaken by thematic analysis, critical interpretative synthesis, meta-narrative synthesis and realist synthesis (Frantzen & Fetters, 2016). Both quantizing and qualitizing approaches are accepted in the literature; however, one is not recommended over the other with both having their strengths and weaknesses.

Integration of findings

Integration refers to how transformed data are merged or how quantitative and qualitative evidence are combined. The literature indicates there are various methods for undertaking integration; some of these are described below

A. Integration following data transformation

Quantitative approach: this type of integration is applied when qualitative data are quantitized. Commonly used approaches include content analysis and vote counting.

- In content analysis, themes or categories are developed *a priori* (i.e. before integration) and then all extracted data (i.e. quantitative data and quantitized qualitative data) are coded according to these categories or themes (Dixon-Woods, Agarwal, Jones, Young, & Sutton, 2005; Spilsbury et al., 2008). This is followed by creating tabulations of frequency counts to identify key findings (Dixon-Woods et al., 2005; Spilsbury et al., 2008).
- Vote counting involves two steps: first, the findings of the included studies are classified into those that yield positive results, those that yield negative results, and those that show no difference (i.e. not positive and not negative); second, the number of primary studies allocated to each classification are counted (Hayvaert et al., 2017; Hong et al., 2017). The classification which has the most number of counts is declared the 'winning category' and therefore provides the most convincing evidence according to the vote-counting approach (Hayvaert et al., 2017; Hong et al., 2017).

Qualitative approach: this type of integration is applied when quantitative data are qualitized; to date, the most common approach to such integration is thematic synthesis. In thematic synthesis, extracted data are coded, followed by grouping of codes which then make up a specific theme (Thomas & Harden, 2008). The descriptive themes might then lead to a conceptual framework. In some instances, a theoretical or conceptual framework is used to develop *a priori* set of themes on which to organize the codes identified from the analysis of extracted data.

B. Integration following quantitative and qualitative synthesis

Methods that are often used for integrating a quantitative evidence synthesis with a qualitative evidence synthesis are realist synthesis, narrative summary, thematic synthesis or framework synthesis.

- Realist synthesis is a theory-driven approach aimed at unpacking how an intervention works in a particular context or setting – '*what works for whom in what circumstances'* (Pawson et al., 2005).
- Narrative summary varies from a *'simple recounting and description of findings to more reflective accounts that include commentary and higher levels of abstraction to explain complex processes'* (Hayvaert et al., 2017) p.231.
- Thematic synthesis uses coding, groups similar codes and develops descriptive themes to generate an overall summary of findings (Hong et al., 2017; Thomas & Harden, 2008).
- Framework synthesis involves a preliminary identification of themes against which to map and configure the findings from the quantitative and qualitative studies (Carroll et al., 2011).

A summary of the methodological approaches for MMSR is provided in Table 8.3.

Table 8.3: Summary of methodological approaches for MMSR

Review design	Description	What is involved in the integration?	Methods for integration
Convergent Integrated	Involves data transformation that allows reviewers to combine quantitative and qualitative data	Direct assimilation	• Content analysis • Vote counting • Thematic synthesis
	Independent synthesis of quantitative data and qualitative data followed by the integration of the two types of evidence	Configuration	• Realist synthesis • Narrative summary • Thematic synthesis

Convergent Segregated			• Framework synthesis
Sequential	Synthesis of one type of data occurs after, or is informed by, the synthesis of the other type of data	Direct assimilation or configuration or both	Integration of quantitative evidence and qualitative evidence may or may not occur

8.3 The JBI approach to mixed method systematic reviews

The JBI methodology for mixed methods systematic reviews aligns with the typology developed by Hong et al. 2017. That is, that the review approach can either be convergent (where the synthesis occurs simultaneously) or sequential (where the synthesis occurs consecutively). However, based on minimal usage of the sequential approach, this guidance for JBI mixed methods systematic reviews currently focuses exclusively on the convergent approach. The convergent design can be broken down into a series of methods that have been simplified into two groups – convergent integrated (involves data transformation that allows reviewers to combine quantitative and qualitative data) and convergent segregated (involves independent synthesis of quantitative data and qualitative data leading to the generation of quantitative evidence and qualitative evidence which are then integrated together). The nature/type of question/s that is/are posed in the systematic review dictates the approach the reviewer should follow for the synthesis.

Nature of the question

The reviewer needs to consider if the review question can be addressed by both quantitative and qualitative studies or if the focus of the review is on different aspects or dimensions of a particular phenomenon of interest. Here are two scenarios highlighting the different question(s) a reviewer may pose for a mixed methods systematic review.

Scenario 1

Consider the following question:

'What are the barriers and enablers to self-management in adolescents with asthma?' (Holley et al., 2017)

Here the focus is on barriers and enablers, which can be addressed through qualitative research (e.g. through a phenomenological study of adolescents with asthma) as well as quantitative research (e.g. through a survey of adolescents with asthma conducted as part of a cross sectional study).

Scenario 2

Consider the following questions:

'What is the impact of mindfulness-based interventions on nurses?' and *'What do nurses perceive the benefits and challenges of mindfulness-based interventions to be?'*

(Guillaumie, Boiral, & Champagne, 2017)

Here both questions relate to a common phenomenon, i.e. mindfulness-based interventions for nurses, but they are addressing two different aspects associated with it – namely, what impact these interventions have on nurses in terms of the effect of the interventions on outcomes such as stress and anxiety, and how nurses experience or perceive them. We know that questions of effectiveness are answered through quantitative research (e.g. through a randomized controlled trial comparing mindfulness-based interventions with standard interventions) and questions of experience/perception are answered through qualitative research (e.g. through an

ethnographic study where the researcher undertakes fieldwork on a group of nurses receiving mindfulness-based interventions).

Following question development, the steps involved in quantitative and qualitative systematic reviews apply to mixed methods systematic reviews, such as development of eligibility criteria, literature searching and retrieval, critical appraisal and data extraction (please see Chapter 2 and Chapter 3 of the JBI Manual for Evidence Synthesis for further information). Hence, the guidance described in this section will focus on synthesis and the distinct features of a mixed method systematic review – that is, the integration of quantitative and qualitative evidence, and the transformation of quantitative and qualitative data. Ultimately which approach is utilized will depend on the nature of the question(s) posed, as outlined above.

Approaches to synthesis and integration

If the review question can be addressed by both quantitative and qualitative research designs the **convergent integrated approach** should be followed; if the focus of the review is on different aspects or dimensions of a particular phenomenon of interest the **convergent segregated approach** is undertaken. Let's now take another look at our two examples to explain why.

Scenario 1

'What are the barriers and enablers to self-management in adolescents with asthma?' (Holley et al., 2017)

- Here the focus is on barriers and enablers, which can be addressed through qualitative research (e.g. through a phenomenological study of adolescents with asthma) as well as quantitative research (e.g. through a survey of adolescents with asthma conducted as part of a cross sectional study).
- Since this review question can be answered by both quantitative AND qualitative studies it would follow a **convergent integrated approach** to its synthesis and integration.

Scenario 2

'What is the impact of mindfulness-based interventions on nurses?' and *'What do nurses perceive the benefits and challenges of mindfulness-based interventions to be?'*

(Guillaumie et al., 2017)

- Here both questions relate to a common phenomenon, i.e. mindfulness-based interventions for nurses, but they are addressing two different aspects associated with it – namely, what impact these interventions have on nurses in terms of the effect of the interventions on outcomes such as stress and anxiety and how nurses experience or perceive them. We know that questions of effectiveness are answered through quantitative research (e.g. through a randomized controlled trial comparing mindfulness-based interventions with standard interventions) and questions of experience/perception are answered through qualitative research (e.g. through an ethnographic study where the researcher undertakes fieldwork on a group of nurses receiving mindfulness-based interventions).
- Since this review focuses on different dimensions of a phenomenon it would follow a **convergent segregated approach** to its synthesis and integration.

The **convergent integrated approach, suggested for Scenario 1 above,** refers to a process of combining extracted data from quantitative studies (including data from the quantitative component of mixed methods studies) and qualitative studies (including data from the qualitative component of mixed methods studies), and involves data transformation. It is recommended that quantitative data be 'qualitized', as codifying quantitative data is less error-prone than attributing numerical values to qualitative data (The Joanna Briggs Institute, 2014). 'Qualitizing' involves extracting data from quantitative studies and translating or converting it into 'textual descriptions' to allow integration with qualitative data. 'Qualitizing' involves a narrative interpretation of the quantitative results.

At the simplest level, qualitized data might comprise describing a sample (or members of it) using word categories based on supplementary descriptive statistics such as average or percentage scores (Bazeley, 2012). The study by Cohen et al. 2003 (part of the review by Holley et al. 2017 outlined in Scenario 1 above) aimed to examine the perceptions of adolescents with asthma and their attitudes towards self-treatment. Qualitization identified: *29% of survey participants reported feeling embarrassed having an asthma attack while with friends* (Cohen et al., 2003). Qualitized data can also include profiling of the sample using cluster or factor analysis (Bazeley, 2012). Data with a temporal or longitudinal component (Bazeley, 2012), or those that examine associations and relationships using inferential statistics such as linear or logistic regression analysis also have narrative potential and can therefore be qualitized by identifying variables included in the analysis. For example the study by Kyngäs (2000) (also in Holley et al., 2017) identified factors that predict compliance with health regimens by adolescents with asthma using logistic regression. Transformation identified: *support from nurses as a significant factor in predicting compliance with health regimens by adolescents with asthma (OR = 56.87, 95% 17.15-88.58)*. By qualitizing, the reviewer converts the 'quantities' into declarative stand-alone sentences, in a way that answers the review question.

These textual descriptions are then assembled and pooled with the qualitative data extracted directly from qualitative studies. Similar to the meta-aggregative approach for JBI qualitative reviews, reviewers are required to then undertake repeated, detailed examination of the assembled data to identify categories on the basis of similarity in meaning. A category will integrate two or more: qualitative data, 'qualitized' data or a combination of both. In some instances however, data may not have the same meaning as others and therefore cannot be combined to form a category. Where possible, categories are then aggregated to produce the overall finding(s) of the review. This process is illustrated in Figure 8.1.

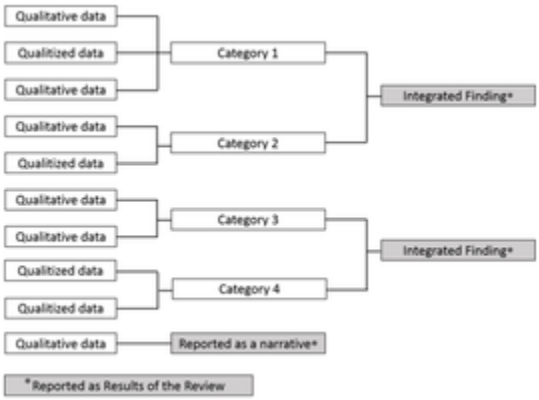

Figure 8.1: Convergent Integrated Approach. Qualitized findings are assembled into categories with qualitative findings extricated directly from qualitative studies based on similarity of meaning.

Using the example outlined above (Scenario 1), reviewers were able to determine six key barriers and/or enablers regarding self-management of asthma, which related to knowledge, lifestyle, beliefs and attitudes, relationships, intrapersonal characteristics and communication (Holley et al., 2017).

The **convergent segregated approach** consists of conducting a separate quantitative synthesis and qualitative synthesis, followed by integration of the results derived from each of the syntheses. By integrating the quantitative and qualitative synthesized findings, we are able to have a greater depth of understanding of the phenomena of interest compared to undertaking two separate component syntheses without formally linking the two sets of evidence. In Scenario 2 above, quantitative data is synthesized in the form of a meta-analysis (or a narrative summary if meta-analysis is not possible) to determine the effects of mindfulness-based interventions on nurses. Additionally, all the qualitative data is pooled (in the case of the JBI approach, through the process of meta-aggregation or narrative summary if deemed inappropriate – refer to Chapter 2 of the JBI Manual for Evidence Synthesis for further information) to determine the experiences/perceptions of nurses receiving these interventions. There is no order to which synthesis is done first as they are independent; however, both must be completed before moving onto the next step: integration of quantitative evidence and qualitative

evidence. This next step involves juxtaposing the synthesized quantitative results with the synthesized qualitative findings and organizing or linking the results and findings into a line or argument to produce an overall 'configured analysis'. This is where the reviewer considers how (and if) the results and findings complement each other by using one type of evidence to explore, contextualize or explain the findings of the other type of evidence. In this step, results and findings cannot be reduced but are organized into a coherent whole (Sandelowski, Voils & Barroso, 2006). In this approach, the reviewer repeatedly compares the results of the quantitative synthesis with the findings of the qualitative synthesis, analyzing the intervention which had been investigated for effectiveness (quantitative) in light of the experiences of the participants (qualitative). The following questions act as a guide for this process:

- Are the results/findings from individual synthesis supportive or contradictory?
- Does the qualitative evidence explain why the intervention is or is not effective?
- Does the qualitative evidence help explain differences in the direction and size of effect across the included quantitative studies?
- Which aspects of the quantitative evidence are/are not explored in the qualitative studies?
- Which aspects of the qualitative evidence are/are not tested in the quantitative evidence?

In some instances, the reviewer may find that the results of quantitative studies are not complementary or have no relationship with the findings of the qualitative studies, or vice-versa. In some cases the reviewer may identify gaps where further research may be useful to explain the contradictory findings or when there is no relationship between the qualitative findings and quantitative findings.

In Scenario 2 (mindfulness-based interventions for nurses), results from statistical meta-analysis showed significant reductions in anxiety and depression following treatment, whereas the qualitative synthesis highlighted improvements in areas such as well-being and work performance. In this example the qualitative synthesis highlighted factors not considered or covered in the quantitative synthesis which led to stronger support of the intervention as well as recommendations for future research (Guillaumie et al., 2017).

This integration follows a formal, structured process which is reported in the results section of the review (i.e. it "marries" the results of separate syntheses). The JBI Framework for undertaking a mixed methods systematic review is outlined in Figure 8.2.

Regardless of the approach taken, the ability to undertake a mixed methods synthesis and integration will ultimately depend on the evidence located and subsequently included in the review. As in a quantitative review focussing on a question of effectiveness where the aim is to be able to conduct a meta-analysis (or similarly a meta-aggregation in a qualitative review), in a mixed methods systematic review there may not be sufficient evidence available, the data may be limited in its 'richness' or thickness of description or the evidence located may not be similar enough to combine or link together. In these situations, the authors may need to undertake a narrative synthesis instead, much like in a quantitative review when a meta-analysis is not possible.

The JBI System for the Unified Management, Assessment and Review of Information (JBI SUMARI) supports reviewers to undertake a mixed methods systematic review using both the convergent integrated and the convergent segregated approaches.

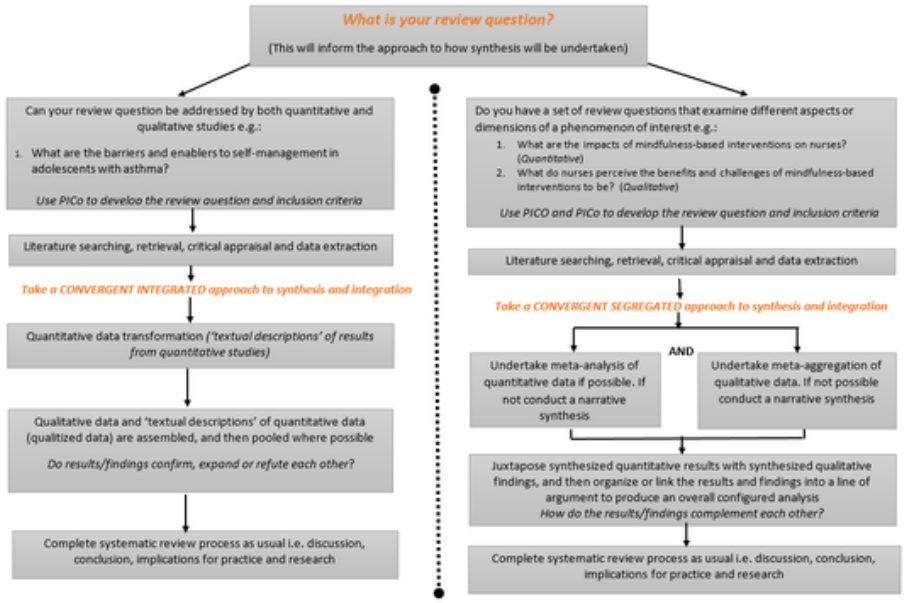

Figure 8.2: The JBI Framework for mixed methods systematic reviews

8.4 Developing a mixed methods review protocol

This section outlines the components of a mixed methods systematic review protocol and provides guidance on the information that each section should address. Specifically, it provides guidance on each of the following components: title, introduction, review question(s), inclusion criteria, methods (search strategy, study selection, assessment of methodological quality, data extraction, data synthesis), references, and appendices.

As discussed in Section 8.3, JBI focuses exclusively on the convergent approach to mixed methods reviews and as such the nature of the question(s) posed dictates the approach reviewers take with their synthesis. While the main steps undertaken in a systematic review are universal, there are some elements between the two approaches for mixed methods systematic reviews that will differ. For this reason, the following section is divided into the two approaches. Reviewers will need to be clear on the type of question(s) (and subsequently the type of synthesis) their proposed review is attempting to answer and follow the corresponding guidance provided below.

8.4.1 MMSR questions that take a CONVERGENT INTEGRATED approach to synthesis and integration

MMSR questions that take a CONVERGENT INTEGRATED approach to synthesis and integration

If the review question(s) can be addressed by both quantitative and qualitative studies, an integrated approach to synthesis and integration is undertaken. In this approach quantitative and qualitative data are synthesized/combined together through data transformation.

Protocol development

Commonly a review following this approach comprises one review question and primarily lends itself to the PICo criteria, where P is the population of interest, I is the Phenomena of interest and Co is the Context. However, where a review question does not fit the PICo approach, reviewers may consider using a different framework (e.g. PICO) to structure their question. The guidance for protocol development provided in Chapter 2 (Systematic reviews of qualitative evidence) of this online reviewer's manual can be followed however some additional considerations are needed for a MMSR and these are detailed below.

Title of a MMSR protocol

The title should be informative and give clear indication of the topic and population of the MMSR. Titles should not be phrased as questions and there should be congruency between the title, review question(s) and inclusion criteria. The title should always include the phrase "…: a mixed methods systematic review protocol" to allow easy identification of the type of document it represents. An example title may be:

Barriers and facilitators to asthma self-management in adolescents: a mixed methods systematic review protocol

Abstract

This section is a summary of the protocol in 300 words. The following headings should be included in the abstract - Objective, Introduction, Inclusion Criteria, Methods, Systematic review registration number (if applicable) and Keywords. The abstract should not contain abbreviations or references.

Introduction

As with all JBI systematic review protocols, the introduction to a MMSR should describe and situate the topic of interest under review. Definitions can assist to provide clarity. Explanation of how the review question can be answered by both quantitative and qualitative studies is required as is an explanation on how the review will add to the evidence base or inform clinical practice.

Additionally, a statement that a preliminary search of databases (with databases listed) has been undertaken and no existing or ongoing mixed method or individual systematic reviews on the topic have been identified should be provided. If other systematic reviews on the topic exist, indication on how the proposed systematic review will differ should be detailed. Finally, the introduction should conclude with an overarching review objective that captures and aligns with the core elements /mnemonic (i.e. PICo) of the inclusion criteria. The introduction should be of sufficient length to

discuss all of the elements of the proposed plan for the review; usually all the relevant information may be provided in approximately 1000 words. This section should be written in simple prose for non-expert readers.

Review question(s)

Clarity in the review question(s) assists in developing a protocol and also ultimately, the conduct of the review. The review question(s) guide and direct the development of the specific review inclusion criteria and facilitate more effective searching, and provide a structure for the development of the full review. There should also be consistency between the review title and the review question(s). Typically for a MMSR that follows a convergent integrated approach to synthesis a broad review question is posed that can be addressed by both quantitative studies and qualitative studies. As such PICo should be used to develop the review question as well as the inclusion criteria. An example of a PICo question that may be posed by a MMSR is:

1. What are the barriers and facilitators to self-management in adolescents with asthma?

In the above example, adolescents with asthma (i.e. those managing their own asthma), healthcare professionals (i.e. those involved in supporting adolescents to self-manage their asthma) and policy makers (i.e. those that assist in deciding how asthma is managed at a population level) are the target audiences since the intention is to determine how adolescents with asthma can best manage their asthma.

Inclusion criteria

This section of the protocol details the basis on which studies will be considered for inclusion into the systematic review and should be as clear and unambiguous as possible. Inclusion criteria should be reasonable, sound and justified. These criteria will be used in the selection process, when it is decided if a study will be included or not in the review.

Population

There needs to be a clear and direct link between the review question, title and the participant characteristics in the inclusion criteria. This section should specify the details about the types of participants considered for the review. Consider what are the most important characteristics of the population? (e.g., age, disease/condition, severity of illness, setting, gender, ethnicity etc.).

For example:

This review will consider studies that include #describe population#

Phenomena of interest

A phenomenon of interest is the experience, event or process occurring that is under study. The level of detail ascribed to the phenomena may vary with the nature or complexity of the topic.

This review will consider studies that investigate #insert text#

Context

Context will vary depending on the question(s) of the review. Context may include, but is not limited to consideration of: cultural or sub-cultural factors, geographic location, specific racial or gender-based interests, or detail about the specific setting (such as acute care, primary health care, or the community).

For example:

This review will consider studies that investigate #insert text#

Types of studies

This section should include the relevant information related to both quantitative and qualitative studies. The time frame chosen for the search should be justified and any language restrictions stated. For example:

This review will consider quantitative, qualitative and mixed methods studies. Quantitative studies will include #insert text#. Qualitative studies will include #insert text#. Mixed method studies will only be considered if data from the quantitative or qualitative components can be clearly extracted.

Studies published in #insert language(s)# will be included. Studies published from #database inception/or insert date# to the present will be included as #justify date range#

There should be a match in this section between the methodology of the primary research studies to be considered for the review and the review question.

Methods

Reference to the JBI methodology for MMSR should be provided. Additionally, if the review title has been registered, the name of the registry (e.g. PROSPERO) and the registration number should be reported below the Methods heading. For example:

The proposed systematic review will be conducted in accordance with the JBI methodology for MMSR #insert a citation to the Chapter in the JBI Manual for Evidence Synthesis # **Note**: if the review title has been registered, report the name of the registry (e.g. PROSPERO) and the registration number.

Search strategy

This section of a review protocol should provide explicit and clear information regarding two different aspects of locating studies: all information sources that will be searched for the review, and the strategies used for searching. The aim of a systematic review is to identify all relevant studies, published or not, on a given topic. Searching should be based on the principle of comprehensiveness, with the widest reasonable collection of information sources that are considered appropriate to the review.

The databases to be searched must be listed, including the search platform used where necessary, along with a completed search strategy for one major database which should be presented as an Appendix.

This section is universal for example:

The search strategy will aim to locate both published and unpublished studies. An initial limited search of #MEDLINE and CINAHL #change as appropriate# was undertaken to identify articles on the topic. The text words contained in the titles and abstracts of relevant articles, and the index terms used to describe the articles were used to develop a full search strategy for #report the name of the relevant database# (see Appendix #). The search strategy, including all identified keywords and index terms will be adapted for each included information source. The reference list of all studies selected for critical appraisal will be screened for additional studies.

Information sources

This section is universal for example:

The databases to be searched include: #insert text#

The search for unpublished studies and gray literature will include: #insert text#

Study selection

This section should describe the process of reviewing the results of the search to see if they meet inclusion criteria and subsequently deciding which of the papers are to be retrieved.

This section is universal for example:

Following the search, all identified citations will be loaded into #insert the name of the bibliographic software or citation management system e.g. EndNote version/year #(Clarivate Analytics, PA, USA) and duplicates removed. Titles and abstracts will then be screened by two independent reviewers for assessment against the inclusion criteria for the review. Potentially relevant studies will be retrieved in full and their citation details imported into the JBI System for the Unified Management, Assessment and Review of Information (JBI SUMARI; JBI, Adelaide, Australia). The full text of selected citations will be assessed in detail against the inclusion criteria by two independent reviewers. Reasons for exclusion of full text studies that do not meet the inclusion criteria will be recorded and reported in the systematic 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 review and presented in a Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram (Page et al. 2021).

Assessment of methodological quality

This section should describe the critical appraisal process and instruments that will be used in the review process and the procedures for solving disagreements between reviewers.

Studies that are eligible for inclusion in the review must be assessed for methodological quality. The decision as to whether or not to include a study can be made based on meeting a pre-determined proportion of all criteria, or on certain criteria being met. It is also possible to weight certain criteria differently. Decisions about a scoring system or any cut-off for exclusion should be made in advance and agreed upon by all reviewers before critical appraisal commences.

All included studies need to be critically appraised using the standard JBI critical appraisal instruments (qualitative instrument available in Appendix 2.1 and quantitative instruments available in Appendices 3.1-3.4). For mixed methods studies the relevant JBI qualitative and quantitative tools can be used. The source of the JBI critical appraisal tool should be cited in the protocol.

The recommended set text should therefore include the relevant information related to both quantitative and qualitative studies, for example:

Quantitative studies (and quantitative component of mixed methods studies) selected for retrieval will be assessed by two independent reviewers for methodological validity prior to inclusion in the review using standardized critical appraisal instruments from JBI SUMARI. #Insert reference to appraisal tools#

Qualitative studies (and qualitative component of mixed methods studies) selected for retrieval will be assessed by two independent reviewers for methodological validity prior to inclusion in the review using the standardized critical appraisal instrument from JBI SUMARI (The Joanna Briggs Institute et al., 2017).

Authors of papers will be contacted to request missing or additional data for clarification, where required. Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer. The results of critical appraisal will be reported in narrative form and in a table.

Choose from one of the following two options:

- All studies, regardless of the results of their methodological quality, will undergo data extraction and synthesis (where possible). #Indicate how the results of the critical appraisal will be incorporated into the review#.
- Following critical appraisal, studies that do not meet a certain quality threshold will be excluded. This decision will be based on #list the decision rules#.

Data extraction

This section of the review protocol should specify the data extraction process and instruments that will be used in the review process, as well as the procedures for solving disagreements between reviewers.

For a MMSR that follows a convergent integrated approach, this section should specify what information from the quantitative and qualitative studies will be considered as constituting the findings.

- Quantitative studies typically include descriptive, or analytic studies that provide information about magnitude and statistical significance.
  - For descriptive studies, the extracted data might comprise an average or a percentage that profiles the sample or members of it.
  - For analytic studies, where the study examines a relationship between variables, data extraction should include ALL relationships RELEVANT to the review question, that is, both significant and non-significant results. Variables/outcomes not reaching statistical significance are important to report, as they may validate or highlight inconsistencies in the literature when integrated and pooled with other quantitative or qualitative findings.
- For qualitative studies, themes or subthemes relevant to the review question are extracted and supported with illustrations (i.e. a direct quotation from a participant, an observation or other supporting data from the paper) to preserve the context of the findings. Each finding should then be assigned a level of credibility based on the congruency of the finding with supporting data. There are three levels of credibility:
  - Unequivocal - relates to evidence beyond reasonable doubt which may include conclusions that are matter of fact, directly reported/observed and not open to challenge
  - Credible - relates to those conclusions that are, albeit interpretations, plausible in light of the data and theoretical framework.
  - Not Supported - is when the findings are not supported by the data

*'Not Supported' data are not included in the synthesis of data.

