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Joanna Briggs Institute
Reviewers' Manual
2014 Edition

Joanna Briggs Institute Reviewers' Manual: 2014 edition

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The Joanna Briggs Institute
The University of Adelaide
South Australia 5005

AUSTRALIA

ABN: 61 249 878 937

Phone: +61 8 8313 4880

Fax: +61 8 8313 4881

Email: jbi@adelaide.edu.au

Web: www.joannabriggs.org

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Prepared for the Joanna Briggs Institute by the Synthesis Science Unit.

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Foreword

The Joanna Briggs Institute (JBI) is now in its eighteenth year of operation and has grown into an international not-for-profit research and development organization within the Faculty of Health Sciences at the University of Adelaide.

We collaborate internationally with over 80 entities across the world who subscribe to our definition of what constitutes evidence and our methodologies and methods in relation to evidence synthesis. The Institute and its collaborating entities promote and support the synthesis, transfer and utilisation of evidence through identifying feasible, appropriate, meaningful and effective healthcare practices to assist in the improvement of healthcare outcomes globally.

Our major role is the global translation of research evidence into practice. We work closely with the Cochrane Collaboration and the Campbell Collaboration and encourage the conduct of reviews of effects (involving the meta-analysis of the results of randomized controlled trials) through Cochrane Review Groups.

Our strength is in the conduct of systematic reviews of the results of research that utilize other approaches, particularly qualitative research, economic research and policy research. This broad, inclusive approach to evidence is important when the association between health care and social, cultural and economic factors is considered.

It is highly recommended that all reviewers, associate reviewers and potential reviewers read this handbook in conjunction with the user guide for the relevant analytical modules of JBI-SUMARI and JBI-CReMS.

We highly value the contribution of reviewers to the international body of literature used to inform clinical decision-making at the point of care. It is important that this work continues and is distributed in a variety of formats to both those working in and using health systems across the world. We hope that this work will contribute to improved global health outcomes.

A handwritten signature in black ink, reading 'A. Pearson', with a long horizontal line extending from the bottom of the signature.

Professor Alan Pearson AM

Executive Director

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“The results came back negative. You won’t ‘just die’ if you don’t get that new designer handbag.”

Introduction:

Purpose of this manual

The JBI Reviewers' Manual is designed to provide authors with a comprehensive guide to conducting JBI systematic reviews. It describes in detail the process of planning, undertaking and writing up a systematic review of qualitative, quantitative, economic, text and opinion based evidence. It also outlines JBI support mechanisms for those doing review work and opportunities for publication and training. The JBI Reviewers Manual should be used in conjunction with the JBI SUMARI User Guide.

Planning a JBI systematic review

The JBI Database of Systematic Reviews and Implementation Reports (JBI-SRIR) contains reviews produced by the Joanna Briggs Collaboration and other reviewers in the area of evidence-based practice. Systematic reviews within the JBI-SRIR focus on the feasibility, appropriateness, meaningfulness and effectiveness of health care interventions. The target audience for JBI Systematic Reviews are academics and health professionals from across the health disciplines, including nurses, doctors and allied health professionals. The JBI-SRIR accepts for peer review (and publication) the following review types:

- systematic reviews of primary research studies (quantitative, qualitative, health economic evaluation);
- comprehensive systematic reviews (a systematic review which considers two or more types of evidence, quantitative, qualitative, health economic evaluation, textual evidence);
- systematic reviews of text and opinion data;
- overview of reviews ('umbrella reviews' or systematic reviews of systematic reviews); and
- scoping reviews.

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. A JBI review requires a minimum of two reviewers to conduct a systematic review: a primary and secondary reviewer. One of these reviewers needs to have been trained in the JBI approach to systematic review, although it is ideal when all reviewers have undergone training. Consideration of expertise in the topic and the systematic review process are needed when planning to undertake a systematic review. Representation from clinical specialties and consumers is recommended where the review is being undertaken by systematic reviewers rather than topic experts and support from a statistician is recommended when conducting a quantitative review.

Some preliminary investigation of the literature is recommended to determine if studies are available on the topic of interest, while potential 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.