Example text that can be reported in this section is as follows:

Quantitative and qualitative data will be extracted from studies included in the review by two independent reviewers using the standardized JBI data extraction tool in JBI SUMARI (tool provided

at Appendix 8.1) (modify if other software or processes will be used for your review). Cite the tool to be used or append the data extraction tool if an existing tool has been modified or a new tool developed. Any modifications to existing tools should be described in the text. The data extracted will include specific details about the populations, study methods, phenomena of interest, context and outcomes of relevance to the review question(s). Specifically, quantitative data will comprise of data-based outcomes of descriptive and/or inferential statistical tests. In addition, qualitative data will comprise of themes or subthemes with corresponding illustrations, and will be assigned a level of credibility.

Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer. Authors of papers will be contacted to request missing or additional data, where required.

Data transformation

Following extraction, quantitative data are then transformed into qualitized data. This section of the review protocol should describe how the extracted quantitative data are converted into qualitized data to facilitate integration with data extracted from qualitative studies (and qualitative component of mixed methods studies). For example:

The quantitative data will then be converted into ‘qualitized data’. This will involve transformation into textual descriptions or narrative interpretation of the quantitative results so as to respond directly to the review question.

Data synthesis and integration

This section should describe how the data will be combined and reported in the systematic review. For a MMSR that follows a convergent integrated approach this should include the relevant information related to how qualitized data and data from qualitative studies will be integrated, for example:

This review will follow a convergent integrated approach according to the JBI methodology for mixed methods systematic reviews using JBI SUMARI. #Insert a citation to the methodology#. This will involve assembling the qualitized data with the qualitative data. Assembled data are categorized and pooled together based on similarity in meaning to produce a set of integrated findings in the form of line of action statements.

Please note: Due to the complexities associated with recommendations being derived from both streams of evidence and the impact of data transformation and/or integration on the grading process, an assessment of the certainty of the evidence using either the GRADE or ConQual approach is currently not recommended for JBI MMSR following either the integrated or segregated approach and requires further investigation.

Conflicts of interest and acknowledgements

Details of requirements in these sections are described in Section 1.6 of this Manual.

Conflicts of interest

A statement which either declares the absence of any conflicts of interest or which describes a specified or potential conflict of interest should be made by the reviewers in this section.

Acknowledgements

Any acknowledgements should be made in this section e.g. sources of external funding or the contribution of colleagues or institutions. It should also be noted if the systematic review contributes towards a degree award.

8.4.2 MMSR questions that take a CONVERGENT SEGREGATED approach to synthesis and integration

The convergent segregated approach adopted by JBI maintains a clear distinction between quantitative and qualitative evidence and requires individual syntheses to be conducted prior to the final integration of quantitative evidence and qualitative evidence.

Protocol development

Protocol development addresses both PICO and PICo criteria and is commonly comprised of separate review questions. As such the guidance for protocol development provided in Chapter 2 (Systematic reviews of qualitative evidence) and Chapter 3 (Systematic reviews of effectiveness) of this online reviewer’s manual should be followed. Some additional considerations are needed for a MMSR and these are detailed below.

Title of a MMSR protocol

The title should be informative and give clear indication of the topic and population of the MMSR. Titles should not be phrased as questions and there should be congruency between the title, review question(s) and inclusion criteria. The title should always include the phrase "…: a mixed methods systematic review protocol" to allow easy identification of the type of document it represents. An example title may be:

Mindfulness-based interventions for nurses: a mixed methods systematic review protocol

Abstract

This section is a summary of the protocol in 300 words. The following headings should be included in the abstract - Objective, Introduction, Inclusion Criteria, Methods, Systematic review registration number (if applicable) and Keywords. The abstract should not contain abbreviations or references.

Introduction

As with all JBI systematic review protocols, the introduction to a MMSR should describe and situate the topic of interest under review. Definitions can assist to provide clarity. Where complex or multifaceted phenomena are being described, it may be important to detail the whole of the phenomenon for an international readership. Justification for the need to examine both quantitative and qualitative evidence in a single review is required as is an explanation on how the review will add to the evidence base or inform clinical practice.

Additionally, a statement that a preliminary search of databases (with databases listed) has been undertaken and no existing or ongoing mixed method or individual systematic reviews on the topic have been identified should be provided. If other systematic reviews on the topic exist, indication on how the proposed systematic review will differ should be detailed. Finally, the introduction should conclude with an overarching review objective that captures and aligns with the core elements /mnemonic (i.e. PICO/PICo) of the inclusion criteria. The introduction should be of sufficient length to discuss all of the elements of the proposed plan for the review; usually all the relevant information may be provided in approximately 1000 words. This section should be written in simple prose for non-expert readers.

Review question(s)

Clarity in the review questions assist in developing a protocol and also ultimately, the conduct of the review. The review question(s) guide and direct the development of the specific review criteria and facilitate more effective searching, and provides a structure for the development of the full review. There should also be consistency between the review title and the review questions.

For a MMSR that takes a convergent segregated approach to synthesis, the review question(s) should focus on different aspects or dimensions of a particular phenomenon of interest and will pose questions that specifically require the inclusion of two or more syntheses that are grounded in different approaches.

As such PICO and PICo mnemonics should be used to develop the review questions as well as the inclusion criteria. Examples of clearly articulated PICO/PICo questions that may be posed by a MMSR are:

1. What is the impact of mindfulness-based interventions on nurses?
2. What do nurses perceive the benefits and challenges of mindfulness-based interventions to be?

The overarching aim of a MMSR is to produce a final integrated synthesis incorporating quantitative and qualitative evidence that informs conclusions and recommendations for clinical practice and policy decision making. In the above example, healthcare professionals and policy makers involved in delivering and planning such interventions are the target audience since the intention is to determine effective and positively experienced interventions for nurses.

Inclusion criteria

This section of the protocol details the basis on which studies will be considered for inclusion into the systematic review and should be as clear and unambiguous as possible. Inclusion criteria should be reasonable, sound and justified. These criteria will be used in the selection process, when it is decided if a study will be included or not in the review.

Population

There needs to be a clear and direct link between the review question, title and the participant characteristics in the inclusion criteria. This section should specify the details about the types of

participants considered for the review. Consider what are the most important characteristics of the population? (e.g., age, disease/condition, severity of illness, setting, gender, ethnicity etc.).

For a MMSR that follows a convergent segregated approach this section is universal (i.e. the population should be the same for both the quantitative and qualitative questions) for example:

The review will consider studies that include #describe population#

Intervention

Details about the intervention of interest should be specified, for example, the nature of intervention, frequency, intensity, timing, and details about those administering the intervention. The same kind of information should be specified for all comparators considered in the review. Where possible, the intervention should be described in detail, particularly if it is multifaceted.

The quantitative component of the review will consider studies that evaluate #insert text#.

Phenomena of interest

The qualitative component of this review will consider studies that investigate #insert text#

A phenomenon of interest is the experience, event or process occurring that is under study. The level of detail ascribed to the phenomena may vary with the nature or complexity of the topic. There should be congruence between the intervention and phenomena of interest.

Outcomes

This should address the quantitative component only, for example:

The quantitative component of this review will consider studies that include the following outcome measures: #insert text#

Outcomes should be measurable and appropriate to the review question(s). The relevance of each outcome to the review question(s) should be justified in the introduction section. Both beneficial outcomes and harms should be considered. The appropriateness of the number and scope of outcomes depend on the specifics of the review question(s).

Context

This should address the qualitative component only, for example:

The qualitative component of this review will consider studies that investigate #insert text#

Context will vary depending on the question(s) of the review. Context may include, but is not limited to consideration of: cultural or sub-cultural factors, geographic location, specific racial or gender-based interests, or detail about the specific setting (such as acute care, primary health care, or the community).

Types of studies

This should address each of the syntheses included in the review. The time frame chosen for the search should be justified and any language restrictions stated. For example:

This review will consider quantitative, qualitative and mixed methods studies. Quantitative studies will include #insert text#. Qualitative studies will include #insert text#. Mixed method studies will only be considered if data from the quantitative or qualitative components can be clearly extracted.

Studies published in #insert language(s)# will be included. Studies published from #database inception/or insert date# to the present will be included as #justify date range#

There should be a match in this section between the methodology of the primary research studies to be considered for the review and the review question.

Methods

Reference to the JBI methodology for MMSR should be provided. Additionally, if the review title has been registered, the name of the registry (e.g. PROSPERO) and the registration number should be reported below the Methods heading. For example:

The proposed systematic review will be conducted in accordance with the JBI methodology for mixed methods systematic reviews #insert a citation to the Chapter in the JBI Manual for Evidence Synthesis# **Note**: if the review title has been registered, report the name of the registry (e.g. PROSPERO) and the registration number.

Search strategy

This section of a review protocol should provide explicit and clear information regarding two different aspects of locating studies: all information sources that will be searched for the review, and the strategies used for searching. The aim of a systematic review is to identify all relevant studies, published or not, on a given topic. Searching should be based on the principle of comprehensiveness, with the widest reasonable collection of information sources that are considered appropriate to the review.

The databases to be searched must be listed, including the search platform used where necessary, along with a completed search strategy for one major database which should be presented as an Appendix.

This section is universal, for example:

The search strategy will aim to locate both published and unpublished studies. An initial limited search of #MEDLINE and CINAHL #change as appropriate# was undertaken to identify articles on the topic. The text words contained in the titles and abstracts of relevant articles, and the index terms used to describe the articles were used to develop a full search strategy for #report the name of the relevant database# (see Appendix #). The search strategy, including all identified keywords and index terms will be adapted for each included information source. The reference list of all studies selected for critical appraisal will be screened for additional studies.

Depending on the review questions that are posed, authors may find that it is appropriate to search for all forms of evidence simultaneously with the one search strategy or they may develop separate search strategies for the different review questions. This decision will need to be made by the reviewers and consideration should be given to the review questions posed, the amount of literature available in the topic area and the searching expertise of the reviewers.

Information sources

This section is universal for example:

The databases to be searched include: #insert text#

The search for unpublished studies and gray literature will include: #insert text#

Where databases/registries/sources are specific to a particular design, the reviewers should clearly indicate such e.g.:

Cochrane Central Register of Controlled Trials (For quantitative studies only)

Study selection

This section should describe the process of reviewing the results of the search to see if they meet inclusion criteria and subsequently deciding which of the papers are to be retrieved.

For a MMSR that follows a convergent segregated approach, this section is universal - for example:

Following the search, all identified citations will be loaded into #insert the name of the bibliographic software or citation management system e.g. EndNote version/year (Clarivate Analytics, PA, USA)# and duplicates removed. Titles and abstracts will then be screened by two independent reviewers for assessment against the inclusion criteria for the review. Potentially relevant studies will be retrieved in full and their citation details imported into JBI's System for the Unified Management, Assessment and Review of Information (JBI SUMARI). The full text of selected citations will be assessed in detail against the inclusion criteria by two independent reviewers. Reasons for exclusion of full text studies that do not meet the inclusion criteria will be recorded and reported in the systematic 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 Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram (Page et al. 2021).

Assessment of methodological quality

This section should describe the critical appraisal process and instruments that will be used in the review process and the procedures for solving disagreements between reviewers.

Studies that are eligible for inclusion in the review must be assessed for methodological quality. The decision as to whether or not to include a study can be made based on meeting a pre-determined proportion of all criteria, or on certain criteria being met. It is also possible to weight certain criteria differently. Decisions about a scoring system or any cut-off for exclusion should be made in advance and agreed upon by all reviewers before critical appraisal commences.

All included studies need to be critically appraised using the standard JBI critical appraisal instruments (qualitative instrument available in Appendix 2.1 and quantitative instruments available in Appendices 3.1-3.4). The source of the JBI critical appraisal tool should be cited in the protocol.

The recommended set text should therefore address each of the syntheses included in the review, for example:

Quantitative studies (and quantitative component of mixed methods studies) selected for retrieval will be assessed by two independent reviewers for methodological validity prior to inclusion in the review using standardized critical appraisal instruments from JBI SUMARI. #Insert reference to appraisal tools#

Qualitative studies (and qualitative component of mixed methods studies) selected for retrieval will be assessed by two independent reviewers for methodological validity prior to inclusion in the review using the standardized critical appraisal instrument from JBI SUMARI (The Joanna Briggs Institute et al., 2017).

Authors of papers will be contacted to request missing or additional data for clarification, where required. Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer. The results of critical appraisal will be reported in narrative form and in a table.

Choose from one of the following two options:

- All studies, regardless of the results of their methodological quality, will undergo data extraction and synthesis (where possible). #Indicate how the results of the critical appraisal will be incorporated into the review#.
- Following critical appraisal, studies that do not meet a certain quality threshold will be excluded. This decision will be based on #list the decision rules#.

Data extraction

This section of the review protocol should specify the data extraction process and instruments that will be used in the review process, as well as the procedures for solving disagreements between reviewers.

For a MMSR that follows a convergent segregated approach this should address each of the syntheses included in the review, for example:

For the quantitative component, data will be extracted from quantitative and mixed methods (quantitative component only) studies included in the review by two independent reviewers using the standardized JBI data extraction tool in JBI SUMARI #modify if other software or processes will be used for your review#. #Cite the tool to be used or append the data extraction tool if an existing tool has been modified or a new tool developed# Any modifications to existing tools should be described in the text# The data extracted will include specific details about the populations, study methods, interventions, and outcomes of significance to the review objective.

For the qualitative component, data will be extracted from qualitative and mixed methods (qualitative component only) studies included in the review by two independent reviewers using the standardized JBI data extraction tool in JBI SUMARI #modify if other software or processes will be used for your review#. #Cite the tool to be used or append the data extraction tool if an existing tool has been modified or a new tool developed. Any modifications to existing tools should be described in the text#. The data extracted will include specific details about the population, context, culture, geographical location, study methods and the phenomena of interest relevant to the review objective. Findings, and their illustrations will be extracted and assigned a level of credibility.

Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer. Authors of papers will be contacted to request missing or additional data, where required.

Data synthesis and integration

This section should describe how the data will be synthesized, combined and reported in the systematic review. For a MMSR that follows a convergent segregated approach this should address the quantitative synthesis and the qualitative synthesis as well as how they will be integrated in the final synthesis, for example:

This review will follow a convergent segregated approach to synthesis and integration according to the JBI methodology for mixed methods systematic reviews using JBI SUMARI. #Insert a citation to the methodology#. This will involve separate quantitative and qualitative synthesis followed by integration of the resultant quantitative evidence and qualitative evidence.

Quantitative synthesis

Data will, where possible, be pooled with statistical meta-analysis using JBI SUMARI. Effect sizes will be expressed as either odds ratios (for dichotomous data) or weighted (or standardized) final post-intervention mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis #modify as appropriate#. Heterogeneity will be assessed statistically using the standard chi squared and I^2 tests. Statistical analyses will be performed using #insert model (random or fixed effects)#. #Cite the Tufanaru et al study# Subgroup analyses will be conducted where there is sufficient data to investigate #add text as appropriate#. Sensitivity analyses will be conducted to test decisions made regarding #add text as appropriate#. Where statistical pooling is not possible the findings will be presented in narrative form including tables and figures to aid in data presentation, where appropriate. A funnel plot will be generated #state software to use# to assess publication bias if there are 10 or more studies included in a meta-analysis#. Statistical tests for funnel plot asymmetry (Egger test, Begg test, Harbord test) will be performed where appropriate.

Qualitative synthesis

Qualitative research findings will, where possible be pooled using JBI SUMARI with the meta-aggregation approach. #Insert a citation to the methodology#. This will involve the aggregation or synthesis of findings to generate a set of statements that represent that aggregation, through assembling the findings and categorizing these findings based on similarity in meaning. These categories are then subjected to a synthesis to produce a comprehensive set of synthesized findings that can be used as a basis for evidence-based practice. Where textual pooling is not possible the findings will be presented in narrative form.

Integration of quantitative evidence and qualitative evidence

The findings of each single method synthesis included in this review will then be configured according to the JBI methodology for mixed methods systematic reviews. #Insert a citation to the methodology# This will involve quantitative evidence and qualitative evidence being juxtaposed and organized/linked into a line of argument to produce an overall configured analysis. Where configuration is not possible the findings will be presented in narrative form.

Please note: Due to the complexities associated with recommendations being derived from both streams of evidence and the impact of data transformation and/or integration on the grading process, an assessment of the certainty of the evidence using either the GRADE or ConQual approach is currently not recommended for JBI MMSR following either the integrated or segregated approach and requires further investigation.

Conflicts of interest and acknowledgements

Details of requirements in these sections are described in Section 1.6 of this Manual.

Conflicts of interest

A statement which either declares the absence of any conflicts of interest or which describes a specified or potential conflict of interest should be made by the reviewers in this section.

Acknowledgements

Any acknowledgements should be made in this section e.g. sources of external funding or the contribution of colleagues or institutions. It should also be noted if the systematic review contributes towards a degree award.

8.5 Conducting and reporting a JBI MMSR

This section provides further guidance on components that should be included in the final JBI MMSR, and information regarding each component as found in JBI SUMARI. The content of the sections of the review protocol (Section 8.3) and the review report are conceptually the same, particularly the introduction and the methods section. The review protocol specified the proposed plan for the review; the review reports on what was actually performed and the results of the review undertaken.

Please refer to publication criteria for *JBI Evidence Synthesis* for specific submission requirements for systematic reviews.

As in Section 8.4, the following section is divided into the two approaches. Reviewers should follow the appropriate guidance provided below.

8.5.1 Mixed methods systematic review using a CONVERGENT INTEGRATED approach to synthesis and integration

Title of a mixed methods systematic review

The title should be informative and give clear indication of the topic of the MMSR. The title should always include the phrase "…: a mixed methods systematic review" to allow easy identification of the type of document it represents. An example title may be:

Barriers and facilitators to asthma self-management in adolescents: a mixed methods systematic review

Abstract

This section is a summary of the review in 500 words, stating the objective, methods, main findings and principal conclusions of the review. The abstract should not contain abbreviations or references.

The following headings should be included in the abstract.

Objective: State an overarching review objective structured using the key components of the inclusion criteria (approximately one to two sentences).

Introduction: Briefly describe what is already known on the topic and what this review will add to the evidence base (approximately two to three sentences).

Inclusion criteria: Summarize the inclusion criteria as it relates to the type of review being conducted. Present the information in one or two sentences – **NOT** under individual subheadings.

Methods: List the key information sources searched (those that provided the majority of included studies), any limits placed on the scope of the search (e.g. language), and the date range, or the date of the last search. State the recommended JBI approach to MMSR was followed e.g. study selection, critical appraisal, data extraction and data synthesis and integration. The method of synthesis and integration should be clearly reported (convergent integrated). Otherwise, briefly describe any notable deviations to the methodological approach taken (e.g. criteria used to exclude studies on the basis of methodological quality etc.).

Results: The bulk of the abstract should be reserved to convey the main results of the review.

As a general rule, report the number and type of included studies, and any pertinent study characteristics. Summarize the overall quality of the included studies.

Report the findings obtained from the integration of 'qualitized' data and qualitative data.

Conclusions: Provide a conclusion based on a general interpretation of the results considering, for example, the methodological quality of the included studies and any limitations of the review. Briefly convey key implications for practice and/or research.

Introduction

As with all JBI systematic reviews, the introduction to a MMSR should describe and situate the topic of interest under review. Definitions can assist to provide clarity. Where complex or multifaceted phenomena are being described, it may be important to detail the whole of the phenomenon for an international readership. Explanation of how the review question can be answered by both quantitative and qualitative studies is required as is an explanation on how the review will add to the evidence base or inform clinical practice.

Additionally, a statement that a preliminary search of databases (with databases listed) has been undertaken and no existing or ongoing mixed method or systematic reviews on the topic have been identified should be provided. If other systematic reviews on the topic exist, indication on how the proposed systematic review differed should be detailed. Finally, the introduction should conclude with an overarching review objective that captures and aligns with the core elements of the inclusion criteria. The introduction should be approximately 1000 words.

Review question(s)

The review question(s) should be explicitly stated in unambiguous terms. See Section 8.4 of this Chapter for further information regarding the question(s) of a MMSR.

Inclusion criteria

This section of the review details the basis on which studies were considered for inclusion in the systematic review and should be as clear and unambiguous as possible. Inclusion criteria should be reasonable, sound and justified and address the elements in the PICo question(s).

Population

This section should specify the details about types of participants considered for the review (e.g., age, disease/condition, severity of illness, setting, gender, ethnicity etc.). This section is universal for example:

The review considered studies that included #describe population#

Phenomena of Interest

A phenomenon of interest is the experience, event or process occurring that is under study. The level of detail ascribed to the phenomena may vary with the nature or complexity of the topic.

Like the protocol, details about the phenomena of interest should be adequately described. For example:

This review considered studies that investigated #insert text#

Context

Context may include, but is not limited to, consideration of: cultural or sub-cultural factors, geographic location, specific racial or gender-based interests, or details about the specific setting (such as acute care, primary health care, or the community). Like the protocol, details regarding the context should be provided. For example:

This review considered studies that investigated #insert text#

Types of studies

This section should include the relevant information related to quantitative, qualitative and mixed methods studies. For example:

This review considered quantitative, qualitative and mixed methods studies. Quantitative studies included #insert text#. Qualitative studies included #insert text#. Mixed method studies where data from the quantitative or qualitative components could be clearly extracted were also considered.

There should be a congruence in this section between the methodology of the primary research studies that were considered for the review and the review question(s).

Methods

This section of the review is reserved for the methods used to conduct the review and should be presented under the relevant subheadings, including any deviations from the method outlined in the *a priori* protocol and a rationale.

Directly below the Methods heading provide the following information:

- State and appropriately cite the JBI methodology that was employed in the conduct of the review and synthesis.
- Refer to and cite the *a priori* protocol that was either publicly available, published, or accepted for publication/'in press' (e.g. in *JBI Evidence Synthesis*).
- If the protocol was registered with PROSPERO, provide registration information including registration number (e.g. PROSPERO CRD42015425226).

Search strategy

The search strategy section of a review should provide explicit and clear information regarding all information sources that were used in the review, and the actual strategies used for searching. The review should provide details regarding all information sources that were used in the review: electronic bibliographic databases (including the search platform used); gray literature sources; relevant journals; websites of relevant organizations; etc. The review should specify the timeframe for the search, the date of last search for each database, and any language and date restrictions, with appropriate justifications. For example:

The search strategy aimed to find both published and unpublished studies. A three-step search strategy was utilized in this review. First an initial limited search of #MEDLINE and CINAHL# change as appropriate# was undertaken followed by analysis of the text words contained in the title and abstract and the index terms used to describe the articles. The search strategy, including all identified keywords and index terms was adapted for each included information source and a second search was undertaken on #insert month and date searched#. The full search strategies are provided in Appendix #. Finally, the reference list of all studies selected for critical appraisal will be screened for additional studies.

Information sources

The databases that were searched included: #insert databases with platforms as appropriate#.

Sources of unpublished studies and gray literature included #insert text, e.g. trial registers etc.#

Study selection

The review report should describe the actual process of study screening for all stages of selection (e.g. title and abstract examination; full text examination) and the actual procedures used for solving disagreements between reviewers. For example:

Following the search, all identified citations were collated and uploaded into #insert bibliographic software or citation management system (e.g. EndNote version/year (Clarivate Analytics, PA, USA))# and duplicates removed. Titles and abstracts were then screened by two reviewers for assessment against the inclusion criteria for the review. Studies that met the inclusion criteria were retrieved in full and their details imported into the JBI System for the unified Management Assessment and Review of Information package (JBI SUMARI). The full text of selected studies were retrieved and assessed in detail against the inclusion criteria by two independent reviewers. Full text studies that did not meet the inclusion criteria were excluded and reasons for exclusion are provided in #insert Appendix number#. Any disagreements that arose between the reviewers were resolved through discussion (OR There were no disagreements that arose between reviewers).

Assessment of methodological quality

The review should specify the critical appraisal process and instruments that were used in the review process and the procedures for solving disagreements between reviewers. The details of the decision processes and criteria used for exclusion of studies based on the results of critical appraisal should be explicitly provided. All details about the scoring systems and the cut-off scores (if applicable) for inclusion of studies in the review should be described and justified. For example:

Eligible studies were critically appraised by two independent reviewers for methodological quality using the #insert names of tools used and cite them.# Authors of papers were contacted to request missing or additional data for clarification, where required. Any disagreements that arose between the reviewers were resolved through discussion, or with a third reviewer.

Indicate what constituted acceptable levels of information for a study to receive a positive, negative or unclear response to a critical appraisal question and if applicable, the rationale and criteria for excluding studies on the basis of methodological quality.

Data extraction

The review should specify the data extraction process and instruments that were used in the review process and the procedures for solving disagreements between reviewers. As outlined in Section 8.4 of this Chapter, for a MMSR that follows a convergent integrated approach it needs to be specified what information from the quantitative and qualitative studies were considered as constituting the findings. For example:

Quantitative and qualitative data were extracted from included studies by two independent reviewers using the standardized JBI data extraction tool. #modify if other software or processes were used for your review#. #Cite the tool used or append the data extraction tool if an existing tool was modified or a new tool developed. Any modifications to existing tools should be described in the text#. The data extracted included specific details about the population, study methods, the phenomenon of interest, context and outcomes of relevance to the review question(s). In addition, qualitative data comprised of themes or subthemes with corresponding illustrations, which were assigned a level of credibility. Any disagreements that arose between the reviewers will be resolved through discussion, or with a third reviewer. Authors of #insert number of studies# were contacted for missing information or additional data.

Data transformation

The review should specify the data transformation process that was used to convert the extracted quantitative data into qualitized data to facilitate integration with data extracted from qualitative studies (and the qualitative component of mixed methods studies). For example:

The quantitative data was converted into ‘qualitized data’. This involved transformation into textual descriptions or narrative interpretation of the quantitative results from experimental and observational studies (including the quantitative component of mixed methods studies), in a way that answered the review questions by repeated detailed examination.

Data synthesis and integration

The review should indicate that a convergent integrated approach was applied. The review should detail how the reviewers analyzed and integrated the data extracted from included quantitative, qualitative and mixed methods studies and detail the aggregative approach to integration. For example:

The convergent integrated approach according to the JBI methodology for mixed methods systematic review using JBI SUMARI was used in this review. #Insert a citation to the methodology#. This involved assembling the 'qualitized' data with the qualitative data. Assembled data were categorized and pooled together based on similarity in meaning to produce a set of integrated findings in the form of line of action statements.

Results

This section of the review has distinct sub-sections describing the study inclusion, the methodological quality of included studies, detailed characteristics and description of the included studies and, importantly, the findings of data transformation and the integration processes.

Study inclusion

This section should allow the reader to clearly follow how the included studies were identified and selected for inclusion in the review. There should be a narrative description of the process accompanied by a PRISMA flowchart; details to be reported include narrative summary of the numbers of studies identified, numbers screened, studies selected for retrieval and included /excluded and their reasons for exclusion, numbers appraised and included/excluded, and numbers included in the review.

Ideally, a list of all excluded studies, excluded after full text examination and after critical appraisal, with the explicit reasons for exclusion, should be provided in appendices to the review. As a minimum, at least the list of studies excluded after critical appraisal and the reasons for exclusion should be reported. If no studies were excluded after critical appraisal then the list of all studies excluded after full text examination including the explicit reasons for exclusion, should be provided in appendices to the review.

Methodological quality

This section should focus on methodological quality as determined by the relevant critical appraisal instrument. There should be a separate narrative summary for the overall methodological quality of the quantitative (and quantitative component of mixed methods studies) and qualitative studies (and qualitative component of mixed methods studies), which can be supported by tables showing the results of the critical appraisal (see Tables 8.4 and 8.5 for examples). Please note, not all quantitative study designs are shown below). Where only few studies are identified, or there are specific items of interest from included studies, these should be addressed in the narrative also, particularly where studies were deficient, or particularly good. Use of 'Unclear' and 'Not Applicable' should also be explained in the text.

Table 8.4: Critical appraisal results for included studies using the JBI Critical Appraisal Checklist for Randomized Controlled Trials (and RCT component of mixed methods studies)

Study	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13
Author(s) [ref]	Y	Y	Y	N	Y	U	Y	N	Y	U	Y	Y	U
Author(s) [ref]	Y	N	Y	Y	Y	U	Y	N/A	Y	Y	Y	Y	U

Y - Yes, N - No, U - Unclear, N/A - not applicable

Table 8.5: Critical appraisal results for included studies using the JBI Qualitative Critical Appraisal Checklist (and qualitative component of mixed methods studies)

Study	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10
Author(s) [ref]	Y	Y	Y	N	Y	U	Y	N	Y	U
Author(s) [ref]	Y	N	Y	Y	Y	U	Y	N/A	Y	Y

Y - Yes, N - No, U - Unclear, N/A - not applicable

If modified appraisal tools are not appended to the review, the appraisal questions should be added as a footnote/caption to the tables so readers can clearly interpret the information presented.

Characteristics of included studies

This section of the results should include an overall description of the included studies (with reference to the table of included study characteristics in the appendices), with the main aim to

provide some context to the results section and sufficient detail for the reader to confirm that the studies match the eligibility criteria for the review. This includes the descriptive and demographic features (e.g. the country and setting of the study) of the included studies, methodology of included studies, geographic context of included studies, participant characteristics, and phenomena of interest, as they relate to the review question(s) and the inclusion criteria. Specific items/points of interest from individual studies may also be highlighted here and synthesized in a narrative.

Findings of the review

Review findings are structured according to the phenomena of interest and should describe all the identified integrated finding(s), the categories that form them and the underpinning qualitative and/or qualitized data. Integrated findings should be presented with an explanatory statement that conveys the inclusive meaning of a group of similar categories (i.e. line of action statements). This section should also provide a narrative of all the data that cannot be combined to form a category.

A schematic of the synthesis (See Figure 8.1) should constitute part of this section, which must be accompanied by sufficient narrative to explain the categories and integrated findings. *Where textual pooling was not possible the findings should be presented in narrative form.* The suggested structure for reporting findings:

#insert Integrated Finding# (where appropriate)

#Brief explanatory statement#

#insert underpinning Category 1#

#Report the qualitative and/or qualitized data underpinning the category#

#insert underpinning Category 2#

#Report the qualitative and/or qualitized data underpinning the category#

Please note: Due to the complexities associated with recommendations being derived from both streams of evidence and the impact of data transformation and/or integration on the grading process, an assessment of the certainty of the evidence using either the GRADE or ConQual approach is *curre ntly* not recommended for JBI MMSR following either the integrated or segregated approach and requires further investigation.

Discussion

This section should provide a detailed discussion of issues arising from the conduct of the review, as well as a discussion of the findings of the review and of the significance of the review findings in relation to practice and research. The findings should be discussed in the context of current literature, practice and policy. It should also include a narrative discussion of the review results in comparison with other external literature, and against the broad directions established in the introduction of the review. The discussion does not bring in new findings that have not been reported in the results section but does seek to establish a line of argument based on the findings regarding the phenomenon of interest.

Conclusions and Recommendations

This section should include the overall conclusions of the review. The conclusions should provide direct answers to the review question(s). These conclusions should be based only on the results of the review and directly inferred from the review results.

Recommendations for practice

This sub-section of the Conclusion section should include the recommendations for practice inferred from the results of the integration of the ‘qualitized’ data and qualitative data. Recommendations should be assigned a JBI Grade of Recommendation.

Recommendations for research

This sub-section of the Conclusion should include the recommendations for future research inferred from the results of the integration of the ‘qualitized’ data and qualitative data, and issues and problems noted in the review process related to the search, selection of studies, critical appraisal, data extraction, and data synthesis.

Conflicts and acknowledgements

Details of requirements in these sections are described in Section 1.6 of this Manual.

Conflicts of interest

A statement which either declares the absence of any conflicts of interest or which describes a specified or potential conflict of interest should be made by the reviewers in this section.

Funding

Authors should provide details regarding any sources of funding for the review project. The role of all funders in the review process, if any, should be explicitly described. If the review is funded, then any potential conflicts of interest or intellectual bias of the funders should be specified in the review.

Acknowledgements

Any acknowledgements should be made in this section e.g. sources of external funding or the contribution of colleagues or institutions. It should also be noted if the systematic review contributes towards a degree award.

8.5.2 Mixed methods systematic review using a CONVERGENT SEGREGATED approach to synthesis and integration

Title of a mixed method systematic review

The title should be informative and give clear indication of the topic and population of the MMSR. Titles should not be phrased as questions and there should be congruency between the title, review question(s) and inclusion criteria. The title should always include the phrase "…: a mixed methods systematic review" to allow easy identification of the type of document it represents. An example title may be:

Mindfulness-based interventions for nurses: a mixed methods systematic review

Abstract

This section is a summary of the review in 500 words, stating the objective, methods, main findings and principal conclusions of the review. The abstract should not contain abbreviations or references.

The following headings should be included in the abstract.

Objective: State an overarching review objective structured using the key components of the inclusion criteria (approximately one to two sentences).

Introduction: Briefly describe what is already known on the topic and what this review will add to the evidence base (approximately two to three sentences).

Inclusion criteria: Summarize the inclusion criteria as it relates to the type of review being conducted. Present the information in one or two sentences – **NOT** under individual subheadings.

Methods: List the key information sources searched (those that provided the majority of included studies), any limits placed on the scope of the search (e.g. language), and the date range, or the date of the last search. State the recommended JBI approach to MMSR was followed e.g. study selection, critical appraisal, data extraction and data synthesis and integration. The method of synthesis and integration should be clearly reported (convergent segregated). Otherwise, briefly describe any notable deviations to the methodological approach taken (e.g. criteria used to exclude studies on the basis of methodological quality etc.).

Results: The bulk of the abstract should be reserved to convey the main results of the review. As a general rule, report the number and type of included studies, and any pertinent study characteristics. Summarize the overall quality of the included studies.

Report the results obtained from quantitative synthesis, and the findings from the qualitative synthesis. Key findings from the integration of quantitative evidence and qualitative evidence should also be presented.

Conclusions: Provide a conclusion based on a general interpretation of the results considering, for example, the methodological quality of the included studies and any limitations of the review. Briefly convey key implications for practice and/or research.

Introduction

As with all JBI systematic reviews, the introduction to a MMSR should describe and situate the topic of interest under review. Definitions can assist to provide clarity. Where complex or multifaceted

phenomena are described, it may be important to detail the whole of the phenomenon for an international readership. Explanation of how the review question can be answered by both quantitative and qualitative studies is required as is an explanation on how the review will add to the evidence base or inform clinical practice.

Additionally, a statement that a preliminary search of databases (with databases listed) was undertaken and no existing or ongoing mixed method or individual systematic reviews on the topic were identified should be provided. If other systematic reviews on the topic existed, indication on how the proposed systematic review differed should be detailed. Finally, the introduction should conclude with an overarching review objective that captures and aligns with the core elements of the inclusion criteria. The introduction should be approximately 1000 words.

Review question(s)

The review question(s) should be explicitly stated in unambiguous terms. See Section 8.4 of this Chapter for further information regarding the question(s) of a MMSR.

Inclusion criteria

This section of the review details the basis on which studies were considered for inclusion in the systematic review and should be as clear and unambiguous as possible. Inclusion criteria should be reasonable, sound and justified and address the elements in the PICO/PICo questions.

Population

This section should specify the details about types of participants considered for the review (e.g., age, disease/condition, severity of illness, setting, gender, ethnicity etc.). This section is universal, for example:

The review considered studies that included #describe population#

Intervention

Details about the intervention of interest should be specified, for example:

The quantitative component of the review considered studies that evaluated #insert text# Information about the comparator(s) should also be detailed here.

Phenomena of interest

The qualitative component of this review considered studies that investigated #insert text#

Like the protocol, details about the phenomena of interest should be adequately described.

Outcomes

This should address the quantitative component only, for example:

The quantitative component of this review considered studies that included the following outcome measures: #insert text#

Like the protocol, all outcomes should be adequately described including how they will be measured.

Context

This should address the qualitative component only, for example:

The qualitative component of this review considered studies that investigated #insert text#

Like the protocol, details regarding the context should be provided.

Types of studies

This should address each of the syntheses included in the review, for example:

This review considered quantitative, qualitative and mixed methods studies. Quantitative studies included #insert text#. Qualitative studies included #insert text#. Mixed method studies were considered if data from the quantitative or qualitative components could be clearly extracted.

There should be a congruence in this section between the methodology of the primary research studies to be considered for the review and the review question(s).

Methods

This section of the review is reserved for the methods used to conduct the review and should be presented under the relevant subheadings, including any deviations from the method outlined in the *a priori* protocol and a rationale.

Directly below the Methods heading provide the following information:

- State and appropriately cite the JBI methodology that was employed in the conduct of the review and synthesis.
- Refer to and cite the *a priori* protocol that was either publicly available, published, or accepted for publication/'in press' (e.g. in *JBI Evidence Synthesis*).
- If the protocol was registered with PROSPERO, provide registration information including registration number (e.g. PROSPERO CRD42015425226).

Search strategy

The search strategy section of a review should provide explicit and clear information regarding all information sources (electronic bibliographic databases; gray literature sources; relevant journals; websites of relevant organizations; etc.) that were used in the review, and the actual strategies used for searching (all should be provided in the appendix). The review should specify the timeframe for the search, the date of the last search for each database, and any language and date restrictions, with appropriate justifications. For example:

The search strategy aimed to find both published and unpublished studies. A three-step search strategy was utilized in this review. First an initial limited search of #MEDLINE and CINAHL# change as appropriate# was undertaken followed by analysis of the text words contained in the title and abstract and the index terms used to describe the articles. The search strategy, including all identified keywords and index terms was adapted for each included information source and a second search was undertaken on #insert month and date searched#. The full search strategies are provided in Appendix #. Finally, the reference list of all studies selected for critical appraisal will be screened for additional studies.

Information sources

The databases that were searched included: #insert databases with platforms as appropriate#.

Sources of unpublished studies and gray literature included #insert text, e.g. trial registers etc.#

Where databases/registries/sources were specific to a particular design, the reviewers should clearly indicate such e.g.:

Cochrane Central Register of Controlled Trials (For quantitative studies only)

Study selection

The review should describe the actual process of study screening for all stages of selection (e.g. title and abstract examination; full text examination) and the procedures used for solving disagreements between reviewers. For example:

Following the search, all identified citations were collated and uploaded into #insert bibliographic software or citation management system (e.g. EndNote version/year (Clarivate Analytics, PA, USA)# and duplicates removed. Titles and abstracts were then screened by two reviewers for assessment against the inclusion criteria for the review. Studies that met the inclusion criteria were retrieved in full and their details imported into the JBI System for the Unified Management Assessment and Review of Information package (JBI SUMARI). The full text of selected studies were retrieved and assessed in detail against the inclusion criteria by two independent reviewers. Full text studies that did not meet the inclusion criteria were excluded and reasons for exclusion are provided in #insert Appendix number#. Any disagreements that arose between the reviewers were resolved through discussion (OR There were no disagreements that arose between reviewers).

Assessment of methodological quality

The review should specify the critical appraisal process, the instruments that were used and the procedures for solving disagreements between reviewers. The details of the decision processes and criteria used for exclusion of studies based on the results of critical appraisal should be explicitly provided. All details about the scoring systems and the cut-off scores (if applicable) for inclusion of studies in the review should be described and justified. For example:

Eligible studies were critically appraised by two independent reviewers for methodological quality using the #insert names of tools used and cite them.# Authors of papers were contacted to request missing or additional data for clarification, where required. Any disagreements that arose between the reviewers were resolved through discussion, or with a third reviewer.

Indicate what constituted acceptable levels of information for a study to receive a positive, negative or unclear response to a critical appraisal question and if applicable, the rationale and criteria for excluding studies on the basis of methodological quality.

Data extraction

The review should specify the data extraction process and instruments that were used in the review process and the procedures for solving disagreements between reviewers. For example:

Quantitative and qualitative data were extracted from included studies by two independent reviewers using the relevant JBI data extraction tool. #modify if other software or processes were used for your review#. #Cite the tool used or append the data extraction tool if an existing tool was modified or a new tool developed. Any modifications to existing tools should be described in the text#. For quantitative studies (and the quantitative component of mixed methods studies), data extracted included specific details about the populations, interventions, study methods and outcomes of significance to the review question. For qualitative studies (and the qualitative component of mixed methods studies), data extracted included specific details about the population, context, culture, geographical location, study methods and the phenomenon of interest relevant to the review question. Findings with their corresponding illustrations were also extracted and assigned a level of credibility. Any disagreements that arose between the reviewers will be resolved through discussion, or with a third reviewer. Authors of #insert number of studies# were contacted for missing information or additional data.

Data synthesis and integration

The review should indicate that a convergent segregated approach to synthesis and integration was applied. This section should also indicate the approach used to perform the quantitative synthesis (i.e. meta-analysis and/or narrative synthesis) and the qualitative synthesis (i.e. meta-aggregative or narrative synthesis). See Section 8.4 of this Chapter for further information. The approach to the integration of the quantitative and qualitative evidence should be described in as much detail as is reasonably possible. For example:

Quantitative evidence and qualitative evidence were integrated using configurative analysis. This involved constant comparison of the quantitative evidence and the qualitative evidence, followed by the analysis of interventions, which had been investigated in the quantitative studies, in line with the experiences of participants explored in the qualitative studies in order to organize/link the evidence into a line of argument. Where configuration was not possible the findings are presented in narrative form.

Results

This section of the review has distinct sub-sections describing study inclusion, the methodological quality of included studies, detailed characteristics and description of the included studies and, importantly, the findings of the individual syntheses and results of the integration of the quantitative evidence and qualitative evidence.

Study inclusion

This section should allow the reader to clearly follow how the included studies were identified and selected for inclusion in the review. There should be a narrative description of the process accompanied by a PRISMA flowchart; details to be reported include narrative summary of the numbers of studies identified, numbers screened, studies selected for retrieval and included /excluded and their reasons for exclusion, numbers appraised and included/excluded, and numbers included in the review. This section should report the number of studies which contributed to the quantitative component and the number of studies which contributed to the qualitative component.

Ideally, a list of all excluded studies, excluded after full text examination and after critical appraisal, with the explicit reasons for exclusion, should be provided in appendices to the review. As a minimum, at least the list of studies excluded after critical appraisal and the reasons for exclusion should be reported. If no studies were excluded after critical appraisal then the list of all studies excluded after full text examination including the explicit reasons for exclusion, should be provided in appendices to the review.

Methodological quality

This section should focus on methodological quality as determined by the relevant critical appraisal instrument. There should be a separate narrative summary for the overall methodological quality of the quantitative (and quantitative component of mixed methods studies) and qualitative (and qualitative component of mixed methods studies) studies, which can be supported by tables showing the results of the critical appraisal (see Tables 8.6 and 8.7 for examples). Please note, not all quantitative study designs are shown below). Where only few studies are identified, or there are

specific items of interest from included studies, these should be addressed in the narrative also, particularly where studies were deficient, or particularly good. Use of ‘Unclear’ and ‘Not Applicable’ should also be explained in the text.

Table 8.6: Critical appraisal results for included studies using the JBI Critical Appraisal Checklist for Randomized Controlled Trials (and RCT component of mixed methods studies)

Study	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13
Author(s) [ref]	Y	Y	Y	N	Y	U	Y	N	Y	U	Y	Y	Y
Author(s) [ref]	Y	N	Y	Y	Y	U	Y	N/A	Y	Y	Y	U	U

Y - Yes, N - No, U - Unclear, N/A - not applicable

Table 8.7: Critical appraisal results for included studies using the JBI Qualitative Critical Appraisal Checklist (and qualitative component of mixed methods studies)

Study	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10
Author(s) [ref]	Y	Y	Y	N	Y	U	Y	N	Y	U
Author(s) [ref]	Y	N	Y	Y	Y	U	Y	N/A	Y	Y

Y - Yes, N - No, U - Unclear, N/A - not applicable

If modified appraisal tools are not appended to the review, the appraisal questions should be added as a footnote/caption to the tables so readers can clearly interpret the information presented.

Characteristics of included studies

This section of the results should include an overall description of the included studies (with reference to the table of included study characteristics in the appendices), with the main aim to provide some context to the results section and sufficient detail for the reader to confirm that the studies match the eligibility criteria for the review. This includes the descriptive and demographic features (e.g. the country and setting of the study) of the included studies, methodology of included studies, geographic context of included studies and participant characteristics, characteristics of the interventions, and phenomena of interest, as they relate to the review questions and the inclusion criteria. Specific items/points of interest from individual studies may also be highlighted here and synthesized in a narrative.

Findings of the review

Quantitative evidence

This section should be organized in a meaningful way based on the review question(s) and types of interventions and outcomes. This section should provide comprehensive information regarding the results of all performed meta-analyses and additional analyses (e.g. sub-group analysis). Summary results from meta-analyses should be reported as summary point estimates and interval estimates (confidence intervals) with consideration of any heterogeneity present. The meta-analysis forest plots should also be presented in this section. A narrative summary should complement the forest plots and provide additional commentaries and explanations for all performed meta-analyses (Munn, Tufanaru, & Aromataris, 2014).

If meta-analysis is not performed, a narrative summary should be included. The narrative summary should provide an overall summary of the findings of the included studies and their biases, strengths and limitations. Textual commentaries and tables are used in order to summarize the results from the included studies and to provide context information for these results, thus facilitating understanding of the summarized results.

Qualitative evidence

This section should be organized in a meaningful way based on the review question(s). A meta-aggregative schematic should constitute part of this section, which must be accompanied by sufficient narrative to explain the categories and synthesized findings. *Where textual pooling was not possible the findings should be presented in narrative form.*

Findings and illustrations should be located in an appendix, or may be incorporated into the body of the review. There should be a logical and informative presentation of the findings, categories and synthesized findings.

Integration of quantitative evidence and qualitative evidence

This section should provide a narrative summary that represents the configured analysis of the quantitative and qualitative evidence. This should include statements that address ALL of the following questions:

- Are the results/findings from individual syntheses supportive or contradictory?

For example, the quantitative evidence might show improvements in patient outcomes following exposure to the intervention. These results support the qualitative evidence, which might demonstrate patients' perceived benefits from taking part in the intervention. In this example, the quantitative evidence supports the qualitative evidence. In some instances, however, the results /findings from individual syntheses may be conflicting. For example, while the qualitative evidence might describe patients' perceived benefits from the treatment, the quantitative evidence might fail to demonstrate a reduction of patient symptoms following the intervention.

- Does the qualitative evidence explain why the intervention is/is not effective?

For example, findings from the qualitative evidence might reveal that patients perceived the intervention of interest as a pleasant experience and that it contributed to their sense of well-being. This can then be used to explain and support why compliance to the intervention was high and why the majority of patients actively engaged with their health practitioners, which would be useful for explaining the effectiveness of the intervention.

- Does the qualitative evidence explain differences in the direction and size of effect across the included quantitative studies?

For example, results from the quantitative evidence might show differences in the effects of the intervention which might have been explored in the qualitative studies e.g. it is possible that some results in the quantitative evidence are better understood when the results from the qualitative evidence are taken into account?

- Which aspects of the quantitative evidence were/were not explored in the qualitative studies?

For example, the reviewer might indicate that some outcomes measured in the quantitative studies (e. g. health-related quality of life, family relationships, anxiety) were not explored in the qualitative studies and can therefore be investigated in future qualitative studies.

- Which aspects of the qualitative evidence were/were not tested in the quantitative studies?

For example, findings from the qualitative evidence might indicate some perceived positive effects (e. g. improved mood) from the intervention which might not have been measured in the quantitative studies; this would have implications for future trials.

All of the questions above should be answered, however dependent on the evidence included in the review it is acknowledged that some responses will be more detailed than others.

Please note: Due to the complexities associated with recommendations being derived from both streams of evidence and the impact of data transformation and/or integration on the grading process, an assessment of the certainty of the evidence using either the GRADE or ConQual approach is *curre ntly* not recommended for JBI MMSR following either the integrated or segregated approach and requires further investigation.

Discussion

This section should provide a detailed discussion of the findings of the review and of the significance of the review findings in relation to practice and research as well as a discussion of issues arising from the conduct of the review. The findings should be discussed in the context of current literature, practice and policy. It should also include a narrative discussion of the review results in comparison with other external literature, and against the broad directions established in the introduction of the review. The discussion does not bring in new findings that have not been reported in the results section but does seek to establish a line of argument based on the findings regarding the intervention and phenomenon of interest.

Conclusions and Recommendations

This section should include the overall conclusions of the review. The conclusions should provide direct answers to the review question(s). These conclusions should be based only on the results of the review and directly inferred from the review results.

Recommendations for practice

This sub-section of the Conclusions section should include the recommendations for practice inferred from the results of the integration of the quantitative evidence and qualitative evidence. Recommendations should be assigned a JBI Grade of Recommendation.

Recommendations for research

This should include the recommendations for future research inferred from the results of the integration of the quantitative evidence and qualitative evidence, specifically, inferred from the gaps identified during the configurative analysis, and issues and problems noted in the review process related to the search, selection of studies, critical appraisal, data extraction, and data synthesis.

Conflicts and acknowledgements

Details of requirements in these sections are described in Section 1.6 of this Manual.

Conflicts of interest

A statement which either declares the absence of any conflicts of interest or which describes a specified or potential conflict of interest should be made by the reviewers in this section.

Funding

Authors should provide details regarding any sources of funding for the review project. The role of all funders in the review process, if any, should be explicitly described. If the review is funded, then any potential conflicts of interest or intellectual bias of the funders should be specified in the review.

Acknowledgements

Any acknowledgements should be made in this section e.g. sources of external funding or the contribution of colleagues or institutions. It should also be noted if the systematic review contributes towards a degree award.

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Guidelines: 19. Assessing the certainty of evidence in the importance of outcomes or values and preferences—Risk of bias and indirectness. *Journal of Clinical Epidemiology*. doi: 10.1016/j.jclinepi.2018.01.013

Appendix 8.1 JBI Mixed Methods Data Extraction Form following a Convergent Integrated Approach

Note: This form should only be used for reviews that follow a convergent integrated approach, i.e. integration of qualitative data and 'qualitized' data following data transformation. For reviews that follow a convergent segregated approach, reviewers should use separate data extraction forms: the JBI quantitative data extraction tool and the JBI qualitative data extraction tool.

Reviewer: _____ Date: _____

Author(s) of the publication: _____ Year: _____

Journal: _____ Record Number: ____

Type of study

- ☐ Quantitative study
- ☐ Qualitative study
- ☐ Mixed methods study

Methodology: (e.g. randomized controlled trial, phenomenology)

Number of participants:

Characteristics of participants:

Phenomena of interest:

Setting and other context-related information (e.g. cultural, geographical):

Outcomes or findings of significance to the review objectives

For a quantitative study, for example:

Results

· 29% of survey participants reported feeling embarrassed having an asthma attack with friends; only 39% disclosed their asthma to friends

· 32% were embarrassed about taking asthma medication in front of friends; only 38% reported taking asthma pump when going out

Reference: (Cohen et al., 2003)

For a qualitative study, for example:

Themes or Subtheme	**Illustration (a direct quotation from a participant, an observation or other supporting data from the paper)**
Parental support	'I can take my medicines by myself, but my parents remind me of taking the medicines and they fill prescriptions at the pharmacy. I always talk to the pediatrician or asthma nurse together with my parents.' (page 834, Koster et al., 2015)

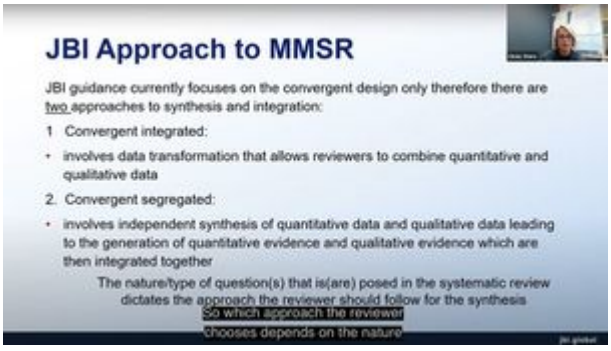
Author's conclusion

Reviewer's comments

Mixed Methods Resources

Digital Resources

Data Transformation in Mixed Methods Systematic Reviews



Which approach? Convergent integrated or convergent segregated?

A

When and how to use data transformation in mixed methods systematic reviews

An excerpt from the JBI LIVE webinar, 'The JBI Approach to Mixed Methods Systematic Reviews'

An excerpt fr
Methods Sys

'The JBI Approach to Mixed Methods Systematic Reviews'

An overview of the JBI approach to mixed methods systematic reviews, with practical considerations for people conducting their own mixed methods systematic reviews, or for those who use them.

Importance of mixed methods systematic reviews

A short podcast

Publications

Five common pitfalls in mixed methods systematic reviews: lessons learned

Lizarondo, L et al 2022

Common pitfalls in conducting a mixed methods systematic review relate to the justification for undertaking a mixed methods approach to the systematic review, mismatch between the review questions and the synthesis/integration approach used, inadvertent or deliberate exclusion of mixed methods primary research in the review, lack of clarity about data transformation, and the lack of integration of the quantitative and qualitative components of the review.

Methodological guidance for the conduct of mixed methods systematic reviews

Stern, C et al 2020

This paper outlines the updated methodological approach for conducting a JBI mixed methods systematic review with a focus on data synthesis; specifically, methods related to how data are combined and the overall integration of the quantitative and qualitative evidence.