Reviewers are encouraged to register their review title. This enables other centres and reviewers to identify topics that are currently in development and avoids accidental duplication of topics. Once registered, a title is valid for six months from the date of entry in the database. Should a protocol not be completed within that time-frame for a nominated topic, the topic becomes de-registered and available to any other JBI entity whose members may wish to conduct the review. A review title becomes registered with JBI on completion of the title registration form. The form is shown in (Appendix I). The form should be downloaded from the website and once complete, it should be emailed to the synthesis science unit (SSU). Once titles become registered with JBI, they are listed on the website:

http://joannabriggs.org/research/registered_titles.aspx

Protocols and reviews should be submitted to the JBI Library for publication in the *JBI Database of Systematic Reviews and Implementation Reports*.

<http://www.joannabriggslibrary.org/jbilibrary/index.php/jbisrir/index>

JBI entities that do not have access to a range of electronic databases to facilitate searching of published and unpublished literature are encouraged to contact the JBI Collaboration liaison officer regarding access to the University of Adelaide's Barr Smith Library to enable them to access an increased range of electronic resources.

JBI Reviewers

Reviewers from the Joanna Briggs Collaboration who have undergone JBI Comprehensive Systematic Review (CSR) training (or equivalent Cochrane or Campbell Collaboration systematic review training) are eligible to submit a JBI systematic review. A reviewer can submit through the following JBI entities:

- Collaborating Centres;
- Affiliate Centres;
- Evidence Synthesis Groups (ESGs); or
- JBISRIIR directly as a Remote Reviewer.

At least one Reviewer should have completed the JBI CSR training program or equivalent systematic review training programs (Cochrane or Campbell) within the last two years, and been an active contributor to the development of systematic reviews for JBI. If this is not possible, at least the first or second reviewer should have completed the JBI training program. JBI keeps a record of who has undergone JBI CSR training.

Reviewers associated with a JBI entity should be listed as core staff or affiliate members of that entity on the JBI website. Students undertaking systematic reviews through a collaborating entity should also be listed as core staff or affiliates in the same way. There is no similar requirement for remote reviewers, who should submit protocols directly to JBISRIIR.

Review authors are required to list their JBI affiliation (i.e. Centre details) on the protocol.

- ***The Reviewers affiliation with a JBI Centre/ESG must be stated on Protocols and Systematic Reviews in order to be considered Centre output.***

Initiating a new JBI review

The Joanna Briggs Institute System for the Unified Management, Assessment and Review of Information (SUMARI) is the Institute's premier software for the systematic review of literature. It is designed to assist researchers and practitioners in fields such as health, social sciences and humanities to conduct systematic reviews of evidence of

- feasibility
- appropriateness
- meaningfulness
- effectiveness

SUMARI includes the Comprehensive Review Management System (CReMS) software, designed to assist reviewers manage and document a review by incorporating the review protocol, search results and findings. CReMS links to four analytic modules of SUMARI:

- JBI Qualitative Assessment and Review Instrument (QARI)
- JBI Meta-Analysis of Statistics Assessment and Review Instrument (MAStARI)
- JBI Narrative, Opinion and Text Assessment and Review Instrument (NOTARI)
- JBI Analysis of Cost, Technology and Utilisation Assessment and Review Instrument (ACTUARI).

Before reviewers are able to use any of the JBI SUMARI modules or CReMS, they need to register for access and obtain a username and password. Individuals who wish to access the JBI SUMARI software should visit:

<http://www.nursingcenter.com/evidencebasedpracticenetwork/Home/JBI@LWW.aspx> at the Lippincott Evidence Based Practice Network to obtain login details.

JBI CONnect+ members who wish to access the JBI SUMARI software should login to JBI CONnect+ (www.jbiconnectplus.org) and follow the JBI@LWW link. To submit your protocol or review for feedback to the JBI Library, you will need to register for access as an author, which is free and can be done via the JBI library website.

<http://www.joannabriggslibrary.org/jbilibrary/index.php/jbisrir/index>

JBI reviews require both a primary and a secondary reviewer. The primary reviewer leads the review and has access to the protocol in CReMS, as well as the selected analytical modules. The secondary reviewer is assigned by the primary reviewer and has access to the selected analytical modules only. The technical aspects of setting up a JBI systematic review is the same for whichever type of evidence is to be examined and is covered in detail in the SUMARI user guide.