9. Umbrella reviews

Edoardo Aromataris, Ritin Fernandez, Christina Godfrey, Cheryl Holly, Hanan Khalil, Patraporn Tungpunkom

How to cite:

Aromataris E, Fernandez R, Godfrey C, Holly C, Khalil H, Tungpunkom P. Umbrella Reviews (2020). Aromataris E, Lockwood C, Porritt K, Pilla B, Jordan Z, editors. *JBI Manual for Evidence Synthesis*. JBI; 2024. Available from: https://synthesismanual.jbi.global. https://doi.org/10.46658/JBIMES-24-08

Contents

- Appendix 9.3 JBI Data Extraction Form for Review for Systematic Reviews and Research Syntheses
- Umbrella Reviews Resources

Interim Guidance

JBI Methodology Groups are continuously working to improve, update and further the science of JBI Evidence Syntheses. JBI Methodology chapters are updated when there have been significant changes to a methodology, as determined by the JBI Scientific Committee. Interim guidance for steps, sections or stages of a review methodology is often provided via publications ahead of formal chapter updates. Please see below for relevant interim guidance:

Five common pitfalls in mixed methods systematic reviews: lessons learned

Lizarondo, L et al 2022

Common pitfalls in conducting a mixed methods systematic review relate to the justification for undertaking a mixed methods approach to the systematic review, mismatch between the review questions and the synthesis/integration approach used, inadvertent or deliberate exclusion of mixed methods primary research in the review, lack of clarity about data transformation, and the lack of integration of the quantitative and qualitative components of the review.

Methodological guidance for the conduct of mixed methods systematic reviews

Stern, C et al 2020

This paper outlines the updated methodological approach for conducting a JBI mixed methods systematic review with a focus on data synthesis; specifically, methods related to how data are combined and the overall integration of the quantitative and qualitative evidence.

9.1 Umbrella reviews and evidence-based practice

The volume of literature pertinent to healthcare is growing at an increasing rate, with thousands of studies published annually. Systematic reviews in healthcare have evolved in large part out of the recognition that this overwhelming amount of research evidence makes it difficult for decision makers to utilize the best available evidence to inform their decision making. Systematic reviews involve a rigorous scientific approach to an existing body of research evidence in an attempt to identify original research, critically appraise eligible studies and summarize and synthesize the results of high quality research ultimately informing a single manuscript.

A number of country-specific organizations, including the Agency for Healthcare Research and Quality (AHRQ) in the USA, the National Institute for Healthcare Excellence (NICE) in the UK, and international organizations, such as Cochrane and JBI, have dedicated themselves to the production of systematic reviews to inform healthcare policy and practice. In doing so, these organizations have contributed to the growing number of systematic reviews that have been published in recent years. Consequently, the number of systematic reviews published is, as with the bulk of scientific literature, also increasing at a phenomenal rate and now risks compounding the problem already faced by healthcare decision makers in sorting through multitudes of evidence to inform their questions. Bastian et al (2010) recently estimated that 11 systematic reviews were published every day! Still, decision-making can be challenging for healthcare practitioners and policy makers, even with systematic reviews readily available. The purpose of this chapter is to provide guidance on a method of review that can address these issues. Called an Umbrella Review, this method of review is essentially an overview of existing systematic reviews.

9.1.1 - Why an umbrella review?

Considering the large numbers of systematic reviews and research syntheses available to inform many topics in health care, systematic reviews of existing reviews are now being undertaken to compare and contrast published reviews and to provide an overall examination of a body of information that is available for a given topic (Hartling et al. 2012).

Conduct of an Umbrella Review offers the possibility of addressing a broad scope of issues related to a topic of interest. The wide picture obtainable from the conduct of an Umbrella Review is also ideal in highlighting if the evidence base around a topic or question is consistent or if contradictory or discrepant findings exist, and in exploring and detailing the reasons why. Investigation of the evidence with an Umbrella Review allows assessment and consideration of whether reviewers addressing similar review questions independently observe similar results and arrive at generally similar conclusions. Reviews of systematic reviews are referred to by several different names in

scientific literature as: umbrella reviews, overviews of reviews, reviews of reviews, a summary of systematic reviews and also a synthesis of reviews. In essence however they all have the same defining feature: a systematic review is the main and often sole “study type” that is considered for inclusion (Becker and Oxman 2011; Hartling et al. 2012; Smith et al, 2011).

For JBI syntheses of existing systematic reviews, the term “Umbrella Review” will be used. JBI Umbrella Reviews are designed to incorporate all types of syntheses of research evidence, including systematic reviews in their various forms (effectiveness, meta-aggregative, integrative, etc.) and meta-analyses.

Beyond the impetus for Umbrella Reviews which is driven by the sheer volume of systematic reviews being published, the need for “fast” evidence in reduced timeframes has also reinforced the attractiveness of undertaking such a review. Decision makers are increasingly required to make evidence informed policy decisions and often require evidence in short timeframes – as a result, “rapid reviews” are also appearing in research literature. Rapid reviews are essentially a streamlined approach to evidence synthesis in health care that attempt to accommodate an evidence informed decision as quickly as possible (Kangura et al, 2012). While the conduct of a rapid review may impinge on, or result in, undesirable modification of some of the processes required of a well-conducted systematic review, this may be alleviated to some extent by considering if any existing systematic reviews on the topic of interest are already available.

Using existing systematic reviews also reinforces the necessity for some measure of efficiency in scientific undertakings today. In short, if current, multiple, good quality, systematic reviews exist about a given topic or question, any reviewer should reconsider the need to conduct yet another review addressing the same issue. Rather, these may be the basis to conduct an Umbrella Review and summarize or synthesize the findings of systematic reviews already available.

9.1.2 - Not just effectiveness - JBI umbrella reviews

Similar to Cochrane, the JBI has historically focused on reviews that inform the effectiveness of an intervention or therapy; however the emphasis on “best available” evidence in JBI reviews of effectiveness has not been confined solely to randomized controlled trials and other experimental studies that occupy the uppermost levels of the evidence hierarchy.

JBI Umbrella Reviews are intended to compile evidence from multiple research syntheses. Any review author will recognize the advantage of having a good understanding of study design and research methodologies, whether quantitative or qualitative in nature. Similarly, it is recommended that reviewers intending or attempting to undertake a JBI Umbrella Review should have a good understanding of systematic reviews and the diversity and methodological nuances among the various types of reviews (and different organizations and authors that conduct them) before conducting an Umbrella Review themselves.

The reasons for conducting a JBI Umbrella Review are manifold. The principal reason is to summarize evidence from many research syntheses (Becker and Oxman 2011). These may include analyses of evidence of different interventions for the same problem or condition, or evidence from more than one research synthesis investigating the same intervention and condition but addressing and reporting on different outcomes. Similarly, a researcher or reviewer may wish to summarize more than one research synthesis for different conditions, problems or populations.3 The principle focus of a JBI Umbrella Review is to provide a summary of existing research syntheses related to a given topic or question and not to re-synthesize, for example, the results of existing reviews or syntheses with meta-analysis or meta-synthesis.

A reviewer familiar with the JBI methodology for the conduct of systematic review will appreciate that many questions that are asked in health care practice do not lend themselves directly to experimentation or gathering of numerical data to establish the answer regarding what the effectiveness or outcomes of a particular intervention. Rather, the questions are more of *how and why* interventions do or do not work, and how recipients of the intervention may experience them.

As a result, many JBI syntheses are of original qualitative research and apply a meta-aggregative approach to synthesis of qualitative data (see Chapter 2). Similarly, JBI Umbrella Reviews may find they inevitably ask questions that direct the reviewer predominantly to existing qualitative reviews. As with the combinations of PICO elements to organize the conduct an Umbrella Review mentioned above, the common denominator or feature across such multiple qualitative syntheses may be the population or subpopulation of interest, coupled with the context of the review question.

9.2 Development of an Umbrella review protocol

9.2.1 Title and author information

The title should be informative and give clear indication of the topic of the Umbrella Review. The title of a JBI Umbrella Review should always include the phrase “…:an Umbrella Review” to allow easy

identification of the type of document it represents. The names of all reviewers, affiliations for each author including their JBI centre affiliations and email address for the corresponding author should be included.

9.2.2 Developing the title and question

Although the Umbrella Review may aim to examine existing research syntheses for different types of interventions or phenomena of interest with the same condition, or different outcomes for the same intervention or phenomena of interest, the PICO and PICo mnemonic should be used to generate a clear and meaningful title and question. Ideally, the title for a quantitative Umbrella Review may incorporate some of the PICO elements, including the Population, the Intervention, the Comparison and Outcome, and the PICo elements if considering a question or topic that lends itself to qualitative data, including the Population, the Phenomena of Interest and Context. If a JBI Umbrella Review intends to review both quantitative and qualitative systematic reviews, both the intervention and phenomena of interest need to be clearly specified in the protocol (see below). The title of the Umbrella Review protocol must be concise enough to reflect the interventions or the phenomena of interest as a whole; however, it should also be as descriptive as possible. If the Umbrella Review is examining an intervention used across different patient conditions or different interventions with the same patient condition, this should be further delineated in the inclusion criteria section. The PICO or PICo mnemonic can provide potential readers with a significant amount of information about the focus, scope and applicability of the Umbrella Review to their needs. The following are examples of Umbrella Review titles:

1. “Non-pharmacological management for aggressive behaviors in dementia: an Umbrella Review protocol”

2. “The experiences of caregivers who are living with and caring for persons with dementia: an Umbrella Review protocol”

As an illustration of the use of the PICO elements to aid in articulating the title of an Umbrella Review, note that in example 1, the population (dementia), the intervention (non-pharmacological management), and the outcome (aggressive behaviors) are clearly evident. In this example this appears as the title of an Umbrella Review that lends itself to the inclusion of systematic reviews of randomized controlled trials to inform the effectiveness of an intervention or therapy, or potentially a broader investigation of research syntheses, that not only explore effectiveness of interventions but also the experiences of patients that received these therapies and their acceptability. Such an approach to this Umbrella Review will provide a comprehensive picture of the available evidence on the topic.

Similarly, example 2, provides readers with a clear indication of the population (caregivers of persons dementia), the phenomena of interest (experiences of caregiving), and the context (living with and caring for) as well as the fact that it is Umbrella Review protocol of qualitative evidence.

9.2.3 Introduction

The introduction should be comprehensive and cover all the main elements of the topic under review. It should cover the extant knowledge addressing the question of the Umbrella Review. The reason for undertaking the Umbrella Review should be clearly stated together with the target audience and what the Umbrella Review is intended to inform.

The suggested length for the introduction of the review protocol is approximately 1000 words. The background should detail any definitions important to the topic of interest. The information in the introduction section must also be sufficient to put the inclusion criteria into context, including an indication that there are existing systematic reviews or research syntheses available on the topic, hence supporting the rationale to conduct an Umbrella Review. The introduction should conclude a statement that a preliminary search for existing Umbrella Reviews on the topic has been/will be conducted (state the databases searched or search platforms utilized e.g. Cochrane Library, CINAHL, PubMed, EPPI, Epistomonikos and PROSPERO where relevant). If there is an existing Umbrella Review or overview of systematic reviews available on the topic, a justification that specifies how the proposed review will differ from those already conducted and identified should be detailed.

The introduction should conclude with an overarching review objective that captures and aligns with the core elements/mnemonic of the inclusion criteria (e.g. PICO). The stated objective should clearly indicate what the review project is trying to achieve. The objective(s) may be broad and will be aligned to specific review question(s). For example, using the first title introduced above, the objectives or aims may be: To examine non-pharmacological interventions for the management of aggressive behaviors in elderly patients with dementia.

For publication in *JBI Evidence Synthesis*, Vancouver style of referencing should be used throughout the protocol with superscript numbers without brackets, used for in-text citations.

9.2.4 Review question(s)

The review question(s) must be clearly stated. The review question(s) should be consistent with the title and direct the development of the specific inclusion criteria from clearly identifiable PICO. For example, using the first title introduced above, the objectives or aims of this review would be: To examine non-pharmacological interventions for the management of aggressive behaviors in elderly patients with dementia.

An example of the corresponding questions for this review would be:

1. What are effective non-pharmacological interventions to manage aggressive behavior in elderly patients with dementia?; and

2. What are the experiences of dementia patients and their caregivers with the use of non-pharmacological interventions to manage aggressive behavior?

9.2.5 Inclusion criteria

For the purposes of an Umbrella Review, the term “studies” refers exclusively to syntheses of research evidence including systematic reviews and meta-analyses. The “Inclusion criteria” of the protocol detail the basis on which studies will be considered for inclusion into the Umbrella Review and should be clearly defined.

These criteria provide a guide for the reader to clearly understand what is proposed by the reviewers and, more importantly a guide for the reviewers themselves to base decisions about the studies to be included in the Umbrella Review.

Types of participants

Important characteristics of participants should be detailed, including age and other qualifying criteria that make them appropriate for the objectives of the Umbrella Review and match the review question. In the example question above these characteristics include elderly people with dementia. Umbrella Reviews that aim to encompass multiple population groups should define each group clearly. Justification for the inclusion or exclusion of participants should be explained. In many cases, defining characteristics of the participants for a review may also include details of the setting of interest such as acute care, primary health care, or the community.

Interventions/phenomena of interest

The interventions or phenomena of interest for an Umbrella Review should be defined in detail and should be congruent with the review objective and intervention(s) or the phenomena of interest. Umbrella Reviews that aim to address multiple interventions and treatments should define each potential intervention of interest clearly.

Outcomes

Outcomes of interest should be predefined in Umbrella Reviews that lend themselves to quantitative evidence. Outcomes should be relevant to the question of the Umbrella Review and also the important outcomes for the participant group of the review. Surrogate outcomes should be explained and presented where there is a clear association with patient relevant outcomes. To provide a balanced overview of the evidence base related to a particular topic and fully inform decision-making, an Umbrella Review should attempt to report both beneficial and adverse outcomes.

Context

Context will vary depending on the objective(s)/question(s) of the review. The context should be clearly defined and may include but is not limited to consideration of cultural factors such as geographic location, specific racial or gender based interests. In some cases, context may also encompass details about the specific setting (such as acute care, primary health care, or the community).

Types of studies

As mentioned at the outset, the unit of analysis for an Umbrella Review is a completed research synthesis; therefore, the types of studies included in an Umbrella Review are exclusively syntheses of existing research from systematic reviews (using internationally accepted methodologies) and meta-analyses. Research syntheses included in an Umbrella Review should represent syntheses of empirical research evidence. Due to the enormous range of “review” types and articles available in the literature (Grant and Booth, 2009), authors of Umbrella reviews will have to stipulate clearly which review types should be included *a priori* in the protocol. Reviews that incorporate theoretical studies or text and opinion as their primary source of evidence should not be included in a JBI Umbrella Review and should be listed as an explicit exclusion criterion in the protocol.

9.2.6 Search Strategy

The search for an Umbrella Review should aim to identify all research syntheses relevant to the review question. The protocol should provide a detailed strategy for locating research syntheses including the key terms to be used and the resources to be searched. Predefined search filters for

reviews for various databases already exist and they are worthwhile investigating when developing the search strategy for the review. An example is the “systematic[sb]” search filter for PubMed. As many databases do not have a predefined search filter for review articles, in these cases, it is preferable to search with key terms such as “systematic” or “meta- analysis” across the title or abstract fields. Most authors will use these terms in the title of their publications to clearly identify the type of publication. Authors of JBI systematic reviews will be familiar with the recommendation to identify the document as a systematic review in the manuscript title to maximize the likelihood that it will be retrieved and read.

The search terms used should be broad enough to capture all relevant reviews. A three- phase search process should be used. First, initial keywords are identified followed by analysis of the text words contained in the title and abstract, and of the index terms to describe relevant reviews. The additional terms i.e., meta-analysis or systematic review need to be included in the key terms for searching. Second, database-specific search filters for each bibliographic citation database stipulated in the protocol are constructed, and finally the reference list of all included reviews should also be searched.

The search for systematic reviews rarely needs to extend prior to 1990 as there were very few systematic reviews published prior to that time (Smith et al, 2012). Essentially searching for the research syntheses conducted within the last five to ten years will yield original/primary research conducted 30+ years prior that has been included in the located reviews and research syntheses. As well as biomedical citation databases such as Medline, PubMed, EMBASE, and CINAHL, other sources to search include the major repositories of systematic reviews such as *JBI Evidence Synthesis*, the *Cochrane Database of Systematic Reviews*, DARE and the PROSPERO register. The federated search engine Epistemonikos that specifically targets research syntheses is also worthwhile using, particularly for initial searches. The databases searched for an Umbrella Review will depend on the review questions and objectives, for example, PEDro is a database indexing reviews relevant to physiotherapy, OTseeker, indexing reviews relevant to Occupational Therapy while BEME and the EPPI Centre Evidence Library are repositories of reviews relevant to education. Due to limitations of available resources, most JBI Umbrella Reviews will inevitably focus on including studies published in the English language. Where a review team has capacity, the search should ideally attempt to identify research syntheses published in any language and may expand the search to include databases that index languages other than English.

A comprehensive search for a JBI Umbrella Review should also encompass a search for grey literature or reports that are not commercially published. As decision makers are increasingly required to base their decisions on available evidence, more and more research syntheses are being commissioned by practitioners and health care policy makers in governments globally; as a result many reports available via government or organizational websites are syntheses of research evidence and may be eligible for inclusion in a JBI Umbrella Review. A JBI Umbrella Review should include a search of at least two or three relevant sources for “grey” reports.

9.2.7 Study Selection

The Umbrella review protocol should describe the process of study selection for all stages of selection (based on title and abstract examination; based on full text examination) and the procedures for solving disagreements between reviewers. Selection is performed based on inclusion criteria pre-specified in the review protocol. For any systematic review, study selection (both at title /abstract screening and full text screening) is performed by two or more reviewers, independently. Any disagreements are solved by consensus or by the decision of a third reviewer.

9.2.8 Assessment of methodological quality

Research syntheses that are eligible for inclusion in a JBI Umbrella Review must be assessed for methodological quality. Ideally, only high quality systematic reviews should be included in an Umbrella Review. There are a variety of checklists and tools available to assess research syntheses and systematic reviews. Most checklists use a series of criteria that can be scored as being “met” or “not met” or “unclear” and in some instances as “not applicable”. The decision as to whether or not to include a study can be made based on meeting a pre-determined proportion of all criteria, or on certain criteria being met. It is also possible to weight certain criteria differently. Decisions about a scoring system or any cut-off for exclusion should be made in advance and agreed upon by all reviewers before critical appraisal commences. The protocol, therefore, should detail how selected research syntheses will be assessed for quality, e.g. use of a predetermined cut off score.

It is the JBI policy that all systematic reviews need to be critically appraised using the standard JBI critical appraisal instrument for Systematic reviews and Research Syntheses that is available in Appendix 10.1 of this chapter (further details regarding the appraisal questions can be found in Appendix 10.2). For a JBI Umbrella Review the assessment criteria are available for selection in the JBI SUMARI software. The tool is designed to be used with two independent reviewers conducting the critical appraisal of each research synthesis selected. Reviewers are blinded to each other’s assessment and assessments can only be compared once initial appraisal of an article is completed by both reviewers. Where there is a lack of consensus, discussion between reviewers should occur.

In some instances it may be appropriate to seek assistance from a third reviewer. The source of the JBI critical appraisal tool for research syntheses should be cited in the protocol (Aromataris et al., 2015).

9.2.9 Data collection

Data collection is the procedure for extracting relevant details and data from the included systematic reviews and meta-analyses for the Umbrella Review. To avoid risk of bias, the standardized JBI data extraction tools (see Appendix 10.3 of this chapter) should be used to extract the data from the included reviews. Reviewers should have discussed and piloted its use prior to launching into extraction of data for the Umbrella Review to maximize consistency and the likelihood that the relevant results are being identified and detailed sufficiently for the purposes of reporting in the Umbrella Review. Without some discussion and piloting, reviewers may interpret fields in the tool or their relevance to the Umbrella Review questions slightly differently; differences unearthed at the completion of extraction for the review will invariably create more, unnecessary work for the review team. Any additions or modifications to the data extraction tool that are demanded by the nature of review question should be reviewed through by all reviewers and discussed in detail before extracting the data independently. Any additions or modifications should be identified and submitted with the review protocol and approved for publication in the *JBI Evidence Synthesis* prior to use by any reviewer.

Guided by the data extraction tool, information regarding the citation details, the objectives of the included review, the participants, the setting and context, the number of databases sourced and searched, the date range of database searching, the date range of included studies that inform each outcome of interest, the number/types of studies/country of origin of primary research studies in the included research synthesis, the instrument used to appraise the primary studies in the research synthesis and the rating of their quality, the outcomes reported by the included reviews that are relevant to the Umbrella Review question, and the type of review and the method of synthesis /analysis employed to synthesize the evidence as well as any comments or notes the Umbrella review authors may have regarding any included study.

Importantly, specific details of the factor or issue of interest to the Umbrella Review; for example the range of interventions, phenomena of interest, population details or outcome differences should be extracted in detail with the key findings/results. Extraction for a JBI Umbrella Review should be conducted independently by two reviewers to further minimize the risk of error. The protocol must therefore describe how data will be extracted and include the JBI data extraction instruments for systematic reviews in the appendices of the protocol. Extraction and presentation of data for a JBI Umbrella Review should be limited to the results and findings presented by the included research syntheses; in this regard it is not recommended that the researchers conducting the Umbrella Review retrieve primary studies (original research) in an included systematic review, for example, to access extra data. It is unlikely that authors of a JBI Umbrella review will need to contact the authors of an included research synthesis as is often the norm when undertaking a JBI Systematic Review (see other Chapters of this Manual).

9.2.10 Data summary

The aim of the JBI Umbrella review is to present a summary of existing research syntheses relevant to a particular topic or question and not any further “meta-analysis” of the results of these publications. To this end, the results of all included studies should be presented to the reader to allow for a ready and easily interpretable overview of the findings.

In the Umbrella Review protocol the means by which the results of the reviews will be presented should be described in as much as detail as possible. Tabular presentation of findings is recommended when overall effect estimates extracted from systematic reviews or other similar numerical data are presented. Where quantitative data is being presented, the number of studies that inform the outcome, the number of participants (from included studies) and the heterogeneity of the results of included reviews should also be reported (Smith et al, 2011). Where the results of qualitative systematic reviews are included in the Umbrella Review, the final or overall synthesized findings from included reviews should be presented, also in tabular format and with enough relevant contextual information alongside each synthesized finding to ensure each is interpretable to the reader of the Umbrella Review. Clear indication of any overlaps of original research studies in each of the included research syntheses must also be presented in the JBI Umbrella Review. For example, if one study is included in multiple syntheses this must be indicated.

The Principles from Grading of Recommendations Assessment, Development, and Evaluation (GRADE) should be used for an overall assessment of the quality of evidence for each intervention or phenomena of interest. The GRADE concept is based on an assessment of the following criteria: quality of primary studies, design of primary studies, consistency and directness (Guyat et al, 2008).

9.3 Umbrella Review and Summary of the evidence of research syntheses

This section provides further guidance on components that should be included in the final report of an Umbrella Review and information that each component should contain. It illustrates how each component of the review is managed in JBI SUMARI. This section also provides a brief outline of the

format and stylistic conventions for Umbrella Reviews to ensure the review meets publication criteria for the *JBI Evidence Synthesis*. For further information please refer to the Author Guidelines of the journal. Specifically, guidance is provided on the following components: outline of the report, inclusion criteria (i.e. PICO), search strategy, critical appraisal, data extraction, data synthesis, results and conclusions. All JBI Umbrella Reviews should be based on a peer reviewed Umbrella Review protocol that has been accepted for publication in the *JBI Evidence Synthesis*. Deviations from a published review protocol are rare and must be clearly detailed and justified in the methods section of the report where they occur.

9.3.1 Title of the Umbrella Review

The title should be clear, explicit and reflect the core elements of the review. Titles should not be phrased as questions or conclusions and there should be congruency between the title, review objectives/questions and inclusion criteria. The title should include the phrase: “An Umbrella Review“. Conventional wisdom suggests that the title should not be more than 12-14 words for ease of understanding. See the informative examples above in Section 10.2.1.

9.3.2 Review Authors

Each reviewer should have fist and last name listed. Affiliations for each author need to be stated, including the JBI affiliation of each reviewer. A valid email address must be provided for the corresponding author.

9.3.3 Abstract

This section forms a structured abstract of the main features of the systematic review. It must be no longer than 500 words and should contain no abbreviations or references. The abstract must accurately reflect and summarize the systematic review with the main focus on the results of the review.

The abstract should report the essential elements of the review using the following sub-headings in this order:

- **Objective**: State an overarching review objective structured using the key components of the inclusion criteria (approximately one to two sentences).
- **Introduction**: Briefly describe what the issue is under review and what is already known on the topic (approximately two to three sentences).
- **Inclusion criteria:** Summarize the inclusion criteria as it relates to the type of review being conducted. Present the information in one or two sentences – **NOT** under individual subheadings.
- **Methods:** List the key information sources searched (those that provided the majority of included studies), any limits placed on the scope of the search (e.g. language), and the date range, or the date of the last search. If the recommended JBI approach to critical appraisal, study selection, data extraction and data synthesis was used, simply state it as such (without naming the actual tool). Otherwise, briefly describe any notable deviations to the methodological approach taken (e.g. criteria used to exclude studies on the basis of methodological quality etc.).
- **Results**: The bulk of the abstract should be reserved to convey the main results of the review.
  - As a general rule, report the number and type of included studies and participants, as well as any pertinent study characteristics. Summarize the overall quality of the included studies and notable aspects of risk of bias.
  - Report the results for all main outcomes (not only those that were statistically significant or clinically important). If meta-analyses were conducted report the summary measures (estimated effect) and confidence intervals and ensure statistics are presented in a standard way. If a meta-analysis was proposed but not conducted, report the reason (e.g. clinical or methodological heterogeneity). Where possible, indicate the number of studies and participants for each main outcome. Describe the direction of the effect (e.g. lower, fewer, greater, more, etc.) in a way that is understandable to patients and health care professionals (i.e. which group was favored and the size of the effect) and indicate the measurement scale used, where applicable.
- **Conclusions**: Articulate brief overall conclusions based on the Umbrella Review findings should be articulated, including a clear answer to the question(s)/objective(s) of the Umbrella Review. Briefly convey key implications for practice and/or research.

9.3.4 Introduction

The introduction should be comprehensive and cover all of the main elements of the topic under review, as well as appropriate information about pathophysiology, diagnosis, prognosis, prevalence or incidence or other detail important to the review and why the topic or question of interest lends itself to an Umbrella Review for example, addressing a range of interventions relevant to a particular diagnosis. The primary objective of the Umbrella Review should be evident in the introduction as it situates the justification and importance of the question(s) posed. While many of these details will

already have been addressed in "Introduction" of the protocol, many reviewers will find that the background information provided with the protocol needs modification or extension following the conduct of the review proper. The introduction should conclude with a statement that a preliminary search for previous Umbrella Reviews on the topic was conducted (state the sources searched e.g. *JBI Evidence Synthesis*, The Cochrane Library, Campbell Collection etc.).

The introduction should conclude with an overarching review objective that captures and aligns with the core elements/mnemonic of the inclusion criteria (e.g. PICO). The stated objective should clearly indicate what the review project is trying to achieve. The objective(s) may be broad and will be aligned to specific review question(s). The objectives or aims of an example review may be: To examine non-pharmacological interventions for the management of aggressive behaviors in elderly patients with dementia. For publication in JBI Evidence Synthesis, Vancouver style referencing should be used throughout the review with superscript numbers without brackets used for in-text citations.

9.3.5 Review question(s)

The primary questions of the review should be stated. It can be followed by specific sub-questions that relate to differing comparisons contained in the Umbrella Review, such as, participant groups, interventions or outcome measures or a more in depth understanding of a particular phenomenon of interest. See example above in Section 10.2.4.

9.3.6 Inclusion criteria

This section of the review details the basis on which systematic reviews and/or meta-analyses were considered for inclusion in the Umbrella Review and should be as transparent and unambiguous as possible. The inclusion criteria for an Umbrella Review will depend on the question(s) asked. As a guiding principle, they should follow the norm for any JBI systematic review, where a question of effectiveness of an intervention(s) or therapy, for example, will stipulate a PICO (Population, Intervention, Comparator, Outcome), or an Umbrella Review that addresses a question that would lend itself to inclusion of qualitative systematic reviews that include a PICo (Population, Phenomena of interest and Context). Umbrella reviews that address multiple questions and evidence types may stipulate both PICO and PICo elements.

Types of participants

The types of participants should be related to the review objectives. The reasons for the inclusion or exclusion of participants detailed in this section should be explained to the reader of the Umbrella Review in the background section of the report.

Interventions/phenomena of interest

There should be congruence between the review objective and the outcomes of interventions under review and/or the phenomena of interest. Interventions may be focused, for example, to only pharmacological management or may be broad, including both pharmacology and other interventions (e.g. diet, exercise, surgery). Relationships should be clearly detailed in the background section. It is beneficial to use definitions where appropriate for the purposes of clarity.

Context/setting

In an Umbrella Review, the context or setting will vary depending on the objective of the review. Context may include but is not limited to consideration of cultural factors such as geographic location, racial or gender based interests. The setting details important features of the study location, such as acute care, primary health care or the community.

Outcomes

Outcomes for Umbrella Reviews should be described and defined and relevant to the question posed by the review. If outcomes are measured in a particular way, this should be included in the description (e.g., measurement of quality of life using the SF-36 questionnaire).

Types of studies

While it is clear that an Umbrella Review will include only existing research syntheses and systematic reviews, there should be a match in this section between the methodology of the systematic review to be considered for inclusion in the Umbrella Review and its primary objective. For example, an Umbrella Review that aims to assess the effectiveness of a range of interventions for aggressive behaviors in elderly dementia patients may limit itself to including systematic reviews that assessed effectiveness by including only randomized controlled trials and other experimental study designs.

9.3.7 Methods

This section of the review report is reserved for the methods used to conduct the review and should be presented under the relevant subheadings (See Sections 10.3.7.1 - 10.3.7.5), including any deviations from the method outlined in the *a priori* protocol. In empty reviews for example, this section should not refer to methods that were not performed.

Directly below the Methods heading provide the following information:

- State and appropriately cite the JBI methodology that was employed in the conduct of the review and synthesis.
- Refer to and cite the *a priori* protocol that was published, or accepted for publication (e.g. 'in press'), in the *JBI Evidence Synthesis*.
- If the protocol has been registered with PROSPERO, provide registration information including registration number (e.g. PROSPERO CRD42015425226).

9.3.7.1 Search strategy

This section should document how the reviewers searched for relevant papers to include in the Umbrella Review. The search strategy needs to be comprehensively reported and as a minimum, a detailed search strategy for all major bibliographic citation databases and other sources that were searched should be appended to the review. Ideally the search strategies for all of the databases searched should be presented sequentially in the single appendix. Clear documentation of the search strategy(ies) is a key element of the scientific validity of an Umbrella Review. A JBI Umbrella Review should consider papers published both commercially and in non-commercially in the gray literature. The timeframe chosen for the search should be justified and any language restrictions stated (e.g. only studies published in English were considered for inclusion). The databases that were searched must be listed along with the search dates. Any hand searching of relevant journals should be described by journal name and years searched. Author contact, if appropriate, should also be included with the results of that contact.

9.3.7.2 Study screening and selection

The review report should describe the actual process of study screening and for all stages of selection (based on title and abstract examination; based on full text examination) and the actual procedures used for solving disagreements between reviewers.

9.3.7.3 Assessment of methodological quality/critical appraisal

This section should detail the approach to critical appraisal, not the assessment results, and should be consistent with the details in the published JBI Umbrella Review protocol. Any deviations from the protocol must be reported and explained in this section of the review report. The JBI critical appraisal instrument for Systematic Reviews and Research Syntheses embedded in the JBI SUMARI software (See Appendices 10.1 and 10.2) must be used and either cited or appended to the review report.

9.3.7.4 Data collection

Standardized data extraction tools maximize the consistent extraction of accurate data across the included studies and are required for JBI Umbrella Reviews. The review should detail what data the reviewers extracted from the included systematic reviews and the JBI data extraction tool for Systematic Reviews and Research Syntheses must be appended to the review report (see Appendix 10.3). As mentioned , individual study level data should not be reported in an Umbrella Review (except where an outcome is only informed by one included study); the focus of reporting should be the results and findings of the included syntheses. Using the JBI extraction tool, at a minimum, details and data relevant to the items listed below should be extracted where the information is available. The majority of this information will appear in the Table of Included Study Characteristics to be appended to the review report, while other important details extracted, particularly relevant to the findings of the review (see below) will appear in the body of the review report:

Author/year

The citation details of included studies should be consistently referred to throughout the document. The citation details should include the name of the first author (Vancouver reference) and year of publication.

Objective(s)

A clear description of the objective of the included research synthesis should be stated.

Participants (characteristics/total number)

The defining characteristics of the participants in studies included in the research syntheses should be detailed, for example this may include diagnostic criteria, or age or ethnicity. The total number of participants that inform the outcomes relevant to the Umbrella Review question from all studies included studies should be presented also.

Setting/context

Details of the setting of interest such as acute care, primary health care, or the community or a particular geographical location should be included. For some Umbrella Reviews, particularly those

that draw upon qualitative research syntheses, the context that underpins the review question will be important to clearly reveal to the reader and may include but is not limited to consideration of cultural factors such as geographic location and specific racial or gender based interests.

Interventions/phenomena of interest

Clear, succinct details of the interventions or phenomena of interest should be described, including the type of intervention, the frequency and/or intensity of the intervention for example. A statement of the phenomena of interest is also required where applicable.

Number of databases/sources searched

The number of sources searched should be reported. Though this will have been considered during critical appraisal of the research synthesis, reporting to the reader of the review will allow rapid and easy comparison between differences of included reviews and also consideration of potential for publication bias in the event no formal analysis has been conducted. Where possible the names of databases and sources should be listed (i.e. if <5-10). The search range of each database should also be included.

Date range of included studies

The date range spanning from the earliest study that informs the included research synthesis to the latest should be reported. This is important information that allows for consideration of the currency of the evidence base not necessarily reflected in the year of publication of the research synthesis. If this is not readily identifiable in the table of study characteristics provided by the included synthesis, it should be discer nable by scanning the date range of publications through the results section of the included review.

Number of Studies/Type of Studies/Country of origin of included studies

Summary descriptive details of the included studies in the research synthesis should be reported. This includes the number of studies in the included research synthesis, the types of study designs included in the research synthesis, for example randomized controlled trials, prospective cohort study, phenomenology, ethnography etc., and also the country of origin of the included studies. The latter is important to allow the reader of the review to consider the external validity and generalizability of the results presented.

Appraisal instrument and rating

The instrument or tool used to assess risk of bias, rigor or study quality should be reported along with some summary estimate of the quality of primary studies in the included research synthesis. For example, for Umbrella Reviews that use the Jadad Scale, a mean score for quality may be reported whereas for checklist appraisals, reporting of cut-off score or any ranking of quality should be reported. An example of the latter would be exclusion of studies that score <3/10, and inclusion of four moderate quality studies (4-6/10) and two high quality studies (7-10/10).

Type of Review/Method of analysis

The type of research synthesis as stated by the authors of the included review should be detailed. The method of analysis or synthesis used by the included research synthesis should be reported. For example, this may include random effects meta-analysis, fixed effect meta-analysis, meta-aggregative synthesis or meta-ethnography.

Outcome(s)

Included here should be the outcomes of interest to the Umbrella Review question reported on by the research synthesis, i.e. the names or labels of the outcomes (see below for presentation of results).

Results/findings

The relevant findings or results presented by the included research syntheses must be extracted. For quantitative reviews, this will ideally be an effect estimate or measure from a presented meta-analysis. Measures of heterogeneity should also be extracted where applicable. In the absence of this a statement indicating the key result relevant to an outcome may be inserted in the required field. For qualitative syntheses, the key synthesized finding should be extracted.

Comments

There should be provision to extract and present in the table of included study characteristics any relevant details or comments on the included research synthesis by the authors of the Umbrella Review. These comments may be relevant details regarding the included research synthesis, for example, the congruence between the review results and conclusions, and for highlighting any potential methodological differences between the individual included reviews.

9.3.7.5 Data Summary

This section should detail the approach to the presentation of findings and the results from included research syntheses, not the results of this process. The types of data detailed in this section should be consistent with the methods used for data collection and the included study designs.

9.3.8 Results

This section of the review report has distinct sub-sections describing the process of study inclusion, the methodological quality of the eligible studies, detailed characteristics and description of the included studies and, importantly, the findings of the review and results of the synthesis processes.

9.3.8.1 Study inclusion

This section should provide a narrative summary of the search results and selection process and results. The number of papers identified by the search strategy and the number of papers that were included and excluded should be stated.

A complete and accurate report should be provided regarding:

- the number of studies identified by the search in diverse sources;
- the number of studies excluded after the examination of title and abstract against inclusion criteria;
- the number of full text articles retrieved for examination;
- the number of studies excluded after full text examination against inclusion criteria;
- the number of critically appraised studies;
- the number of studies excluded after critical appraisal;
- the final total number of included studies.

A flowchart using the PRISMA template for the reporting of the selection process should be included (Page et al. 2021).

Ideally, a list of all excluded studies, excluded after full text examination and after critical appraisal, with the explicit reasons for exclusion, should be provided in appendices to the review. As a minimum, at least the list of studies excluded after critical appraisal and the reasons for exclusion should be reported. If no studies were excluded after critical appraisal then the list of all studies excluded after full text examination including the explicit reasons for exclusion, should be provided in appendices to the review.

9.3.8.2 Methodological quality

This section should focus on methodological quality as determined by the JBI critical appraisal checklist for Systematic Reviews and Research Syntheses (see Appendices 10.1 and 10.2). There should be a narrative summary of the overall methodological quality of the included studies, which can be supported (optional) by a table showing the overall results of the critical appraisal (see Table 10.1 for example). Where only few studies are identified, or there are specific items of interest from included studies, these should be addressed in the narrative also, particularly where studies were deficient, or particularly good. i.e. with clear narrative regarding risk of bias/rigor of included studies. Use of N/A should also be justified in the text. Importantly, in a JBI Umbrella Review, it is important to present to the reader with clear indication of the quality of the included original research studies in each of the systematic reviews or research syntheses that are included in the Umbrella Review. This will have an impact on the interpretation and implications for practice and research and must be noted with clarity to the reader of the review in the body of the report. This detail will appear in the appended Table of Included Study Characteristics (see above).

Table 10.1: Critical appraisal results for included studies

Study	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10
Author(s) ref	Y	Y	Y	N	Y	U	Y	N	Y	U

Y - Yes, N - No, U - Unclear

9.3.8.3 Characteristics of included studies

This section of the results should also include an overall description of the included studies (with reference to the detailed table of included study characteristics in the appendices). The main aim is to provide context to the results section and sufficient descriptive detail for the reader to support the inclusion of the systematic reviews in the Umbrella Review, the relevance of included systematic review to the Umbrella Review question and the evidence base they offer to the question. Specific items/points of interest/outcomes from individual reviews may also be highlighted here. A summary table of included studies should be appended to the report that will be populated from the appropriate extraction fields form the extraction tool (See Appendix 10.3).

9.3.8.4 Findings of the review

The findings of the review and presentation of the results should flow logically from the review objection/question i.e. they must ultimately answer the questions posed. The findings and key results

extracted from the included research syntheses should constitute part of this section and may include presentation of quantitative and qualitative data. Both quantitative and qualitative findings presented in the JBI Umbrella Review report should be presented in a tabular format with supporting text.

Quantitative tabulation of results presented in this section must include clear presentation of the name of the intervention, the study or citation details that inform the intervention, the number of studies and individual participants that inform the outcome measure, the calculated effect estimate where possible or the main finding of the study related to the intervention and relevant outcome, as well as any details of measures of heterogeneity about the effect estimate(s). An example of the table of findings is below in Table 10.2 for one outcome. In this example it is for 'aggressive behaviors', if other outcomes were included, the final three columns of the table would be repeated for each. Tabular presentation must be accompanied by a clear and detailed description of the interventions addressed.

Table 10.2: Tabular presentation of quantitative findings for an Umbrella Review

Interventions/ phenomena of interest	Author/year	Number of studies/Participants	Results/Findings	Heterogeneity
Staff training programs	Kynoch, et al, 2009	1	No difference in Patient aggression between staff training and control group.	N/A
Physical restraint	Kynoch, et al, 2009	1	Not calculated	
Music therapy	Kynoch, et al, 2009	2	Not calculated	
Multiple interventions	Kynoch, et al, 2009	2	Not calculated	
Bright light	Forbes	5 /343 participants	Agitation at 1 year follow-up -2.00 (-11.71,7.71)	N/A

Qualitative findings should also be tabulated in this section of the Umbrella Review report. A description of the phenomenon of interest alongside the key synthesized findings extracted from each included qualitative meta- synthesis or systematic review should be presented. Individual findings and illustrations that would be the norm for presentation in a JBI meta-aggregative review would not be presented in a JBI Umbrella Review presenting qualitative data. To facilitate interpretability and clarity of the findings in this section of the review, adequate contextual and descriptive detail should also be presented.

An example of tabular presentation of qualitative findings in a JBI Umbrella Review is presented in Table 10.3. In this table the synthesized finding presented must be an accurate, verbatim replication of the finding from the source review. The descriptive information in the final column may constitute the Umbrella Review authors' own words to provide the necessary detail for interpretability. Depending on the review, it is likely that an individual table would be presented for each included qualitative synthesis; otherwise, further rows could be added to the example table. This tabular presentation must be accompanied by further descriptive detail of the phenomena of interest to the review in the text.

Table 10.3: Tabular presentation of qualitative findings for an Umbrella Review

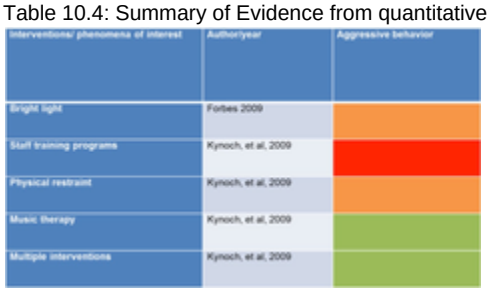
Phenomena of interest/context	Synthesized finding	Details of strategies
Nurse's perspective of therapeutic interventions to manage verbal and behavioural aggression among patients with dementia or brain injury	Entering the patient's world Nurses are encouraged to become a part of the patient's world and to strive for mutual understanding and action. Patient negativity is downplayed and interactions are shaped in thoughtfully creative ways	**Normalization:** Getting to know the patient behind the aggression and normalizing their experiences. Aggression is seen as part of the condition **Person-centered care:** During care the person's needs, experiences, and feelings remain a focal point instead of procedures **Nurse-patient mutuality:** Nurses are encouraged to mutually work through problems rather than always doing things to and for patients **Downplaying negativity:** Nurses are urged to develop a positive interaction style with potentially aggressive patients and to disregard or overlook negative behavior **Thoughtful creativity:** Nurses are urged to be reflective, use their imaginations, and be flexible when providing care
	Utilitarian care: Nurses are inflexibly committed to rules and routines, focused on duty, responsibility, being in charge, and streamlining care	**Inflexible routines**: When inflexible routines are maintained, patients tend to be seen as troublesome, and their behaviors are viewed as meaningless

9.3.9 Summary of Evidence

In line with the objectives of a JBI Umbrella Review to present an accurate and informative overview of the findings of research syntheses that inform a broad topic or question, all JBI Umbrella Reviews should conclude the results section of the report with a final and easily interpretable table that presents the overall "Summary of Evidence".

For quantitative findings, a final table should be presented that names the intervention, identifies the included research synthesis and provides a simple, visual indication of the results. Visual indication should follow a simple "stop-light" indicator, where green indicates the intervention is beneficial (effective), amber that there is no difference in the investigated comparison, and red that the results suggest the intervention is detrimental or less effective than the comparator. Actual details and effect estimates are presented in the findings of the review (see above). Table 10.4 presents an example for "aggressive behavior". Further outcomes reported in an Umbrella Review could be added in columns to the right. Where a study does not report on an outcome, the indicator square should be left blank.

Table 10.4: Summary of Evidence from quantitative research syntheses in a JBI Umbrella Review



Interventions/ phenomena of interest	Author/year	Aggressive behavior
Bright light	Forbes 2009	
Staff training programs	Kynoch, et al, 2009	
Physical restraint	Kynoch, et al, 2009	
Music therapy	Kynoch, et al, 2009	
Multiple interventions	Kynoch, et al, 2009	

Similarly, Umbrella Reviews that include qualitative syntheses should also conclude the results section with a clear summary of the overall findings of the included research syntheses.

In the final summary table, the key synthesized findings should be presented for the reader; for other contextual details the main findings can be referred to (see above). Similar to a summary presentation of qualitative findings, visual indicators of the finding should be included where possible. In the example provided in Table 10.5, those perspectives (see phenomenon) that are beneficial or facilitative are highlighted in green, while those that are inhibitory are highlighted in red.

Table 10.5: Summary of Evidence from qualitative research syntheses in a JBI Umbrella Review

Phenomena of interest	Authors	Synthesized finding
Nurse's perspective of optimal therapeutic interventions	Fintgeld-Connett et al.	Entering the patient's world - becoming part of the patient's world characterised by: • Normalization • Person-centered care • Nurse-patient mutuality • Downplaying negativity • Thoughtful creativity
		Utilitarian care – characterized by: • Being inflexibly committed to rules and routines • Focused on duty, responsibility, being in charge and streamlining care

9.3.10 Discussion

This section should discuss the results of the review as well as any limitations of the systematic reviews or research syntheses included in the Umbrella Review and of the review itself (i.e. language, access, timeframe, study design, etc.). The results should be discussed in the context of current literature, practice and policy. Umbrella Reviews are subject to many of the limitations of any systematic review including that potentially relevant studies have been omitted and that some systematic error occurred during the selection, appraisal or data extraction processes. Similarly, Umbrella Reviews are ultimately dependent on the reporting of the included research syntheses which may limit reporting of desirable details of interventions for example in the Umbrella Review report. Inherent bias exists in the reporting of an Umbrella Review as one round of appraisal and extraction, where errors may arise, has already been performed in the conduct of the included systematic review or meta-analysis. Umbrella Reviews will also always be limited by the coverage of existing systematic reviews or research syntheses. For example, if an existing intervention or phenomena of interest is yet to be addressed in a systematic review, an Umbrella Review will never identify it.

9.3.11 Conclusions and recommendations

This section should include the overall conclusions of the review. The conclusions should provide direct answers to the review objectives/questions. These conclusions should be based only on the results of the review and directly inferred from the review results.

Recommendations for practice

This sub-section of Conclusions section should include the recommendations for practice inferred from the results of the review and inferred also based on the discussion of the generalizability of the results and the potential factors that may affect the applicability of results. It should be stated how the findings of the review impact on clinical practice or policy in the area. Where there is sufficient evidence to make specific recommendations for practice, these should be clearly articulated Recommendations should be assigned a JBI Grade of Recommendation.

Recommendations for research

This sub-section should include clear, specific recommendations for future research based on gaps in knowledge identified from the results of the review. Umbrella Review authors may find they are able to make comment both on the future conduct of research syntheses and systematic reviews as well as to provide comment on the primary research conducted in the area of interest.

9.3.12 Conflicts and acknowledgements

Details of requirements in these sections are described in Section 1.6. of this Manual.

Conflicts of interest

A statement which either declares the absence of any conflicts of interest or which describes a specified or potential conflict of interest should be made by the reviewers in this section.

Funding

Authors should provide details regarding any sources of funding for the review project. The role of all funders in the review process, if any, should be explicitly described. If the review is funded, then any potential conflicts of interest or intellectual bias of the funders should be specified in the review.

Acknowledgements

Any acknowledgements should be made in this section e.g. sources of external funding or the contribution of colleagues or institutions. It should also be noted if the systematic review is to count towards a degree award.

9.3.13 Review Appendices

Appendix 1: Search strategy

- A detailed and complete search strategy for all of the major databases and other sites and sources searched must be appended. Major databases that were searched must be identified, including the search platform used where necessary. All search filters with logic employed should be displayed, including the number of records returned.

Appendix 2: Data extraction instrument

- The data extraction instrument used must be appended i.e JBI Data Extraction Form.

Appendix 3: List of excluded studies

- Studies excluded following examination of the full-text should be listed along with their reason for exclusion at that stage (i.e. a mismatch with the inclusion criteria). This may be as a separate appendix or itemized in some fashion within the one appendix with those studies excluded at the critical appraisal stage. Reasons for exclusion following appraisal should be provided for each study (these reasons should relate to the methodological quality of the study, not study eligibility).

Appendix 4: Table of included study characteristics

- A table of included studies is required to provide quick reference to important details extracted from of the studies included in the review.

9.4 Chapter references

Aromataris, E., Fernandez, R., Godfrey, C., Holly, C., Kahlil, H. & Tungpunkom, P. 2015 Summarizing systematic reviews: methodological development, conduct and reporting of an Umbrella review approach International Journal of Evidence based Healthcare, 13(3):132-140.

Bastian H, Glasziou P, Chalmers I. Seventy-five trials and eleven systematic reviews a day: how will we ever keep up? PLoS Med 2010; 7(9):e1000326.

Becker LA, Oxman AD. Chapter 22: Overviews of reviews. In: Higgins JPT, Green S (editors), Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Grant M, Booth A. A typology of reviews: an analysis of 14 review types and associated methodologies. Health Information and Libraries Journal; 2009 26:91-108 10.1111/j.1471-1842.2009.00848.x

Guyatt GH, Oxman AD, Vist G, Kunz R, Falck-Ytter Y, Alonso-Coello P, Schünemann HJ, for the GRADE Working Group. Rating quality of evidence and strength of recommendations GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ; 2008; 336: 924-926.

Hartling L, Chisholm A, Thomson D, Dryden DM. A descriptive analysis of overviews of reviews published between 2000 and 2011. PLoS One 2012; 7(11)e49667.

Khangura S, Konnyu K, Cushman R, Grimshaw J, Moher M. Evidence summaries: the evolution of a rapid review approach. Systematic Reviews 2012; 1:10.

Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71.

Smith V, Devane D, Begley C, Clarke M Methodology in conducting a systematic review of systematic reviews of healthcare interventions. BMC Medical Research Methodology; 211; 11:15. doi: 10.1186/1471-2288-11-15

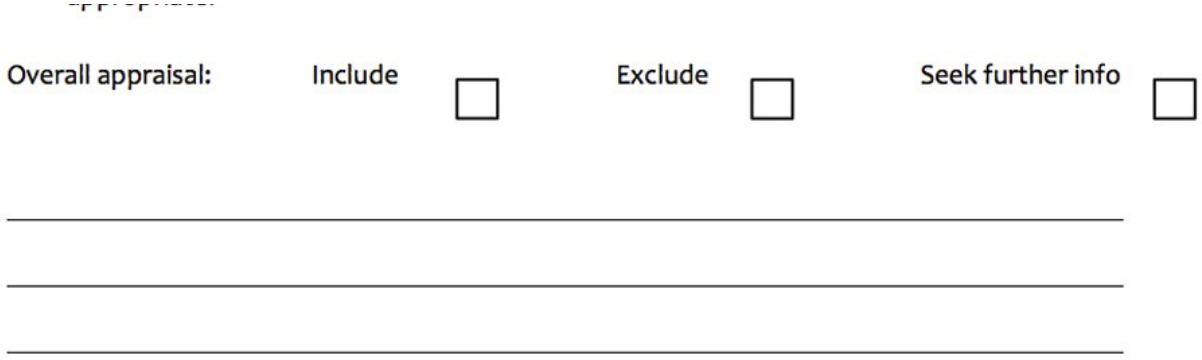
Appendix 9.1 JBI Critical Appraisal Checklist for Systematic Reviews and Research Syntheses

JBI Critical Appraisal Checklist for Systematic Reviews and Research Syntheses

Reviewer _____ Date _____

Author _____ Year _____ Record Number

		Yes	No	Unclear	Not applicable
1.	Is the review question clearly and explicitly stated?	☐	☐	☐	☐
2.	Were the inclusion criteria appropriate for the review question?	☐	☐	☐	☐
3.	Was the search strategy appropriate?	☐	☐	☐	☐
4.	Were the sources and resources used to search for studies adequate?	☐	☐	☐	☐
5.	Were the criteria for appraising studies appropriate?	☐	☐	☐	☐
6.	Was critical appraisal conducted by two or more reviewers independently?	☐	☐	☐	☐
7.	Were there methods to minimize errors in data extraction?	☐	☐	☐	☐
8.	Were the methods used to combine studies appropriate?	☐	☐	☐	☐
9.	Was the likelihood of publication bias assessed?	☐	☐	☐	☐
10.	Were recommendations for policy and/or practice supported by the reported data?	☐	☐	☐	☐
11.	Were the specific directives for new research appropriate?	☐	☐	☐	☐



Appendix 9.2. Discussion of JBI Critical Appraisal Checklist for systematic reviews and research syntheses

This appraisal instrument can be found in the JBI SUMARI software.

Review authors should discuss each item in the appraisal instrument for each study included in their review. In particular, discussions should focus on what is considered acceptable to the aims of the review in terms of the specific study characteristics. When appraising systematic reviews this discussion may include issues such as what represents an adequate search strategy or appropriate methods of synthesis. The reviewers should be clear on what constitutes acceptable levels of information to allocate a positive appraisal compared with a negative, or response of “unclear”. This discussion should ideally take place before the reviewers independently conduct the appraisal.

Within Umbrella reviews, quantitative or qualitative systematic reviews may be incorporated, as well as meta-analyses of existing research. The individual checklist is available in Appendix 9.1.