- ***Reviewers are required to submit draft protocols and systematic reviews using CReMS. The program generates an .rtf document which can be submitted online at the JBI library page.***

Comprehensive systematic reviews

A systematic review is considered to be a comprehensive systematic review when it includes two or more types of evidence, such as both qualitative and quantitative, in order to address a particular review objective. Reviewers do this by utilizing multiple modules of the SUMARI software.

JBIMethodological Development

The Joanna Briggs Institute and staff are continuously reviewing their methodology for systematic reviews based on the needs of healthcare professionals and trends in the international literature. A number of methodological groups have been formed to develop guidance regarding emerging areas of evidence synthesis. The guidance developed by these groups will be included in future editions of this manual once complete. Methodological guidance developed by these groups is available via the JBI website. <http://joannabriggs.org/index.html>

Current methodological groups include:

1. The synthesis of evidence of effects (JBI MASTARI)
2. The synthesis of qualitative evidence (JBI QARI)
3. The synthesis of text and opinion (JBI NOTARI)
4. The synthesis of economic evidence (JBI ACTUARI)
5. The synthesis evidence related to prevalence and incidence (New Analytical Module)
6. Methodology for Mixed method reviews (New Analytical Module)
7. Methodology for Umbrella/Overview reviews (New Analytical Module)
8. The synthesis of evidence related to prognosis (New Analytical Module)
9. The synthesis of evidence related to diagnosis (New Analytical Module)
10. The synthesis of evidence related to correlational data (New Analytical Module)
11. Methodology for Scoping Reviews (New analytical Module).

Roles of primary, secondary and associate reviewers

When using a SUMARI module, the primary and secondary reviewers have distinct roles, particularly in relation to critical appraisal, determining study inclusion and data extraction. The primary reviewer initiates the review in SUMARI, setting up the name of the review (title) and allocating the secondary reviewer, plus any associate reviewers. In leading the review, the primary reviewer also:

- assigns the secondary reviewer to the JBI review;
- is able to add, edit or delete their own reviews;
- determines the time frame of the review;
- critically appraises potentially includable papers;
- provides an overall appraisal of papers following critical appraisal by the secondary reviewer;
- conducts the primary data extraction from included papers; and
- extracts data (with, in most cases, the secondary reviewer) from included papers.

Before a secondary reviewer can work on a project they must be assigned to the review, either when the review is created or later by the primary reviewer. A secondary reviewer assesses every paper selected for critical appraisal, and assists the primary reviewer in conducting the review.

Associate reviewers may also be added to each review and there is no limit on the number of associate reviewers. Associate reviewers contribute to the intellectual progress and directions of reviews, in discussion with the primary and secondary reviewers. Associate reviewers may be selected for content or process expertise either in the approach to reviews being adopted, or in the topic of the review itself, or for other reasons that facilitate the conduct of the review. An associate reviewer can also mediate in circumstances where there are differences in opinion between the primary and secondary reviewer.

Review Panels

It is recommended that review panels are established on commencement of a new systematic review, or on the update of an existing systematic review. The review panel should consist of experts in review methods (i.e. persons who have completed JBI or Cochrane systematic review training), experts in the content area (i.e. nationally or internationally recognized experts in the field of research and/or practice), together with a lay/consumer representative. The type of knowledge needed for a particular review may vary according to the topic and scope of the review. It is recommended that the review panel meet throughout the progress of the project – either face-to-face or via teleconference, as appropriate. Suggested key stages of panel input are:

- prior to submission of the protocol to the JBI Library;
- prior to submission of the report in its first draft; and
- prior to submission of the report in its final draft.

The names, contact details and areas of speciality of each member of the review panel should be included in both the protocol and the report.

Identifying and developing topics for systematic review

All JBI entities have their own areas of interest and expertise and this allows them to focus on specific topics for review. In order to avoid duplication, reviewers are advised to register their review title as mentioned previously. 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 Joanna Briggs Institute Library of Systematic Review Protocols, Joanna Briggs Institute Library of Systematic Reviews, Cochrane Library, MEDLINE, PROSPERO and DARE databases will assist to establish 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 the date of last update longer than three years ago?
- Do the methods reflect the specific criteria of interest for your topic?
- Is there a specific gap in terms of population or intervention outcome that has not been addressed in the identified review?

All Centres and ESGs are required to develop processes to determine priority areas for review.

Topics for systematic reviews conducted by JBI entities may be sourced from within the centre, from the constituency that the centre represents, or topics may be specified by grant or tender opportunities. Centres may use a variety of techniques to identify relevant needs from their jurisdiction and to target their review program at specific areas of health.