There are 11 questions to guide the appraisal of systematic reviews or meta-analyses. Each question should be answered as “yes”, “no”, or “unclear”. Not applicable “NA” is also provided as an option and may be appropriate in rare instances.

1. Is the review question clearly and explicitly stated?

The review question is an essential step in the systematic review process. A well-articulated question defines the scope of the review and aids in the development of the search strategy to locate the relevant evidence. An explicitly stated question, formulated around its PICO (Population, Intervention, Comparator, Outcome) elements aids both the review team in the conduct of the review and the reader in determining if they review has achieved its objectives. Ideally the review question should be articulated in a published protocol; however this will not always be the case with many reviews that are located.

2. Were the inclusion criteria appropriate for the review question?

The inclusion criteria should be identifiable from and match the review question. The necessary elements of the PICO should be explicit and clearly defined. The inclusion criteria should be detailed and the included reviews should clearly be eligible when matched against the stated inclusion criteria. Appraisers of meta-analyses will find that inclusion criteria may encompass criteria around the ability to conduct statistical analyses which would not be the norm for a systematic review. The types of included studies should be relevant to the review question, for example, an Umbrella Review aiming to summarize a range of effective non-pharmacological interventions for aggressive behaviors amongst elderly patients with dementia will limit itself to including systematic reviews and meta-analyses that synthesize quantitative studies assessing the various interventions; qualitative or economic reviews would not be included.

3. Was the search strategy appropriate?

A systematic review should provide evidence of the search strategy that has been used to locate the evidence. This may be found in the methods section of the review report in some cases, or as an appendix that may be provided as supplementary information to the review publication. A systematic review should present a clear search strategy that addresses each of the identifiable PICO components of the review question. Some reviews may also provide a description of the approach to searching and how the terms that were ultimately used were derived, though due to limits on word counts in journals this may be more the norm in online only publications. There should be evidence of logical and relevant keywords and terms and also evidence that Subject Headings and Indexing terms have been used in the conduct of the search. Limits on the search and their potential impact

should also be considered; for example, if a date limit was used, was this appropriate and/or justified? If only English language studies were included, will the language bias have an impact on the review? The response to these considerations will depend, in part, on the review question.

4. Were the sources and resources used to search for studies adequate?

A systematic review should attempt to identify “all” the available evidence and as such there should be evidence of a comprehensive search strategy. Multiple electronic databases should be searched including major bibliographic citation databases such as MEDLINE and CINAHL. Ideally, other databases that are relevant to the review question should also be searched, for example, a systematic review with a question about a physical therapy intervention should also look to search the PEDro database, whilst a review focusing on an educational intervention should also search the ERIC. Reviews of effectiveness should aim to search trial registries. A comprehensive search is the ideal way to minimize publication bias. As a result, a well conducted systematic review should also attempt to search for gray literature, or “unpublished” studies; this may involve searching websites relevant to the review question or thesis repositories.

5. Were the criteria for appraising studies appropriate?

The systematic review should present a clear statement that critical appraisal was conducted and provide details of the items that were used to assess the included studies. This may be presented in “Methods of the review”, as an appendix of supplementary information, or as a reference to a source that can be located. The tools or instruments used should be appropriate for the review question asked and the type of research conducted. For example, a systematic review of effectiveness should present a tool or instrument that addresses aspects of validity for experimental studies and randomized controlled trials such as randomization and blinding – if the review includes observational research to answer the same question, a different tool would be more appropriate. Similarly, a review assessing diagnostic test accuracy may refer to the recognized QUADAS tool (Whiting et al, 2003).

6. Was critical appraisal conducted by two or more reviewers independently?

Critical appraisal or some similar assessment of the quality of the literature included in a systematic review is essential. A key characteristic to minimize bias or systematic error in the conduct of a systematic review is to have the critical appraisal of the included studies completed by members of the review team independently and in duplicate. The systematic review should present a clear statement that critical appraisal was conducted by at least two reviewers working independently from each other and conferring where necessary to reach a decision regarding study quality and eligibility on the basis of quality.

7. Were there methods to minimize errors in data extraction?

Efforts made by review authors during data extraction can also minimize bias or systematic errors in the conduct of a systematic review. Strategies to minimize bias may include conducting all data extraction in duplicate and independently, using specific tools or instruments to guide data extraction and some evidence of piloting or training around their use.

8. Were the methods used to combine studies appropriate?

A synthesis of the evidence is a key feature of a systematic review. The synthesis that is presented should be appropriate for the review question and the stated type of systematic review and evidence it refers to. If a meta-analysis has been conducted this needs to be reviewed carefully. Was it appropriate to combine the studies? Have the reviewers assessed heterogeneity statistically and provided some explanation for heterogeneity that may be present? Often, where heterogeneous studies are included in the systematic review, narrative synthesis will be an appropriate method for presenting the results of multiple studies. If a qualitative review, are the methods that have been used to synthesize findings congruent with the stated methodology of the review? Is there adequate descriptive and explanatory information to support the final synthesized findings that have been constructed from the findings sourced from the original research?

9. Was the likelihood of publication bias assessed?

As mentioned, a comprehensive search strategy is the best means by which a review author may alleviate the impact of publication bias on the results of the review. Reviews may also present statistical tests such as Egger’s test or funnel plots to also assess the potential presence of publication bias and its potential impact on the results of the review. This question should be considered N/A for JBI qualitative reviews.

10. Were recommendations for policy and/or practice supported by the reported data?

Whilst the first nine questions specifically look to identify potential bias in the conduct of a systematic review, the final questions are more indicators of review quality rather than validity. Ideally a review should present recommendations for policy and practice. Where these recommendations are

made there should be a clear link to the results of the review. Is there evidence that the strength of the findings and the quality of the research have been considered in the formulation of review recommendations?

11. Were the specific directives for new research appropriate?

The systematic review process is recognized for its ability to identify gaps in the research, or knowledge base, around a particular topic. Most systematic review authors will provide some indication, often in the discussion section of the report, of future research direction. Where evidence is scarce or sample sizes that support overall estimates of effect are small and effect estimates are imprecise, repeating similar research to those identified by the review may be necessary and appropriate. In other instances, the case for new research questions to investigate the topic may be warranted.

P Whiting, AWS Rutjes, JB Reitsma, PMM Bossuyt, J Kleijnen. The development of QUADAS: a tool for the quality assessment of studies of diagnostic accuracy included in systematic reviews BMC Medical Research Methodology 2003, 3:2

Appendix 9.3 JBI Data Extraction Form for Review for Systematic Reviews and Research Syntheses

Study Details	
Author/year	
objectives	
Participants (characteristics/ total number)	
Setting/context	
Description of Interventions/ phenomena of interest	
Search Details	
Sources searched	
Range (years) of included studies	
Number of studies included /	
Types of studies included	
Country of origin of included studies	
Appraisal	
Appraisal instruments used	
Appraisal rating	
Analysis	
Method of analysis	
Outcome assessed	
Results/Findings	
Significance/direction	
Heterogeneity	
Comments	

Umbrella Reviews Resources

Digital Resources

What are Umbrella Reviews?

In this short podcast A/Prof Edoardo Aromataris explains when to conduct an umbrella review.

Umbrella Reviews: How are they useful?

Assoc Prof Edoardo Aromataris outlines how umbrella reviews a

10. Scoping reviews

Micah DJ Peters, Christina Godfrey, Patricia McInerney, Zachary Munn, Andrea C. Tricco, Hanan Khalil

How to cite:

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Contents

Interim Guidance

JBI Methodology Groups are continuously working to improve, update and further the science of JBI Evidence Syntheses. JBI Methodology chapters are updated when there have been significant changes to a methodology, as determined by the JBI Scientific Committee. Interim guidance for steps, sections or stages of a review methodology is often provided via publications ahead of formal chapter updates. Please see below for relevant interim guidance:

Recommendations for the extraction, analysis, and presentation of results in scoping reviews

Pollock et al 2023

Scoping reviewers often face challenges in the extraction, analysis, and presentation of scoping review results. Using best-practice examples and drawing on the expertise of the JBI Scoping Review Methodology Group and an editor of a journal that publishes scoping reviews, this paper expands on existing JBI scoping review guidance. The aim of this article is to clarify the process of extracting data from different sources of evidence; discuss what data should be extracted (and what should not); outline how to analyze extracted data, including an explanation of basic qualitative content analysis; and offer suggestions for the presentation of results in scoping reviews.

Best practice guidance and reporting items for the development of scoping review protocols

Peters et al 2022

The purpose of this article is to clearly describe how to develop a robust and detailed scoping review protocol, which is the first stage of the scoping review process. This paper provides detailed guidance and a checklist for prospective authors to ensure that their protocols adequately inform both the conduct of the ensuing review and their readership.

Conducting high quality scoping reviews-challenges and solutions

Khalil et al 2021

In this paper, the JBI Scoping Review Methodology Group discuss the challenges that may be faced in the conduct and publishing of scoping reviews, such as developing an a-priori protocol, developing implications or recommendations for research, policy or practice and a lack of understanding of scoping reviews by journal editors, authors and peer reviewers. It presents solutions to these challenges to ensure better understanding of the process of scoping reviews.

Moving from consultation to co-creation with knowledge users in scoping reviews: guidance from the JBI Scoping Review Methodology Group

Pollock et al 2022

This paper presents JBI's guidance for knowledge user engagement in scoping reviews based on the expert opinion of the JBI Scoping Review Methodology Group. We offer specific guidance on how this can occur and provide information regarding how to report and evaluate knowledge user engagement within scoping reviews.

Updated methodological guidance for the conduct of scoping reviews

Peters et al 2021

The latest JBI scoping review guidance is described with this article. There is an updated section on when to conduct a scoping review, the role of methodological appraisal in scoping reviews and inclusion of the PRISMA-SCR reporting guidelines.

PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation

Tricco et al 2018

Even though a scoping review is not considered systematic. An extensive search still needs to be undertaken to ensure that all available evidence is included within your review. This articles describes how you should report on that search in your publications.

10.1 Introduction to Scoping reviews

Evidence-based healthcare is an expanding field. Together with the continual increase in the availability of primary research, the conduct of reviews has also increased and evolved. Different forms of evidence and different review objectives and questions have led to the development of new approaches that are designed to more effectively and rigorously synthesize the evidence. In 2009, Grant and Booth identified 14 different types of reviews (Grant & Booth 2009), whilst in 2016 Tricco and colleagues identified 25 knowledge synthesis methods (Tricco et al. 2016c). Scoping reviews, which have also been called “mapping reviews” or “scoping studies” are one type of review (Ehrich et al. 2002; Anderson et al. 2008). Arksey and O’Malley proposed an original framework for conducting scoping reviews (Arksey & O’Malley 2005). This framework was then advanced and extended by Levac and colleagues (2010). Scoping review methodology was then further refined, and corresponding guidance developed by a working group from JBI and the JBI Collaboration (JBIC) (Peters et al. 2015, 2017). The guidance from this group explicitly addressed the need for this type of knowledge synthesis to be rigorously conducted, transparent and trustworthy. Peters et al. (2015, 2017) used the label ‘systematic scoping review’ in their original guidance for conduct and reporting of these types of reviews (Peters et al. 2015, 2017). In this current update, the nomenclature has been refined to simply ‘scoping reviews’ in acknowledgement that all types of knowledge synthesis should be systematic in their conduct, and that this is the most common term used for these types of reviews (Tricco et al. 2016b). In 2018, the Preferred Reporting Items for Systematic Reviews (PRISMA) Statement was extended to Scoping Reviews – the PRISMA-ScR (Tricco et al. 2018). The PRISMA-ScR was developed by a number of experts in scoping reviews and evidence synthesis, including members of the JBI/JBIC working group, to be consistent with the JBI scoping review methodology (Peters et al. 2017). Following the PRISMA-ScR and meetings of the scoping review methodology group, an updated version of the JBI scoping review methodology is now available.

10.1.1 Why a scoping review?

There are a number of reasons why a scoping review might be conducted. Unlike other reviews that tend to address relatively precise questions (such as a systematic review of the effectiveness of an intervention assessed using a predefined set of outcomes), scoping reviews can be used to map the key concepts that underpin a field of research, as well as to clarify working definitions, and/or the conceptual boundaries of a topic (Arksey & O'Malley 2005). A scoping review may address one of these aims or all of them. A scoping review of scoping reviews found that the three most common reasons for conducting a scoping review were to explore the breadth or extent of the literature, map and summarize the evidence, and inform future research (Tricco et al. 2016b). The indications for scoping reviews are listed below: (Munn et al. 2018a)

- As a precursor to a systematic review.
- To identify the types of available evidence in a given field.
- To identify and analyse knowledge gaps.
- To clarify key concepts/ definitions in the literature.
- To examine how research is conducted on a certain topic or field.
- To identify key characteristics or factors related to a concept.

Scoping reviews undertaken with the objective of providing a 'map' of the available evidence can be undertaken as a preliminary exercise prior to the conduct of a systematic review (Anderson et al. 2008). Scoping reviews are useful for examining emerging evidence when it is still unclear what other, more specific questions can be posed for evidence syntheses and valuably addressed. For example, while there are few studies on the sustainability of knowledge translation interventions in the area of chronic disease management, a scoping review has provided the foundation for a future systematic review to investigate the impact of sustainable knowledge translation interventions on health outcomes (Tricco et al. 2016a).

Authors deciding between the systematic review or scoping review approach should carefully consider the indications discussed above and determine exactly what question they are asking and what purpose they are trying to achieve with their review (Munn et al. 2018a). It is important for authors to clearly articulate *why* they are undertaking a scoping review; i.e. why is it necessary to identify and map the evidence in a given field? What will mapping the evidence achieve in terms of the objective of the review? Perhaps the most important consideration is whether or not the authors wish to use the results of their review as the basis for a trustworthy clinical guideline, to answer a clinically meaningful question, or provide evidence to inform practice or policy (Munn et al. 2018a). If so, then a systematic review approach is best. If the authors have a question addressing the feasibility, appropriateness, meaningfulness or effectiveness of a certain treatment or practice, then a systematic review is likely the most valid approach (Pearson 2004, 2005). A diverse suite of approaches to conducting systematic reviews to answer different types of clinical questions (i.e. effectiveness, prognosis, risk, etc) exist (Munn et al. 2018b). However, authors do not always wish to ask single or precise clinical questions and may be more interested in the identification of certain characteristics/concepts in sources of evidence, and in the mapping, reporting or discussion of these characteristics/concepts. In these cases, a scoping review is the better choice.

Unlike a systematic review, scoping reviews do not tend to produce and report results that have been synthesized from multiple evidence sources following a formal process of methodological appraisal to determine the quality of the evidence. Rather, scoping reviews aim to provide an overview or map of the evidence. Due to this, an assessment of methodological limitations or risk of bias of the evidence included within a scoping review is generally not performed (unless there is a specific requirement due to the nature of the scoping review aim) (Khalil et al. 2016; Peters et al. 2015). Given this assessment of bias is not conducted, the implications/recommendations for practice (from a clinical or policy making point of view) that arise from a scoping review are quite different compared to those of a systematic review. In some cases, there may be no need to articulate implications for practice and if there is a need to do so, these implications may be limited in terms of providing guidance from a clinical or policy making point of view. Conversely, when we compare this to systematic reviews, the provision of implications for practice is a key feature of systematic reviews and is recommended in reporting guidelines for systematic reviews (Liberati et al. 2009). To put it simply, systematic reviews normally inform the development of trustworthy clinical guidelines and recommendations. Scoping reviews are not conducted for this reason but rather to provide an overview of the evidence or to answer questions regarding the nature and diversity of the evidence/knowledge available

Davis and colleagues (2009) explain how, as useful tools for evidence reconnaissance, scoping reviews can be used to provide a broad overview of a topic. For instance, a scoping review that seeks to develop a “concept map” may aim to explore how, by whom and for what purpose a particular term is used in a given field (Anderson et al. 2008). Another example includes where scoping reviews have been performed to establish a comprehensive understanding of how scoping reviews have been conducted and reported (Pham et al 2014; Tricco et al. 2016b). Scoping review methodology was used to identify papers and guidelines that had either utilized or described scoping review methods and/or assessed the quality of reporting for scoping reviews (Tricco et al. 2016b). The review by Tricco et al (2016b) illustrates how the number of scoping reviews has steadily increased since 2012, that there was variation in terms of how they were conducted and reported, and that standardized reporting guidelines were absent.

Scoping reviews may also be used to develop “policy maps” by identifying and mapping evidence from policy documents and reports that guide practice in a particular field (Anderson et al. 2008). For example, a scoping review might include the objective of mapping research papers and policy documents that concern models of transition for young people to adult health services to provide evidence for best practice transitional care for children with complex health needs (Watson et al. 2011).The value of scoping reviews to evidence-based healthcare and practice lies in the examination of a broader area to identify gaps in the research knowledge base (Crilly et al. 2009, clarify key concepts (de Chavez et al. 2005), and report on the types of evidence that address and inform practice in the field (Decaria et al. 2012).

Due to the range of reasons why a scoping review may be conducted, it is important that reviewers clearly describe the rationale behind their particular scoping review within both the protocol and the review. This gives readers a clearer understanding of the importance of the topic and why a particular type of scoping review is being conducted.

10.1.2 Scoping reviews compared to other types of review

The synthesis of evidence in the form of the systematic review is at the center of evidence-based practice (Pearson et al. 2005).

Systematic reviews traditionally bring together evidence from quantitative literature to answer questions on the effectiveness of a specific intervention for a particular condition. Beyond effectiveness, JBI is also interested in the context of care delivery, its cost-effectiveness, as well as patient, carer and healthcare provider preferences. These foci are explored in terms of the appropriateness, meaningfulness, and feasibility of healthcare practices and delivery. These sorts of questions are most commonly answered by consideration of other forms of primary evidence found in qualitative and economic research studies. The results of well-designed research studies of any methodology are regarded by JBI as potential sources of credible evidence to inform healthcare practice and policy. To match this broader and more inclusive view of evidence, JBI has developed a number of methodologies and methods for the synthesis of evidence to support healthcare decision-making for a number of review types (Munn et al. 2018b).

All JBI knowledge syntheses – including scoping reviews – begin with the development of an *a priori* protocol with inclusion and exclusion criteria that relate clearly to the review question/s. A typical systematic review aims to answer a specific question (or series of questions) based on very precise inclusion criteria, for example, a systematic review may pose the following precise question based upon the PICO (Population, Intervention, Comparator, and Outcome) elements of its inclusion criteria (Marshall-Webb et al. 2018):

What is the effectiveness of Nissen fundoplication in comparison to anterior partial fundoplication (90 degree, 120 degree and 180 degree) and posterior 270 degree fundoplication in terms of symptom control of gastro-esophageal reflux disease, and what are the side effects of these surgical interventions?

It is clear from this question that only certain types of experimental evidence and data would be relevant and that the review will be very specific in terms of the population, intervention, comparator and outcomes against which it will determine effectiveness.

A scoping review will have a broader “scope” with correspondingly less restrictive inclusion criteria. The following question based upon the PCC (Population, Concept and Context; see Section 11.2) elements of the inclusion criteria may be posed (Kao et al. 2017a):

“What quality of life questionnaires are available for pediatric patients following tonsillectomies with or without adenoidectomies for chronic infections or sleep disordered breathing?”

The ‘population’ in this question is clearly specified (pediatric patients who have had tonsillectomies with or without adenoidectomies). The ‘concept’ in this example is also clear; the questionaries used to assess quality of life for pediatric patients after a tonsillectomy performed for the purposes of treating either chronic infection or sleep disordered breathing. While not explicit, the ‘context’ in this case is quite ‘open’ in the sense that the quality of life instrument may be used in any setting (primary health care, acute care, or even specialist psychological care or counselling).

An especially important point is that the scoping review may draw upon data from any source of evidence and research methodology, and is not restricted to quantitative studies (or any other study design) alone. This however is not prescriptive; reviewers may decide that particular study designs are beyond the scope of their review or not be appropriate or useful for consideration. For example, the protocol of the above example scoping review specifies that while any type of quantitative study design may be eligible for inclusion, as only psychometrically validated *quantitative* questionnaires were sought, qualitative and gray literature was not considered for inclusion; In this example however, reports from published randomized controlled trials were considered side by side with observational studies (Kao et al. 2017a). Because of the broad nature of scoping review questions, they are particularly useful for bringing together evidence from disparate or heterogeneous sources.

It is important to highlight the distinction between scoping reviews and “mixed methods” systematic reviews that also rely on evidence from different study designs (Lizarondo et al. 2017). While the aim of a scoping review is to determine what kind of evidence (quantitative and/or qualitative etc.) is available on the topic and to represent this evidence by mapping or charting the data, mixed methods systematic reviews are designed to answer a question or questions based on the synthesis of evidence from for example qualitative, and quantitative research.

When contrasting systematic reviews, scoping reviews and traditional literature reviews, the following table (Table 11.1) from Munn et al. 2018 may be useful (as are the comparisons available in Tricco 2018):

Table 11.1: Defining characteristics of traditional literature reviews, scoping reviews and systematic reviews

	Traditional Literature Reviews	Scoping reviews	Systematic reviews
A priori review protocol	No	Yes (some)	Yes
PROSPERO registration of the review protocol	No	No*	Yes
Explicit, transparent, peer reviewed search strategy	No	Yes	Yes
Standardized data extraction forms	No	Yes	Yes
Mandatory Critical Appraisal (Risk of Bias Assessment)	No	No**	Yes
Synthesis of findings from individual studies and the generation of ‘summary’ findings***	No	No	Yes

*Current situation; this may change in time, and we suggest registration/publication of scoping review protocols is critical. Examples of databases where scoping reviews may be registered are: is “Open Science Framework (https://osf.io/) ” and “Figshare (https://figshare.com/). **Critical appraisal is not mandatory, however, reviewers may decide to assess and report the risk of bias in scoping reviews depending on the purpose of the review. ***The use of statistical meta-analysis (for effectiveness, prevalence or incidence, diagnostic accuracy, aetiology or risk, prognostic or psychometric data), or meta-synthesis (experiential or expert opinion data) or both in mixed methods reviews is typically not conducted in a scoping review.

While recommendations or implications for research, including for primary research, other scoping reviews, or systematic reviews, may be generated from the results of a scoping review – especially those conducted with the objective of being precursors to systematic reviews (Anderson et al. 2008). Recommendations for practice are difficult due to the fact that a formal assessment of methodological quality of the included sources of evidence of a scoping review is generally not performed. In addition, a formal synthesis is not normally conducted in a scoping review (at least not in the same way for systematic reviews) and as such the methodology is not naturally aligned to establishing practice or policy recommendations. However, if recommendations for practice or policy are developed, it is expected that they will clearly flow from the objectives of the scoping review (Munn et al. 2018 a, b).

10.1.3 The scoping review framework

The framework originally proposed by Arksey and O’Malley (2005) has been influential in the conduct of scoping reviews. Their framework has been further enhanced by the work of Levac and colleagues (2010) (see Table 11.2). Levac and colleagues (2010) provide more explicit detail regarding what occurs at each stage of the review process and this enhancement increases both the clarity and rigor of the review process. Both of these frameworks have underpinned the development of the JBI approach to the conduct of scoping reviews (Peters et al. 2015).

Table 11.2: Scoping review frameworks

	Arksey and O’ Malley framework (2005, p. 22-23)	Enhancements proposed by Levac et al. (2010, p. 4-8)	*Enhancements proposed by Peters et al (2015, 2017, 2020).
1.	Identifying the research question	Clarifying and linking the purpose and research question	Defining and aligning the objective/s and question/s
2.	Identifying relevant studies	Balancing feasibility with breadth and comprehensiveness of the scoping process	Developing and aligning the inclusion criteria with the objective/s and question/s

3.	Study selection	Using an iterative team approach to selecting studies and extracting data	Describing the planned approach to evidence searching, selection, data extraction, and presentation of the evidence.
4.	Charting the data	Incorporating a numerical summary and qualitative thematic analysis	Searching for the evidence
5.	Collating, summarizing and reporting the results	Identifying the implications of the study findings for policy, practice or research	Selecting the evidence
6.	Consultation (optional)	Adopting consultation as a required component of scoping study methodology	Extracting the evidence
7.			Analysis of the evidence
8.			Presentation of the results
9.			Summarizing the evidence in relation to the purpose of the review, making conclusions and noting any implications of the findings

*Consultation of information scientists, stakeholders and/or experts throughout, including in the topic prioritization, planning, execution and dissemination

10.2 Development of a scoping review protocol

As with all well-conducted systematic reviews, an *a priori* protocol must be developed before undertaking the scoping review. A scoping review protocol is important, as it pre-defines the objectives, methods, and reporting of the review and allows for transparency of the process. The protocol should detail the criteria that the reviewers intend to use to include and exclude sources of evidence and to identify what data is relevant, and how the data will be extracted and presented. The protocol provides the plan for the scoping review and is important in limiting the occurrence of reporting bias. Any deviations of the scoping review from the protocol should be clearly highlighted and explained in the scoping review.

Prospective scoping reviewers should be aware that an extension of the PRISMA statement called the PRISMA-ScR is now available (Tricco et al. 2018). Appendix 10.2 to this chapter contains a fillable checklist for authors to check whether their scoping review conforms to this reporting standard. The JBI approach to conducting and reporting scoping reviews described here is congruent with the PRISMA-ScR checklist. Reviewers should also be aware that PROSPERO (the international prospective register of systematic reviews administered by the University of York's Centre for Reviews and Dissemination) states that scoping reviews (and literature reviews) are currently ineligible for registration in the database (Centre for Reviews and Dissemination, n.d. 'inclusion criteria', para. 5). Although this may change in the future, scoping reviews can be registered with the Open Science Framework (https://osf.io/) or Figshare (https://figshare.com/) in the meantime, or their protocols published in some journals, such as *JBI Evidence Synthesis*.

10.2.1 Title

The title should be informative and give clear indication of the topic of the scoping review. The title of a scoping review should always include the phrase "…:a scoping review" to allow easy identification of the type of document it represents.

10.2.2 Developing the title and question

Title of the scoping review protocol

The title of the protocol (and the subsequent review) should be informative and give a clear indication of the topic of the scoping review. It is recommended that the title should always include the phrase "…: a scoping review" to allow easy identification of the type of document it represents. Correspondingly, protocols should also be identified as such. Titles should not be phrased as questions. This is a simple example of a scoping review protocol title by Kao et al. 2017a:

"Pediatric tonsillectomy quality of life assessment instruments: a scoping review protocol"

A range of mnemonics for different types of review (and research) questions have been suggested. The "PCC" mnemonic is recommended as a guide to construct a clear and meaningful title for a scoping review. The PCC mnemonic stands for the Population, Concept, and Context. There is no need for explicit outcomes, interventions or phenomena of interest to be stated for a scoping review; however elements of each of these may be implicit in the concept under examination.

The title of the protocol (and subsequent review) should be structured to reflect the core elements of the PCC. Using the PCC mnemonic helps to construct a title that provides potential readers with important information about the focus and scope of the review, and its applicability to their needs. For example, if the review aims to map a range of quality of life instruments (concept) for pediatric patients (population) (Kao et al. 2017a) this should be stated in the title. Including the context in the title (if the context is a central focus of the review) can further help readers to position the review when they are searching for evidence related to their own particular information and/or decision-making needs.

As discussed in further depth below, there should be congruence between the title, review question /s, and inclusion criteria.

Scoping review question(s)

The scoping review question guides and directs the development of the specific inclusion criteria for the scoping review. Clarity of the review question assists in developing the protocol, facilitates effectiveness in the literature search, and provides a clear structure for the development of the scoping review. As with the title, the question should incorporate the PCC elements. A scoping review will generally have one primary question, e.g.

“What quality of life questionnaires are available for pediatric patients following tonsillectomies with or without adenoidectomies for chronic infections or sleep disordered breathing?”

If that question sufficiently addresses the PCC and adequately corresponds with the objective of the review, sub-questions will not be needed. However, some scoping review questions benefit from one or more sub-questions that delve into particular attributes of Context, Population or Concept. Sub-questions can be useful in outlining how the evidence is likely to be mapped. For example, the primary question above relates to the types of quality of life questionnaires; however, the further sub-questions could be posed to delve into potential particular issues relating to other important details, such as the population (or participants) of interest. For example:

“What are the ages of the pediatric patients where quality of life questionnaires have been or could be used within the sources of evidence identified for the primary review question?”

Likewise, a sub-question may help to justify mapping the evidence by context, e.g.

“In what geographical (i.e. countries) and clinical (i.e. primary care, acute care, etc.) contexts have the quality of life instruments included for the primary review question been used?”

10.2.3 Introduction

The introduction should be comprehensive and cover all the main elements of the topic under review. Due to scoping reviews being essentially exploratory, it is not expected that the background covers all the extant knowledge in the area under review. The reason for undertaking the scoping review should be clearly stated together with what the scoping review is intended to inform. The rationale of conducting a scoping review should be clearly articulated and stated in this section before stating the aim.

The suggested length for the introduction section of the scoping review protocol is approximately 1,000 words. This section should detail any definitions important to the topic of interest. The information in the introduction must also be sufficient to put the inclusion criteria in context, including an indication of whether or not there are existing scoping reviews, systematic reviews, research syntheses, and/or primary research papers available on the topic, hence supporting the rationale to conduct the scoping review. While the inclusion criteria section of the protocol (explained below) should contain clear details of each of the Population, Concept and Context elements, the introduction must provide sufficient detail in terms of the rationale for each element. Explaining for example, why only primary care settings are of interest in terms of the context of the review question above.

The introduction should conclude with a statement that a preliminary search for existing scoping reviews (and ideally systematic reviews too) on the topic has been conducted. The date of the search (es) and journals and databases searched and search platforms utilized must be stated,

e.g. JBI Evidence Synthesis, Cochrane Database of Systematic Reviews, Cumulative Index to Nursing and Allied Health Literature (CINAHL), PubMed, Evidence for Policy and Practice Information (EPPI), and Epistemonikos, where relevant. If existing scoping reviews or systematic reviews are available on the topic, a justification that specifies how the proposed review will differ from those already conducted should be detailed. This is so that readers can easily establish what new knowledge or insight the proposed review will contain in relation to existing evidence syntheses.

The introduction should conclude with an overarching review objective that captures and aligns with the core elements/mnemonic of the inclusion criteria (e.g. PCC). The objective of the scoping review should indicate what the scoping review project is trying to achieve. The objective may be broad and will guide the scope of the enquiry. For the title example above, the objective has been phrased:

“The objective of this scoping review is to investigate quality of life questionnaires available for pediatric patients following tonsillectomies with or without adenoidectomies for chronic infection or sleep-disordered breathing.”

10.2.4 Inclusion criteria

The “inclusion criteria” of the protocol details the basis on which sources will be considered for inclusion in the scoping review and should be clearly defined. These criteria provide a guide for the reader to clearly understand what is proposed by the reviewers and, more importantly, a guide for the reviewers themselves on which to base decisions about the sources to be included in the scoping review. As explained in Section 11.2.2, as for other review types, there must be clear congruence between the tile, question/s, and inclusion criteria of a scoping review.

Types of participants

Important characteristics of participants should be detailed, including age and other qualifying criteria that make them appropriate for the objectives of the scoping review and for the review question.

In some circumstances, participants *per se* are not a relevant inclusion criterion. For example, for a scoping review that is focused upon mapping the types and details of research designs that have been used in a particular field, it may not be useful or within scope to detail the types of participants involved in that research.

Concept

The core concept examined by the scoping review should be clearly articulated to guide the scope and breadth of the inquiry. This may include details that pertain to elements that would be detailed in a standard systematic review, such as the “interventions”, and/ or “phenomena of interest”, and/or “outcomes” (as relevant for the particular scoping review).

For example, the overarching concept of interest for the above scoping review is quality of life questionnaires that are used following tonsillectomies with or without adenoidectomies for chronic infection or sleep-disordered breathing.

Further elements of this overarching concept may be of importance to this review. For example, the format (e.g. paper or web-based) and contents (i.e. assessment domains) of the included instruments. The validity and reliability (i.e. if and how they have been psychometrically tested) may also be of interest for mapping.

Outcomes may also be a component of a scoping review’s “Concept”. If outcomes of interest are to be explained, they should be linked closely to the objective and purpose for undertaking the scoping review. For example, this scoping review could also identify and map the outcomes of quality of life assessments and/or the outcomes of the psychometric testing of the tools themselves.

Context

The “Context” element of a scoping review will vary depending on the objective/s and question/s of the review. The context should be clearly defined and may include, but is not limited to, consideration of cultural factors, such as geographic location and/or specific social, cultural, or gender-based interests. In some cases, context may also encompass details about the specific setting (such as acute care, primary health care or the community). Reviewers may choose to limit the context of their review to a particular country or health system or healthcare setting, depending on the topic and objectives.

The context of the review in the example provided above has not been stated explicitly (i.e. it could be described to be ‘open’) as sources of evidence pertaining to any contextual setting would be eligible for inclusion. However, a context could be imposed to refine the scope of the review in different ways. For example; only within middle-high income countries or only within primary care settings.

T*ypes of evidence sources*

For the purposes of a scoping review, the “source” of information can include any existing literature, e.g. primary research studies, systematic reviews, meta-analyses, letters, guidelines, websites, blogs, etc. Reviewers may wish to leave the source of information “open” to allow for the inclusion of any and all types of evidence. Otherwise, the reviewers may wish to impose limits on the types of sources they wish to include. This may be done on the basis of having some knowledge of the types of sources that would be most useful and appropriate for a particular topic. For example, the scoping review example on quality of life questionnaires available for pediatric patients following tonsillectomies with or without adenoidectomies for chronic infection or sleep-disordered breathing sought quantitative studies, specifically; experimental and epidemiological study designs including

randomized controlled trials, non-randomized controlled trials, quasi-experimental, before and after studies, prospective and retrospective cohort studies, case-control studies, and analytical cross-sectional studies. Qualitative studies, reviews, and conference abstracts were excluded.

10.2.5 Search Strategy

The search strategy for a scoping review should ideally aim to be as comprehensive as possible within the constraints of time and resources in order to identify both published and unpublished (gray or difficult to locate literature) primary sources of evidence, as well as reviews. Any limitations in terms of the breadth and comprehensiveness of the search strategy should be detailed and justified. As recommended in all JBI types of reviews, a three-step search strategy is to be utilized. Each step must be clearly stated in this section of the protocol. The first step is an initial limited search of at least two appropriate online databases relevant to the topic. The databases MEDLINE (PubMed or Ovid) and CINAHL would be appropriate for a scoping review on quality of life assessment tools. This initial search is then followed by an analysis of the text words contained in the title and abstract of retrieved papers, and of the index terms used to describe the articles. A second search using all identified keywords and index terms should then be undertaken across all included databases. Thirdly, the reference list of identified reports and articles should be searched for additional sources. This third stage may examine the reference lists of all identified sources or examine solely the reference lists of the sources that have been selected from full-text and/or included in the review. In any case, it should be clearly stated which group of sources will be examined. A statement should be included of the reviewers' intent to contact authors of primary sources or reviews for further information, if this is relevant. A search for gray (i.e., difficult to locate or unpublished) material might be necessary, and guidance exists on these search strategies. Finally, a complete search strategy for at least one major database should be included as an appendix to the protocol. McGowan et al. (2016) developed an evidence-based guideline for Peer Review of Electronic Search Strategies (PRESS) for systematic reviews, health technology assessments, and other evidence syntheses and recommended the main search to be done by a librarian and peer-reviewed by another librarian.

Reviewers should include the languages that will be considered for inclusion in the review as well as the timeframe, with an appropriate and clear justification for choices. Our strong recommendation is that there are no restrictions on source inclusion by language unless there are clear reasons for language restrictions (such as for feasibility reasons).

As the review question might be broad, authors may find that it is appropriate to search for all sources of evidence (e.g. primary studies and text/opinion articles) simultaneously with the one search strategy. This also depends on the relevance of the evidence sources to the topic under review and its objectives. This approach will lead to a greater sensitivity in the search, which is desirable for scoping reviews.

The search for a scoping review may be quite iterative as reviewers become more familiar with the evidence base, additional keywords and sources, and potentially useful search terms may be discovered and incorporated into the search strategy. If this is the case, it is of the utmost importance that the entire search strategy and results are transparent and auditable. The input of a research librarian or information scientist can be invaluable in designing and refining the search.

10.2.6 Source of evidence selection

The scoping review protocol should describe the process of source selection for all stages of selection (based on title and abstract examination; based on full-text examination) and the procedures for solving disagreements between reviewers. Selection is performed based on inclusion criteria pre-specified in the review protocol. For any scoping review, source selection (both at title /abstract screening and full-text screening) is performed by two or more reviewers, independently. Any disagreements are solved by consensus or by the decision of a third reviewer.

There should be a narrative description of the process accompanied by a flowchart of review process (from the PRISMA-ScR statement) detailing the flow from the search, through source selection, duplicates, full-text retrieval, and any additions from third search, data extraction and presentation of the evidence. The software used for the management of the results of the search should be specified (e.g. Covidence, Endnote, JBI SUMARI). Details of full-text articles retrieved should be given. There should be separate appendices for details of included and a brief mention of the excluded sources, and for excluded sources; reasons should be stated on why they were excluded. We recommend some pilot testing of source selectors prior to embarking on source selection across a team. This will allow the review group to refine their guidance or source selection tool (if one is being used). One framework for pilot testing is described below:

- Random sample of 25 titles/abstracts is selected
- The entire team screens these using the eligibility criteria and definitions/elaboration document
- Team meets to discuss discrepancies and make modifications to the eligibility criteria and definitions/elaboration document
- Team only starts screening when 75% (or greater) agreement is achieved

10.2.7 Data extraction

In scoping reviews, the data extraction process may be referred to as “data charting”. This process provides the reader with a logical and descriptive summary of the results that aligns with the objective /s and question/s of the scoping review.

A draft charting table or form should be developed and piloted at the protocol stage to record the key information of the source, such as author, reference, and results or findings relevant to the review question/s. This may be further refined at the review stage and the charting table updated accordingly. Some key information that reviewers might choose to chart are:

1. Author(s)
2. Year of publication
3. Origin/country of origin (where the source was published or conducted)
4. Aims/purpose
5. Population and sample size within the source of evidence (if applicable)
6. Methodology / methods
7. Intervention type, comparator and details of these (e.g. duration of the intervention) (if applicable). Duration of the intervention (if applicable)
8. Outcomes and details of these (e.g. how measured) (if applicable)
9. Key findings that relate to the scoping review question/s.

A template data extraction instrument for source details, characteristics and results extraction is provided in Appendix 10.1 of this chapter, which can be adapted by reviewers to use in their own scoping review protocols and reviews with citation to the JBI methodology guidance for scoping reviews.

For ease of reference and tracking, it is suggested that reviewers keep careful records to identify each source. As reviewers chart each source, it may become apparent that additional unforeseen data can be usefully charted. Charting the results can therefore be an iterative process whereby the charting table is continually updated. It is suggested that the review team become familiar with the source results and trial the extraction form on two or three sources to ensure all relevant results are extracted. This pilot step should be done by at least two members of the review team. This approach is favored by other authors on the conduct of scoping reviews (Arksey & O’Malley 2005; Armstrong et al. 2011; Valaitis et al. 2012). If this approach is not feasible, other approaches (such as one reviewer extracting and another verifying the data) can be considered. The most important thing is authors are transparent and clear in their methods regarding what and how they have extracted data. Once again, pilot testing is recommended.

10.2.8 Analysis of the evidence

There are many ways in which data can be analyzed and presented in scoping reviews. Whilst the next section discusses innovative ways to present the results in scoping reviews, this section discusses analysis of data extracted in scoping reviews.

It is important to point out that scoping reviews do not synthesize the results/outcomes of included sources of evidence as this is more appropriately done within the conduct of a systematic review. In some situations scoping review authors may choose to extract results and descriptively (rather than analytically) map them. For example, a scoping review may extract the results from included sources and map these but not attempt to assess certainty in these results or synthesize these in such a way as we would in systematic reviews.

For many scoping reviews, simple frequency counts of concepts, populations, characteristics or other fields of data will be all that is required. However, other scoping review authors may choose to perform more in-depth analyses, such as descriptive qualitative content analysis, including basic coding of data. This may result in scoping review results providing a summary of data coded to a particular category (i.e. coding and classifying interventions/strategies/behaviors to a behavioral change model or theory). For example, a scoping review on characteristics of indigenous primary health care service models (Harfield et al. 2018) performed content analysis techniques using NVivo as a way to code characteristics into overall categories. Principles of framework synthesis (where you may chart and sort findings/data from papers against an *a priori* identified framework) may also be useful in some scoping reviews (Davy et al. 2016; Carroll 2013; Glegg et al. 2018). It is important to note that qualitative content analysis in scoping reviews is generally descriptive in nature and reviewers should not undertake thematic analysis/synthesis (i.e. JBI’s meta-aggregative approach or meta-ethnographic approaches) as this would be beyond the scope of a scoping review and would more appropriately fit within the objectives of a systematic review of qualitative evidence/ qualitative evidence synthesis.

In terms of quantitative data, scoping review authors may choose to investigate the occurrence of concepts, characteristics, populations etc with more advanced methods than simple frequency counts. Whilst this in-depth type of analysis is not normally required in scoping reviews, in other scoping reviews (depending on the aim), review authors may consider some form of more advanced analysis depending on the nature and purpose of their review. It is unlikely that a meta-analysis or interpretive qualitative analysis will be required in scoping reviews.

The way data is analysed in scoping reviews is largely dependent on the purpose of the review and the author's own judgement. The most important consideration regarding analysis is that the authors are transparent and explicit in the approach they have taken, including justifying their approach and clearly reporting any analyses, and as much as possible planned and stipulated a priori.

10.2.9 Presentation of the results

At the time of protocol development, the reviewers should provide some plan for the presentation of results – for example, a draft chart, figure or table (Lockwood et al. 2019). It is recommended that the authors do plan carefully how they intend to present the data extracted from the sources of evidence. Planning at this stage is very useful for an initial sense of what sorts of data might be identified and how best to present that data in relation to the scoping review's objective and question/s. This may be further refined during the review process as the reviewers increase their awareness and consideration of the contents of all of their included sources.

The ultimate purpose of charting the data is to identify, characterize, and summarize research evidence on a topic, including identification of research gaps (Nyanchoka et al. 2019).The results of a scoping review may be presented as a map of the data extracted from the included papers in a diagrammatic or tabular form, and/or in a descriptive format that aligns with the objective/s and scope of the review. The elements of the PCC inclusion criteria may be useful to guide how the data should be mapped most appropriately. In the scoping review example described above, because the objective was to map quality of life questionnaires used for pediatric patients following tonsillectomies with or without adenoidectomies for chronic infection or sleep-disordered breathing, the data may be usefully mapped by a tabular presentation of how the different components of the PCC includes as shown below. Other examples of presenting data from a scoping review can be found below (Table 11.3).

Table 11.3: Example tabular presentation of data for a scoping review

Parameter	Results
Numbers of publications	1. Total number of sources of evidence 2. Total numbers between 2000 until 2016 (5 Sept) 3. Number of publications every year
Types of studies	1. Randomized controlled trials 2. Non-randomized controlled trials 3. Quasi-experimental studies 4. Before-and-after studies 5. Prospective cohort studies 6. Retrospective cohort studies 7. Case-control studies 8. Cross-sectional studies 9. Other quantitative studies
Population/s identified	1. Children 0-4 2. Children 5-7 3. Children 8-10 4. Children 11-13 5. Children 14-16 6. Children 17-18 7. Parent/s and/or caregivers 8. Health Care professionals 9. Not applicable 10. Services 11. Others (not classified in any of the above)
Quality of life domains	1. Physical 2. Emotional 3. Social 4. School/ learning/ education 5. Behaviour 6. Mental health 7. General health 8. Family 9. Speech 10. Other (not classified in any of the above)
Format/ number of items	1. Paper-based 2. Web-based 3. Mobile/tablet (e.g. App)

	4. Others

The tables and charts may also show results as: distribution of sources of evidence by year or period of publication (depends on each case), countries of origin, area of intervention (clinical, policy, educational, etc.) and research methods. A descriptive summary should accompany the tabulated and/or charted results and should describe how the results relate to the review objective/s and question/s.

The results can also be classified under main conceptual categories, such as: “intervention type”, “population” (and sample size, if it is the case), “duration of intervention”, “aims”, “methodology adopted”, “key findings” (evidence established), and “gaps in the research”. For each category reported, a clear explanation should be provided.

The examples below show various formats of charting the evidence depending on the scoping review question. In the first example (Figure 11.1), the authors aimed to clarify if intense sweeteners are effective tools to lower sugar consumption and maintain a healthy weight or, on the contrary, if these compounds promote weight gain (Mosdøl et al. 2018). This will result in identifying gaps where new systematic reviews or primary research are needed, including which hypotheses, types of intense sweeteners and outcomes that need further assessment.

In the second example (Figure 11.2), the authors were interested to map the types of family involvements in intensive care units and identify their level of involvement from passive to active (Olding et al. 2016. In this case, the authors used conventional content analysis to develop codes inductively through immersion with the text, deriving codes from the data itself rather than coding with preconceived categories.

In the third example (Figure 11.3), the authors used relational analysis to present their results. With this technique, all data from eligible sources were used to identify examples of an Integrated Knowledge Translation (IKT) approach or strategy, enabler, barrier, and outcome. This approach allowed gaps in the IKT literature to be identified (Gagliardi et al. 2015). These data were added to the IKT approaches or strategies, enablers, barriers, and outcomes identified in sources referenced in the background of this manuscript and then compiled in a summary of IKT conditions, influencing factors, and outcomes. This approach made clear what was known and not known about IKT interventions. To further understand knowledge gaps, the authors identified relationships between the characteristics of IKT strategies, contextual factors, and outcomes by categorizing IKT as used in eligible sources of evidence.

The fourth example (Figure 11.4) is derived from a scoping review by Pham et al. 2014. The authors provided an example of a bubble chart for results presentation. This method is frequently used in the engineering sector but could also be employed in many other disciplines. The size of each ‘bubble’ is representative of the number of sources of evidence published in each year.

	Evidence used					Intense sweeteners considered									Comparator					Outcomes presented						
	Primary studies																								
Reference	Human, observational	Human, experimental	Animal, experimental	Cell-cultures	Other reviews	Unspecified or grouped	Acesulfame K	Aspartame	Cyclamate	Saccharine	Sucralose	Stevia	Other	Sugar, other saccharides	Water	Intake levels	Nothing/placebo	Unclear	Body weight	Clinical outcomes	Energy/food intake	Appetite/hunger	Hormone secretion	Intestinal glucose absorption	Microbiome
Bellisle 2007 [31]	x	x	x			x								x	x	x	x		x		x	x			
Mattes 2009 [3]	x	x	x			x	x	x		x	x			x	x		x		x		x	x	x		
Yang 2010 [2]	x	x	x			x	x	x		x	x			x	x		x		x		x	x			
EFSA 2011 [32]	x	x			x	x		x						x					x						
Pepino 2011 [33]	x	x	x	x		x	x	x		x	x	x		x		x	x	x	x	x	x		x	x	x
Sylvetsky 2011 [34]	x	x	x	x		x		x		x	x			x	x	x			x		x	x	x		
Andersen 2012 [35]	x	x			x	x								x		x		x	x		x				
Brown 2012 [36]	x	x	x			x	x	x		x	x	x	x	x	x	x	x	x					x	x	x
Raben 2012 [37]	x	x			x	x	x	x		x	x	x		x	x				x	x	x	x	x		
Swithers 2013 [38]	x	x				x		x			x	x		x	x				x	x			x		
Araurjo 2014 [39]	x	x	x		x	x	x	x		x	x			x		x	x	x	x	x	x		x	x	x
Ferreira 2014 [40]	x	x	x			x		x						x	x	x	x		x		x	x			
Freswick 2014 [41]	x	x				x	x	x			x			x	x		x		x		x				
Gardner 2014 [42]	x	x				x		x						x	x	x	x	x	x	x	x				
Bellisle 2015 [43]	x	x				x								x	x		x					x			
Bruke 2015 [44]	x	x	x			x	x	x			x		x					x					x	x	x
Fernstrom 2015 [45]	x	x	x			x	x	x		x	x	x		x	x	x	x		x			x			
Pepino 2015 [46]	x	x	x	x	x	x	x	x		x	x	x		x	x	x	x			x			x	x	x
Roberts 2015 [47]	x	x				x								x	x				x	x	x	x	x		
Swithers 2015 [48]	x	x	x		x	x		x		x	x			x	x		x	x	x				x		x
Fowler 2016 [49]	x	x	x			x	x	x	x	x	x			x		x	x		x		x				
Glendinning 2016 [50]			x		x	x		x						x			x		x		x		x		x
Nettleton 2016 [51]	x	x	x			x		x		x	x				x	x	x		x	x	x	x	x	x	x
Peters 2016 [52]	x	x	x		x	x		x						x	x	x			x		x	x			
Shearer 2016 [53]	x	x	x		x	x		x		x	x				x	x	x	x	x				x	x	x
Swithers 2016 [54]	x	x	x		x	x				x				x	x				x				x		x

Figure 11.1: Example of data presentation (artificial sweeteners and weight loss/ gain). (Mosdøl et al. 2018)

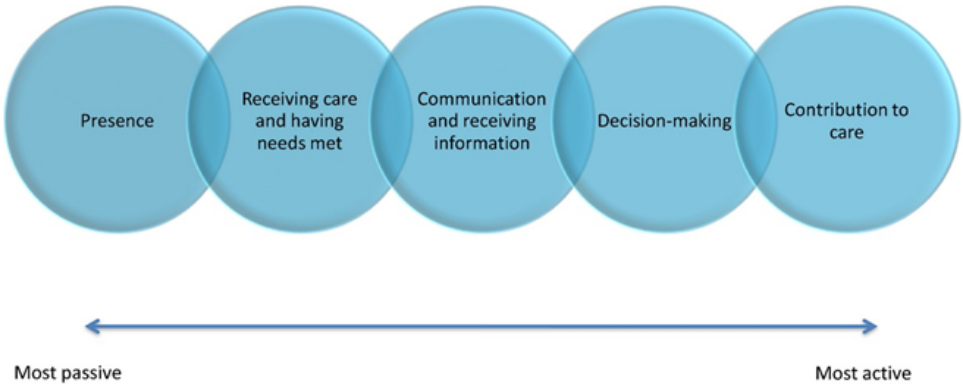


Figure 11:2: Example of data presentation (types of family involvements in intensive care units and level of involvement from passive to active). (Olding et al. 2016)

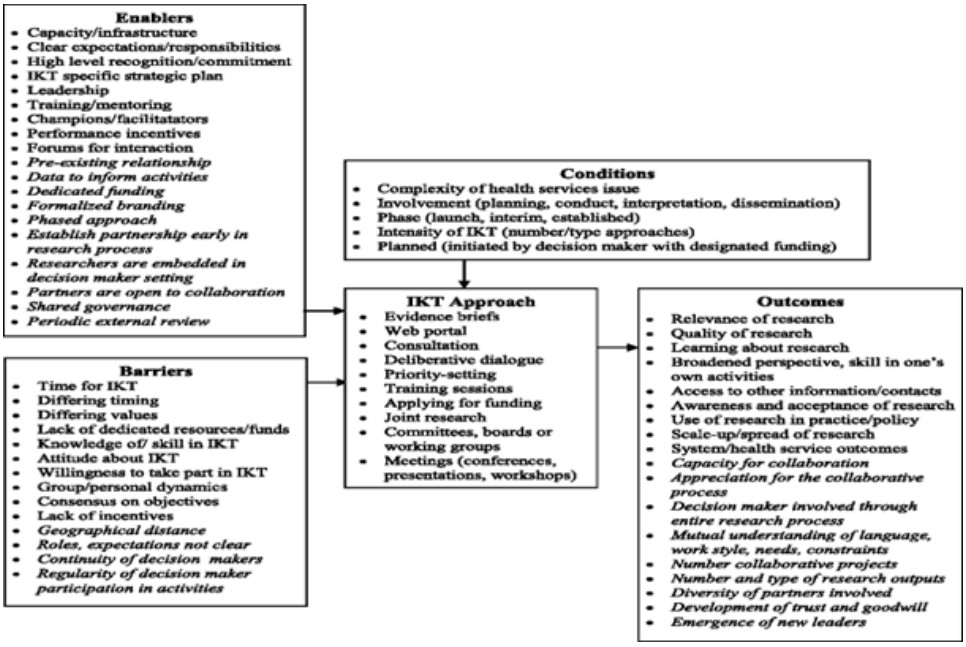


Figure 11.3: Example of data presentation (IKT approaches or strategies, enablers, barriers, and outcomes). (Gagliardi et al. 2015)

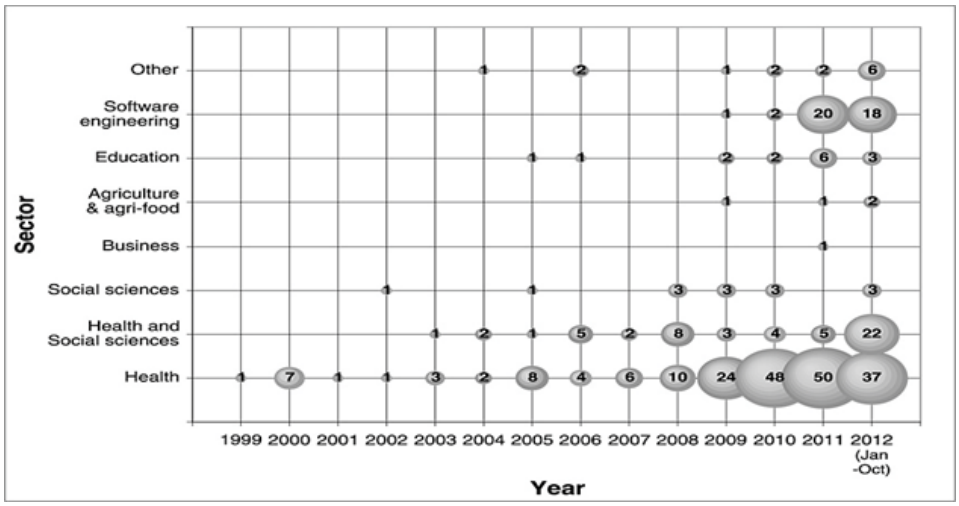


Figure 11:4: Example of data presentation (sources of evidence published by year) (Pham et al 2014)

10.3 The scoping review and summary of the evidence

This section provides further guidance on the components that should comprise the final report of a scoping review and the information that each component should contain. It illustrates how each component of the review is to be managed in the scoping reviews analytical module of JBI's System for the Unified Management, Assessment and Review of Information (SUMARI) software. For authors submitting to *JBI Evidence Synthesis*, please refer closely to the author guidelines available on the *JBI Evidence Synthesis* website.