Developing a systematic review question

Once a topic has been identified, a focussed, answerable question is developed. This question is reflected in the review title and is specified in detail in the review objective section of the protocol. The review title should provide as much detail as possible to allow effective cataloguing on electronic databases. 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.

A range of mnemonics is available to guide the structuring of systematic review questions, the most common for quantitative reviews being PICO. The PICO mnemonic begins with identification of the Population, the Intervention being investigated and its Comparator and ends with a specific Outcome(s) of interest to the review. A specific mnemonic (PICo) for qualitative reviews has also been developed which identifies the key aspects Population, the phenomena of Interest, and the Context.

The level of detail incorporated into each aspect of a mnemonic will vary, and consideration of the following will assist reviewers to determine the appropriate level of detail for their review. The population may be the primary focus of interest (for example, in reviews examining gender-based phenomena such as smoking or alcohol use among women) and may further specify an age group of interest or a particular exposure to a disease or intervention.

In quantitative reviews, the intervention(s) under consideration need to be transparently reported and may be expressed as a broad statement such as 'the management of...', or framed as a statement of 'intervention' and 'outcome' of interest. Comparators may include placebos and/or alternative treatments. In qualitative reviews, the interest relates to the experience of a particular phenomenon (for example, men's experience of healthy living).

Comparators (or controls) should be clearly described. It is important to know what the intervention is being compared with. Examples include: usual care, placebo or alternative treatments.

In quantitative reviews, outcomes should be measurable and chosen for their relevance to the review topic and research question. They allow interpretation of the validity and generalizability of the review findings. Examples of outcomes include: morbidity, mortality, quality of life. Reviewers should avoid the temptation of being too vague when determining review outcomes. In identifying which outcomes will be specified, it is useful to consider the interests of the target audience of the review findings, the impact that having a large number of outcomes may have on the scope and progress of the review, the resources (including time) to be committed to the review and the measurability of each specified outcome.



Does the planned JBI review have a clear, concise title that covers all of the PICO elements of the review? Does the planned JBI review have a primary and secondary reviewer?

The systematic review protocol

A systematic review protocol is important because it pre-defines the objectives and methods of the systematic review. It is a systematic approach to the conduct and report of the review that allows transparency of process, which in turn allows the reader to see how the findings and recommendations were arrived at. The protocol details the criteria the reviewers will use to include and exclude studies, to identify what data is important and how it will be extracted and synthesized. A protocol provides the plan or proposal for the systematic review and as such is important in restricting the presence of reporting bias. Any deviations between the protocol and systematic review report should be discussed in the systematic review report. Additionally, it is recommended that all JBI systematic reviews should contain a sentence clearly indicating:

'The objectives, inclusion criteria and methods of analysis for this review were specified in advance and documented in a protocol. Ref' (The reference should be to the appropriate citation in JBI Database of Systematic Reviews and Implementation Reports, and provide a registration number in PROSPERO where applicable).

This sentence should appear as the final line of the background/introduction section of the review report. This complies with the recommendations for reporting of systematic reviews detailed in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

As with other international organizations, JBI advocates for, and expects standardization in, systematic review development as part of its mission to enhance the quality and reliability of reviews being developed across an international collaboration. To facilitate this process, JBI has developed the SUMARI computer software.

As mentioned previously, SUMARI includes the CReMS software, designed to assist reviewers to manage and document a review by incorporating the review protocol, search results and findings. Reviewers are required to undertake systematic reviews using CReMS software and the SUMARI user guide is a recommended reference for technical aspects of creating a JBI review.

Registering systematic review protocols

Once a topic has been identified and the title registered, the protocol should be submitted for peer review to the JBI Database of Systematic Reviews and Implementation Reports. The protocol is a plan for the proposed systematic review and comprises of a set format that is detailed below. Protocols are to be submitted online to the JBI Library <http://www.joannabriggslibrary.org/jbilibrary/index.php/jbisrir/index>.

The PRISMA guidelines

The Joanna Briggs Institute endorses the PRISMA statement, which provides guidance on items for reporting in systematic reviews and meta-analyses. PRISMA stands for Preferred Reporting Items for Systematic Reviews and Meta-Analyses. The full PRISMA statement can be located at the PRISMA website: <http://www.prisma-statement.org/>

Hierarchy of study designs

For each type of evidence there are assigned JBI levels of evidence. The web link for the JBI Levels of Evidence can be found at: <http://joannabriggs.org/jbi-approach.html#tabbed-nav=Levels-of-Evidence>

The aim of assigning levels of evidence is to provide an estimate of ‘trustworthiness’ of the findings of the review. For quantitative studies at least, JBI Levels of Evidence are based on how the study design limits risk of bias – not so much the quality of the individual report itself, as that will be determined during critical appraisal, not the levels of evidence.

JBI levels of evidence are discussed in a later section of this manual and can be found on the JBI website, but are largely based on how the studies included in the review were conducted and reported.

The hierarchy of study designs has led to a more sophisticated hierarchy or levels of evidence, on the basis of the best available evidence.¹ Several international organizations generate levels of evidence and they are reasonably consistent. Each JBI systematic review will have levels of evidence associated with its findings, based on the types of study design included in the review that support each finding.

<http://joannabriggs.org/jbi-approach.html#tabbed-nav=Levels-of-Evidence>

Note: Current methodological opinion related to qualitative review does not require any distinction between critical or interpretive studies; therefore the choice regarding types of studies is the decision of the reviewer. The inclusion of studies from across paradigms or methodologies does not ignore the philosophic traditions of the approach but aims to integrate the richness of the qualitative traditions in order to capture the whole phenomenon of interest.

Grades of recommendation

In JBI systematic reviews, Grades of Recommendation are assigned to each recommendation under the implications for practice section. Further information can be found at: www.joannabriggs.org/jbi-approach.html#tabbed-nav=Grades-of-Recommendation

The current JBI Grades of Recommendation are:

| JBI Grades of Recommendation | |
|------------------------------|---|
| Grade A | A ‘strong’ recommendation for a certain health management strategy where it is clear that desirable benefits outweigh undesirable benefits of the strategy; where there is evidence of sufficient quality supporting its use; where there is a benefit or no impact on resource use, and values, preferences and the patient experience have been taken into account. |
| Grade B | A ‘weak’ recommendation for a certain health management strategy where desirable benefits appear to outweigh undesirable benefits of the strategy, although this is not as clear; where there is evidence supporting its use, although this may not be of high quality; where there is a benefit, no impact or minimal impact on resource use and values, preferences and the patient experience may or may not have been taken into account. |

Chapter One:

Qualitative evidence and evidence-based practice

The science of systematic review development for quantitative reviews of effects has broad scientific consensus; however, the same cannot be said across the field of methods for qualitative synthesis. The normative values ascribed to systematic reviews of quantitative data have varyingly been challenged, adopted, rejected, or transposed 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 that claim to have a good fit with the needs and expectations of evidence to inform health care decision-making. Meta aggregation is a method of systematic review that mirrors the processes of a quantitative review whilst holding to the traditions and requirements of qualitative research (it aggregates findings into a combined whole that is more than the sum of the individual findings in a way that is analogous with meta-analysis). In this section, the terms meta-aggregation, aggregative review, and meta-synthesis are considered analogous terms for the JBI approach to qualitative systematic review. The term meta-aggregation is the formal name for methodology; however, aggregative review, aggregative synthesis or meta-synthesis have the same meaning in this manual.

Qualitative evidence or qualitative data allows researchers to analyze human experiences and cultural and social phenomena.⁹ 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.¹⁰ 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'.¹¹

In the health care 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'.¹²

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.¹³ 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'.¹⁴

Qualitative evidence and healthcare

Qualitative methods and data are increasing in usage in evidence-based health care 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 health care 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 to exploring the ideas and concerns people who smoke tobacco may have about their smoking habits or the drivers and motivations that compel people who smoke tobacco to continue smoking.¹⁴

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 aspects such 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.'*¹⁵

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 in understanding 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 health care conditions is increasing. As an example, the Guidance for Undertaking Reviews in Health Care published by the Centre for Reviews and Dissemination at the University of York in 2009 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.¹⁶

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.¹⁷⁻¹⁹ 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.¹⁸

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 major 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 following chapter) 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 seeks to understand. The critical paradigm, like the interpretive, is inductive; however it aims to emancipate knowledge and practice.

Each paradigm is associated with 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 1.