Specifically, guidance is provided on the following components: outline of the review, inclusion criteria (i.e. PCC), search strategy, extraction, presenting and summarizing the results, and any potential implications of the findings for research and practice. For a traditional systematic review, while deviations from a published review protocol are rare, due to the more iterative nature of a scoping review, some changes may be necessary. These must still be clearly detailed and justified in the methods section of the scoping review if and when they occur.

Please note that more detailed guidance for the conduct of scoping reviews is outlined in the protocol section of this chapter.

10.3.1 Title of the scoping review

The title should be clear, explicit and reflect the core elements of the review. Titles should not be phrased as questions or conclusions and there should be congruence between the title, review objective/question/s, and inclusion criteria. The title should include the phrase: "…: a scoping review ". The title should not be more than 25 words for ease of understanding (see example above in Section 11.2.2).

10.3.2 Review authors

Affiliations for each author need to be stated, including the JBI affiliation of each reviewer (if relevant). A valid email address must be provided as contact details for the corresponding author.

10.3.3 Abstract

This section forms a structured abstract of the main features of the scoping review. The abstract should accurately reflect and summarize the review with the main focus on the results of the review. Refer to the author guidelines of the journal you plan to submit for journal related guidance.

The abstract should report the essential elements of the review using the following sub-headings in this order:

- **Objective**: State an overarching review objective structured using the key components of the inclusion criteria (approximately one to two sentences).
- **Introduction**: Briefly describe what the issue is under review and what is already known on the topic (approximately two to three sentences).
- **Inclusion criteria:** Summarize the inclusion criteria as it relates to the type of review being conducted. Present the information in one or two sentences – **NOT** under individual subheadings.
- **Methods:** List the key information sources searched (those that provided the majority of included sources of evidence), any limits placed on the scope of the search (e.g. language), and the date

range, or the date of the last search. If the recommended JBI approach (i.e. this chapter) to source selection, data extraction, and the presentation of the data was used. (Alternatively, briefly describe any notable deviations to the methodological approach taken).

- **Results**: The bulk of the abstract should be reserved to convey the main results of the review.
  - As a general rule, report the number and type of included sources and participants, as well as any pertinent source characteristics.
  - Report the main findings and results that have been charted in relation to the review's objective and question/s.
- **Conclusions**: Articulate brief overall conclusions based on the scoping review findings. This should be articulated in a way that directly responds to the objective and question/s of the scoping review. Briefly convey key implications for practice and/or research (if made).

10.3.4 Introduction

The introduction should be comprehensive and cover all of the main elements of the topic under review, as well as important information and why the topic or question of interest lends itself to a scoping review with a clear rationale for conducting the scoping review. The primary objective of the scoping review should be evident in this section as the introduction situates the justification and importance of the question/s posed. While many of these details will already have been addressed in the "Introduction" section of the protocol, reviewers should find that the background information provided with the protocol needs modification or extension following the conduct of the scoping review which now introduces the results of the review project. The introduction should conclude with a statement that a preliminary search for previous scoping reviews (and ideally, systematic reviews) on the topic aligning to the same concept was conducted (state the sources searched e.g. JBI Evidence Synthesis, The Cochrane Database of Systematic Reviews, Campbell Library, etc.).

The introduction should conclude with an overarching review objective that captures and aligns with the core elements/mnemonic of the inclusion criteria (e.g. PCC).

10.3.5 Review question(s)

The primary questions(s) addressed by the scoping review should be stated. It can be followed by sub-questions that relate to differing conceptual foci contained in the scoping review, such as, participant groups, interventions or outcome measures or a more in depth understanding of a particular phenomenon of interest or concept. (See example above in Section 11.2.2)

10.3.6 Inclusion Criteria

This section of the scoping review specifies the basis upon which sources were considered for inclusion in the scoping review. This section should necessarily be as transparent and unambiguous as possible. The inclusion criteria for a scoping review will be contingent on the question/s posed. The PCC should be stipulated (Population, Concept, and Context).

Types of participants

The types of participants in the sources of evidence sought for inclusion should be related to the objectives of the scoping review. The reasons for the inclusion or exclusion of particular participants detailed in this section should be explained clearly in the introduction section of the scoping review.

Concept

The core concept examined by the scoping review should be clearly articulated to guide the scope and breadth of the inquiry. This may include details that pertain to the "interventions" and/or "phenomena of interest" that would be explained in greater detail in a systematic review.

Outcomes may also be a component of a scoping review's "Concept". If outcomes of interest are to be explained, they should be linked closely to the objective and the purpose for undertaking the scoping review.

Context

Context will vary depending on the objective/s and question/s of the review. The context should be clearly defined and may include, but is not limited to, consideration of cultural factors, such as geographic location and/or specific racial or gender-based interests. In some cases, context may also encompass details about the specific setting (such as acute care, primary health care or the community).

Types of sources of evidence

The types of sources of evidence to be included in the scoping review should be explained. 'Sources of evidence ' can include any existing literature, e.g. primary research studies, systematic reviews, meta-analyses, letters, guidelines, etc. The source of information may be left "open" to allow for the inclusion of any, and all sources of evidence and rationale for this should be provided. Otherwise, any limits imposed on the types of studies should be detailed and explained. For example, some sources of evidence such as text and opinion papers and letters would not be particularly appropriate or useful in order to meet the objectives and answer the question(s) of particular scoping reviews.

10.3.7 Methods

This section of the review report is reserved for the methods used to conduct the review and should be presented under the relevant subheadings (See Sections 11.3.7.1 - 11.3.7.4), including any deviations from the method outlined in the *a priori* protocol. A reference to the published or publicly available protocol should be clearly included and cited in this section. In empty reviews for example, this section should not refer to methods that were not performed.

Directly below the Methods heading provide the following information:

- State and appropriately cite the JBI methodology that was employed in the conduct of the review and synthesis.
- Refer to and cite the *a priori* protocol that was either publicly available, published, or accepted for publication/'in press' (e.g. in *JBI Evidence Synthesis*).

An example:

"The objectives, inclusion criteria and methods for this scoping review were specified in advance and documented in a protocol." (citation)

10.3.7.1 Search strategy

This section documents how the reviewers searched for relevant sources of information for inclusion in the scoping review. The search strategy must be comprehensively reported and the detailed search strategy for all of the major bibliographic citation databases and other sources that have been searched should be appended to the review. The individual search strategies for every database searched should be presented in sequence and in a consistent format in an Appendix. Clear documentation of the search strategy is a vital component of the scientific validity of any scoping review with justification of the dates of the search included in the protocol. A scoping review should ideally consider sources of evidence (primary studies, textual papers and reviews) both published and unpublished (gray literature). The time frame (start and end dates) chosen for the search should be clearly justified and any language restrictions specified (e.g. "only sources of evidence published in English were considered for inclusion"). Any hand searching of particular relevant journals should be detailed with the journal names and years examined. Author contact, for example, to request access to known but unavailable sources of evidence should also be included along with the outcomes of that contact.

10.3.7.2 Source of evidence screening and selection

The review should describe the actual process of source of evidence screening and for all stages of selection (based on title and abstract examination; based on full-text examination) and the actual procedures used for solving disagreements between reviewers.

10.3.7.3 Data extraction

Extraction of results for a scoping review should include extraction of all data relevant to inform the scoping review objective/s and question/s. Charting table or forms may be used (see Appendix 10.1 for a template tool). A descriptive summary of the main results organized based on the review inclusion criteria must be included. Examples of extraction fields are identified below.

Author/year

Citation details should be consistent throughout the document. The citation details include the name of the first author (Vancouver referencing style) and year of publication.

Objective/s

A clear description of the objective of the paper should be stated.

Participants (characteristics/total number)

The defining characteristics of the participants in included sources should be provided. This includes demographic details and total numbers.

Concept

Data from included sources of evidence in relation to the concept should be extracted and mapped. The concept examined by the scoping review will vary depending on the review, and should be clearly articulated to guide the scope and breadth of the inquiry. This may include details that pertain to the "interventions" and/or "phenomena of interest" that would be explained in greater detail in a systematic review. Outcomes may also be a component of a scoping review's "Concept". If outcomes of interest are to be explained, they should be linked closely to the objective and the purpose for undertaking the scoping review.

Context

Details of the context, such as location of care (acute, primary health care, community, long term care, etc.) or a particular geographical location, should be described. Cultural, social, ethnic, or gender factors may be relevant.

10.3.7.4 Analysis and Presentation of results

The authors should clearly articulate the method(s) used to present the results of the review. These may be a map of the data extracted from the included papers in a diagrammatic or tabular form, and /or in a descriptive format that responds to the questions of the review.

The tables and charts may also show results as: distribution of sources of evidence by year or period of publication (depends on each case), countries of origin, area of intervention (clinical, policy, educational, etc.) and research methods. A descriptive summary should accompany the tabulated and/or charted results and should describe how the results relate to the review objective/s and question/s.

The results can also be classified under main conceptual categories, such as: “intervention type”, “population” (and sample size, if it is the case), “duration of intervention”, “aims”, “methodology adopted”, “key findings” (evidence established), and “gaps in the research”. For each category reported, a clear explanation should be provided.

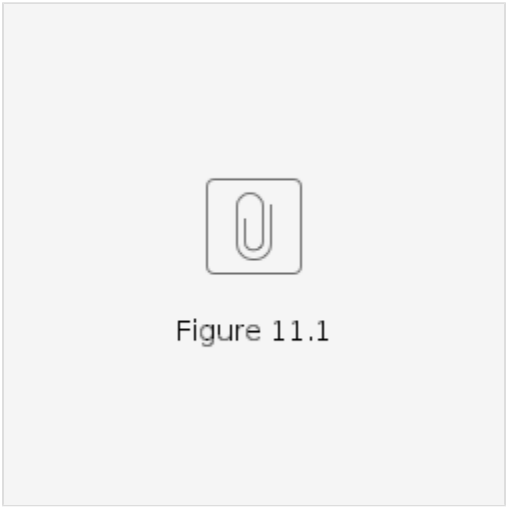
10.3.8 Results

10.3.8.1 Search results

The presentation of results section should identify how many sources of evidence were identified and selected. There should be a narrative description of the search decision process accompanied by the source of evidence identification and inclusion decision flowchart (see Figure 11.1 below). This flowchart has been adapted from the PRISMA flowchart developed by Moher et al. (2009). The flow chart should clearly detail the review decision process, indicating the results from the search, removal of duplicate citations, source selection, full retrieval and additions from a third search, and final summary presentation.

The narrative summary should logically describe the aims or purposes of the reviewed sources, concepts adopted and results that relate to the review question/s.

The results may be classified under main conceptual categories such as: “intervention type”, “population” (and sample size, if it is the case), “duration of intervention”, “aims”, “methodology adopted”, “key findings” (evidence established) and “gaps in the research”. For each category, a clear explanation should be provided.



10.3.8.2 Inclusion of sources of evidence

This section should include an overall description of the included sources with reference to the detailed Table of Included Source of Evidence Characteristics in the appendices (the template data extraction tool in Appendix 10.1 can be readily modified by reviewers to suit this purpose). The aim of this section is to provide detail to support the inclusion of each source (paper, study, report, etc.) in the scoping review. For each source, identify the relevance to the scoping review objective and evidence for the review question. Specific results from sources may be highlighted. A summary table of included sources of evidence should be provided in the appendices of the scoping review.

10.3.8.3 Review findings

Presentation of the results may map out the reviewed material in logical, diagrammatic or tabular form, and/or in a descriptive format that aligns specifically with the objective and scope of the review. The tables and charts may show results as: distribution of sources by year or period of publication (depends on each case), countries of origin, area of intervention (clinical, policy, educational, etc.), and research methods.

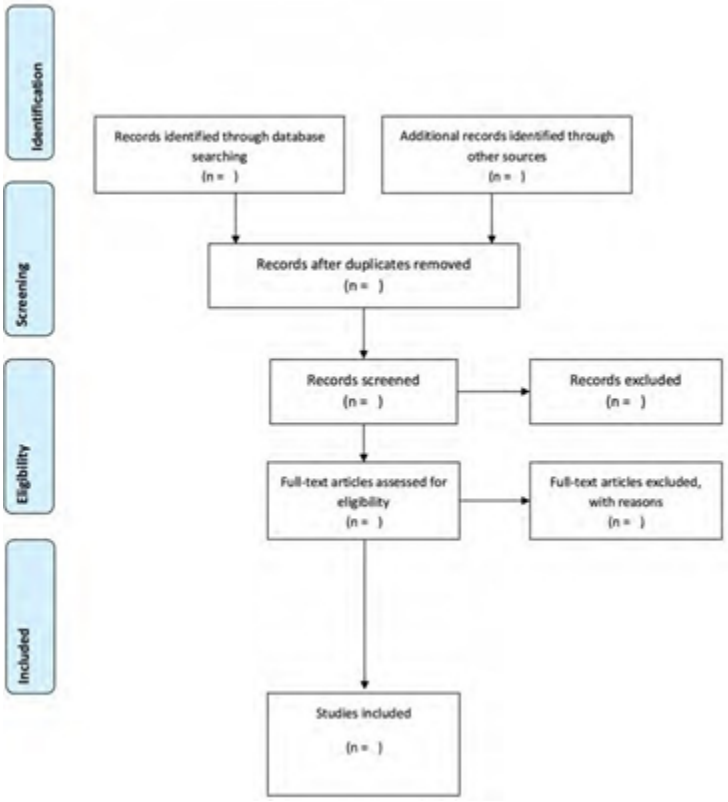


Figure 11.5: Flow diagram for the scoping review process adapted from the PRISMA statement by Moher and colleagues (2009)

10.3.9 Discussion

This section should discuss the results of the review as well as any limitations of the sources included in the scoping review; it should not repeat the results of the review. Results should be discussed in the context of current literature, practice and policy. Scoping reviews are subject to the limitations of any review, relevant sources of information may be omitted and the review is dependent on information on the review question being available. In a scoping review no rating of the quality of evidence is provided, therefore implications for practice or policy cannot be graded.

10.3.10 Conclusions and recommendations

Conclusions

This section should begin with an overall conclusion based on the results. The conclusions drawn should match the review objective/s and question/s.

Implications of the findings for research

This sub-section of the conclusions should include clear, specific implications for future research based on gaps in knowledge identified from the results of the review. Authors may be able to make comments about the future conduct of systematic reviews that may be appropriate, or primary research in the area of interest.

Implications of the findings for practice

If implications for practice are made (note, scoping reviews do not tend to include implications for practice) this sub-section of the conclusions should refer and align to results from the scoping review that can be used to inform practice. It may not be possible to develop implications for practice from the results of a scoping review as no assessment of methodological quality and formal synthesis takes place as part of a scoping review. As such this section may be omitted.

10.3.11 Conflicts and acknowledgements

Details of requirements in these sections are described in Section 1.6. of this Manual.

Conflicts of interest

A statement which either declares the absence of any conflicts of interest or which describes a specified or potential conflict of interest should be made by the authors in this section.

Funding

Authors should provide details regarding any sources of funding for the review project. The role of all funders in the review process, if any, should be explicitly described. If the review is funded, then any potential conflicts of interest or intellectual bias of the funders should be specified in the review. Sources of funding of included sources in the scoping review may also be stated.

Acknowledgements

Any acknowledgements should be made in this section. Acknowledgements should be reserved to individuals who have contributed to the manuscript yet whose contribution does not constitute authorship. Details of the contribution should be included, for example conceptualization, review of draft and feedback. It should also be noted if the scoping review is to count towards a degree award.

10.3.12 References

For publication in the *JBI Evidence Synthesis*, all references should be listed in full using the Vancouver referencing style, in the order in which they appear in the review. Abbreviated journal titles must be used in accordance with the United States National Library of Medicine (2016).

10.3.13 Review appendices

Appendices should be numbered using Roman numerals in the order in which they have been referred to in the body of the text. While reviewers may choose to develop additional appendices for details that are unfeasible to present in the main body of the report, there are three required appendices for a JBI scoping review:

Appendix I: Search strategy

A detailed search strategy for all sources searched must be appended.

Appendix II: Sources excluded following full-text review

A list of sources excluded following full-text review with primary reasons for exclusion

Appendix III: Data extraction instrument

The data extraction instrument used must be appended (see the template in Appendix 11.1)

10.4 Chapter references

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Appendix 10.1 JBI template source of evidence details, characteristics and results extraction instrument

Scoping Review Details	
Scoping Review title:	
Review objective/s:	
Review question/s:	
Inclusion/Exclusion Criteria	
Population	
Concept	

Context	
Types of evidence source	
Evidence source Details and Characteristics	
Citation details (e.g. author/s, date, title, journal, volume, issue, pages)	
Country	
Context	
Participants (details e.g. age/sex and number)	
Details/Results extracted from source of evidence (in relation to the concept of the scoping review)	
E.g. Quality of Life Domains assessed	
E.g. Number of items in tool	
E.g. details of psychometric validation of tool	

Appendix 10.2 PRISMA ScR Extension Fillable Checklist

The below checklists can be downloaded for review authors to refer to when reporting scoping reviews to ensure they are in line with the PRISMA scoping reviews extension.

Update: Implications of PRISMA 2020 for the reporting of Scoping Reviews

Currently, those that undertake Scoping Reviews are asked to use the PRISMA extension for Scoping Reviews reporting guidance.[1] In 2021, the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement was updated from its 2009 version.[2] The changes, whilst necessary to ensure increased transparency and rigour in reporting for systematic reviews, has had some implications for scoping reviews. Since the PRISMA 2020 statement, the following changes can be considered when reporting a scoping review using the PRISMA ScR (table 1):

Table 1: PRISMA- ScR with associated changes

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	CHANGES TO CONSIDER SINCE PRISMA 2020	REPORTED ON PAGE #
	TITLE			
Title	1	Identify the report as a scoping review.		Click here to enter text.
	ABSTRACT			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	Use the abstract reporting checklist (see Item 2 in PRISMA 2020)	Click here to enter text.
	INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.		Click here to enter text.
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.		Click here to enter text.
	METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	Report any protocol amendments (see item 24 in PRISMA 2020)	Click here to enter text.
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.		Click here to enter text.
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.		Click here to enter text.
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	Include the full search strategies for **all** databases, registers, and websites (see item 7 in PRISMA 2020)	Click here to enter text.

Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	Describe if automation tools were used for study selection (see item 8 in PRISMA 2020)	Click here to enter text.
Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	If outcomes were included, describe how they were defined and which results were sought (see item 10 in PRISMA 2020)	Click here to enter text.
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.		Click here to enter text.
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).		Click here to enter text.
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.		Click here to enter text.
	RESULTS			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	Use the updated PRISMA 2020 flow diagram, which has optional boxes for review updates, as well as studies that were identified through means other than searching databases /registers and cite any studies that appeared to meet the inclusion criteria but were excluded (see item 16 in PRISMA 2020)	Click here to enter text.
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.		Click here to enter text.
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).		Click here to enter text.
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.		Click here to enter text.
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.		Click here to enter text.
	DISCUSSION			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.		Click here to enter text.
Limitations	20	Discuss the limitations of the scoping review process.		Click here to enter text.
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as		

		potential implications and/or next steps.		Click here to enter text.
	FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	Report conflicts of interest (see item 26 in PRISMA 2020)	Click here to enter text.
	OTHER CONSIDERATIONS			
In addition, a new item was included in PRISMA 2020, which recommends reporting where data and other materials from the review are publicly available (see item 27 in PRISMA 2020), which can be included when reporting a scoping review.				

* Where sources of evidence (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites. † A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with information sources (see first footnote). ‡ The frameworks by Arksey and O'Malley and Levac and colleagues refer to the process of data extraction in a scoping review as data charting. JBI Guidance uses the term data extraction. § The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

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Scoping Review Resources

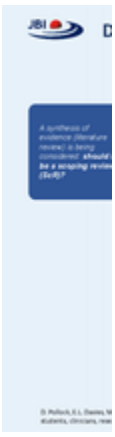
Digital Resources

Knowledge User Engagement

An Infographic regarding using JBI Guidance for Scoping Reviews and knowledge user engagement

The Big Picture Review Family

Infographic: Scoping Reviews, Mapping Reviews, and Evidence and Gap Maps explained



A synthesis

How to Extract, Analyse and Present Data in Scoping Reviews

This presentation provides a practical approach to extracting, analysing and presenting data within scoping reviews, with step-by-step examples

How to conduct and report your scoping review: latest guidance

Assoc Prof Andrea Tricco explains how to conduct and report your scoping review using the latest guidance in this one-hour JBI LIVE webinar

Watch the r

Steps for scoping reviews

We break down the process of beginning and completing a scoping review using JBI methodology. These are the steps you should know before beginning your scoping review

Should I undertake a scoping review or a systematic review?

Our expert at JBI, Prof Zachary Munn, answers scoping review FAQs

Publications

What are scoping reviews? Providing a formal definition of scoping reviews as a type of evidence synthesis

Munn et al 2022

Scoping reviews have been variously defined in the literature. In this article, we provide the following formal definition for scoping reviews: Scoping reviews are a type of evidence synthesis that aims to

Recommendations for the extraction, analysis, and presentation of results in scoping reviews

Pollock et al 2023

Scoping reviewers often face challenges in the extraction, analysis, and presentation of scoping review results. Using best-practice examples and drawing on the expertise of the JBI Scoping
Review Methodology Group and an editor of a journal that
publishes scoping reviews, this paper expands on existing JBI scoping review guidance. The aim of this article is to clarify the process of

Best practice guidance and reporting items for the development of scoping review protocols

Peters et al 2022

The purpose of this article is to clearly describe how to develop a

systematically identify and map the breadth of evidence available on a particular topic, field, concept, or issue, often irrespective of source (ie, primary research, reviews, non-empirical evidence) within or across particular contexts.	extracting data from different sources of evidence; discuss what data should be extracted (and what should not); outline how to analyze extracted data, including an explanation of basic qualitative content analysis; and offer suggestions for the presentation of results in scoping reviews.	robust and detailed scoping review protocol, which is the first stage of the scoping review process. This paper provides detailed guidance and a checklist for prospective authors to ensure that their protocols adequately inform both the conduct of the ensuing review and their readership.
Conducting high quality scoping reviews-challenges and solutions Khalil et al 2021 In this paper, the JBI Scoping Review Methodology Group discuss the challenges that may be faced in the conduct and publishing of scoping reviews, such as developing an a-priori protocol, developing implications or recommendations for research, policy or practice and a lack of understanding of scoping reviews by journal editors, authors and peer reviewers. It presents solutions to these challenges to ensure	**Moving from consultation to co-creation with knowledge users in scoping reviews: guidance from the JBI Scoping Review Methodology Group** Pollock et al 2022 This paper presents JBI's guidance for knowledge user engagement in scoping reviews based on the expert opinion of the JBI Scoping Review Methodology Group. We offer specific guidance on how this can occur and provide information regarding how to report and evaluate knowledge user engagement within scoping reviews.	**Updated methodological guidance for the conduct of scoping reviews** Peters et al 2021 The latest JBI scoping review guidance is described with this article. There is an updated section on when to conduct a scoping review, the role of methodological appraisal in scoping reviews and inclusion of

better understanding of the process of scoping reviews.		the PRISMA-SCR reporting guidelines.
PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation Tricco et al 2018 Even though a scoping review is not considered systematic. An extensive search still needs to be undertaken to ensure that all available evidence is included within your review. This articles describes how you should report on that search in your publications.	**Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach** Zachary Munn, Micah D. J. Peters, Cindy Stern, Catalin Tufanaru, Alexa McArthur & Edoardo Aromataris Have you ever had trouble deciding what type of review you should do? This paper will help you decide and assess if a scoping review is the right choice for research.	

External Methodological Guidance

The following external synthesis methodologies have been endorsed for adoption by the JBI Scientific Committee as follows:

Systematic reviews of prevalence and incidence

The PERSyst (Prevalence Estimates Reviews – Systematic Review Methodology Group) is an academic, collaborative group, with the aim to develop and to disseminate methods for systematic reviews of prevalence and cumulative incidence. Methodological articles published by the group can be found here: https://persyst.group/ . Although this is an external methodology JBI's synthesis software, JBI SUMARI, can support reviews of this nature.

Systematic reviews of diagnostic test accuracy

The *Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy* is the official guide that describes in detail the process of preparing and maintaining systematic reviews of test accuracy for Cochrane. The *Handbook* has been produced by the Cochrane Screening and Diagnostic Test Methods Group. It is a guide for those conducting systematic reviews of test accuracy and a reference for more experienced authors and is available at: https://training.cochrane.org/handbook-diagnostic-test-accuracy

Systematic reviews of measurement properties

Consensus based Standards for the selection of health Measurement Instruments (COSMIN) is an initiative of an international multidisciplinary team of researchers with a background in epidemiology, psychometrics, medicine, qualitative research, and healthcare who have expertise in the development and evaluation of outcome measurement instruments. A comprehensive user manual for systematic reviews of outcomes measurement instruments is available on the COSMIN website: https://www.cosmin.nl/tools/guideline-conducting-systematic-review-outcome-measures/

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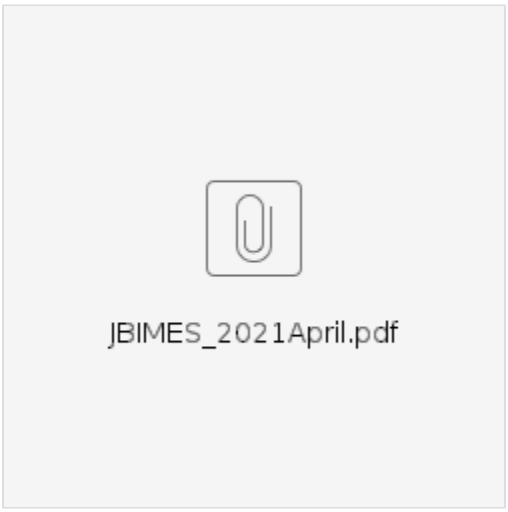

June 2020

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