Table 1: A summary of qualitative philosophy, methodologies and methods

| Paradigm/ philosophy to structure knowledge and understanding | Methodologies | Data collection methods |
|--|---|--|
| Interpretivism <i>Seeks to understand</i> <i>Sees knowledge in the possession of the people</i> | 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 |

| Paradigm/ philosophy to structure knowledge and understanding | Methodologies | Data collection methods |
|---|---|--|
| Critical enquiry <i>Seeks to change</i> | <p>Action research: Involves researchers participating with the researched to effect change</p> <p>Feminist research: Seeks to create social change to benefit women</p> <p>Discourse analysis: Assumes that language socially and historically constructs how we think about and experience ourselves, and our relationships with others</p> | <p>Participative group work Reflective journals Group processes Field work (Quantitative methods can be used in addition to qualitative methods)</p> <p>Qualitative in-depth interviews Focus groups (Quantitative methods can be used in addition to qualitative methods)</p> <p>Study of communications, written text and policies</p> |

Alan Pearson, Suzi Robertson-Malt, Leslie Rittenmeyer, Synthesizing Qualitative Evidence, Synthesis Science in Healthcare Series: Book 2, Lippincott-Joanna Briggs Institute, Australia.

Qualitative textual analysis

There is no hierarchy of evidence among methodologies for qualitative studies. A JBI Meta aggregative systematic review does not require any distinction between critical or interpretive studies. The units of analysis in qualitative papers are the findings, presented as themes, metaphors or concepts as identified by the researchers (not the reviewer). Accordingly, JBI reviews include a range of methodological studies in order to capture the whole phenomenon of interest rather than merely a one dimensional aspect.

The rationale for this is that the traditions of the methodology associated with a particular paper 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 have had a significant impact on the development of methods for qualitative synthesis. It has been proposed that this may in part be 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.²⁰

This is no less appropriate in qualitative synthesis. Indeed, in 2007, Sandelowski and Barroso, 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 (pg XV).²¹ 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 amongst qualitative researchers themselves, based on philosophical and methodological differences between the different qualitative research approaches.^{22,23}

Of the views that characterise 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.

The JBI approach to meta-synthesis

The JBI model of meta-synthesis 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.²⁴

Meta Aggregation is the Institute's methodology for meta synthesis, while the JBI Qualitative Assessment and Review Instrument (QARI) computer software was developed specifically to facilitate the methods for the meta-aggregation of qualitative research. The JBI 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 JBI approach is that it seeks to enable generalizable **statements in the form of recommendations to guide practitioners and policy makers**.²⁵ As such, the JBI approach 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.
- Textual Narrative Synthesis is useful in drawing together different types of research evidence (e.g. qualitative, quantitative, economic).
- 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-QARI software is designed to facilitate meta-aggregation however it can be used successfully in meta-ethnography and other interpretive processes as a data management tool.

The core assumptions detailed in this guide 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 standardized data extraction.
- Synthesis of findings that authentically represents the aggregation of data from primary studies.
- Presentation of a QARI-view graph that represents the findings and their aggregation into categories, and the aggregation of categories into synthesized findings.
- The development of recommendations for policy or practice with assigned grades of recommendation.

Definitions

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.

Category:

- A category is a brief description of a key concept arising from the aggregation of two or more similar findings in the presence of 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.

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.

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

The QARI-view graph on the following page illustrates a complete synthesis of findings; the aggregation of findings in to categories; and the development of synthesized findings and their descriptions. The illustrations for findings, and the descriptions for categories are embedded in the software, while the description for a synthesized finding is listed with the synthesized finding. Levels of credibility are attributed to each finding are parenthesizedized in brackets.

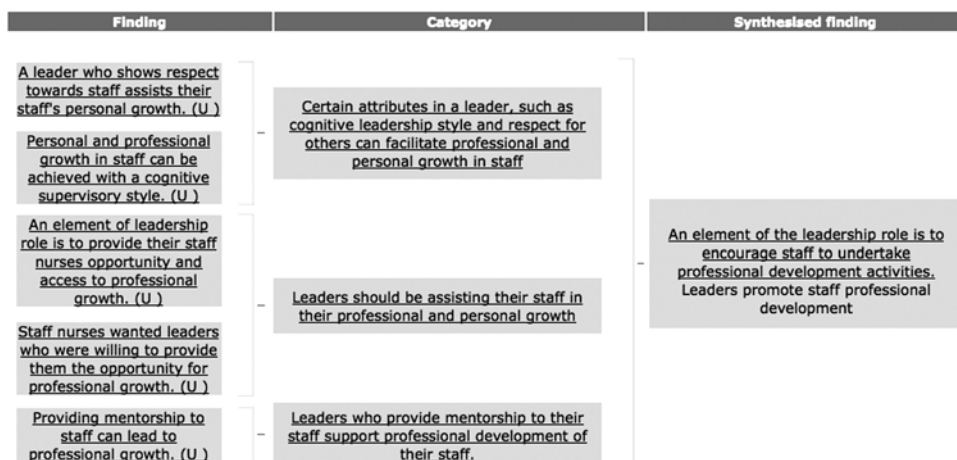


Figure 1: Example QARI-view graph with aggregation of like findings in to categories, and development of a synthesized finding from like categories

Chapter Two:

Qualitative protocol and title development

Protocol design for reviews of qualitative evidence

Title page

A JBI review requires at least two reviewers. The names of the reviewers, together with their post nominal qualifications, contact details and JBI affiliation, should be listed on the title page of the protocol.

Title of systematic review protocol

Although a range of mnemonics have been described for different types of review (and research) questions, it is suggested the PICo mnemonic also be used to construct a clear and meaningful title for a JBI systematic review of qualitative evidence. The PICo mnemonic has been used to frame this section on qualitative reviews. It stands for the Population, the Phenomena of Interest and the Context.

There is no need for an outcome statement in qualitative synthesis. The expression of the phenomena of interest is the outcome; therefore a specific outcome section or statement is not recommended in meta-aggregation.

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 needs to include the phrase 'A systematic review protocol'. The title of the protocol should be structured and reflective of the core elements of the PICo. If the review is examining meaning or lived experience this should be stated in the title. If a specific phenomena of interest is to be examined this should also be included in the title. Including the context in the title assists readers to situate the review when searching for evidence related to particular information needs.

The PICo mnemonic can provide potential readers with a significant amount of information about the focus, scope and applicability of a review to their needs.

Take note of the call out boxes that illustrate each element of the PICO and how they are structured within the examples below:

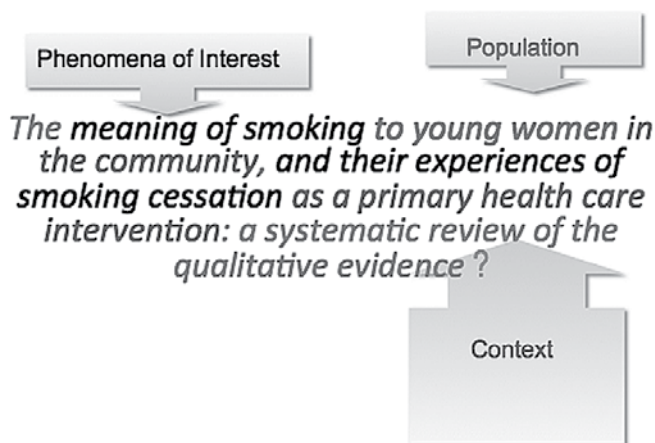


Figure 2: PICO mnemonic of the experience of a primary health care intervention

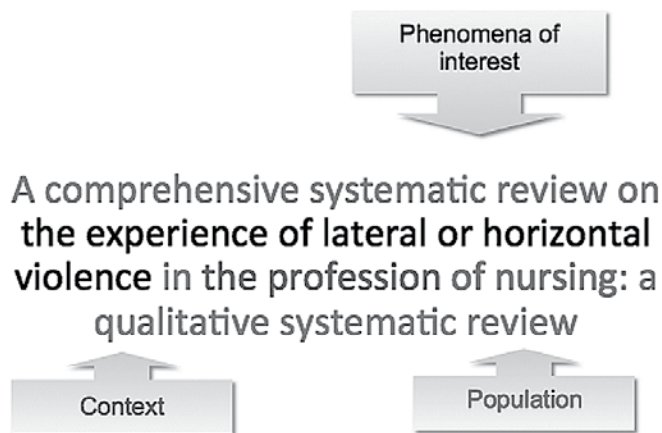


Figure 3: PICO mnemonic of a professional phenomena for review

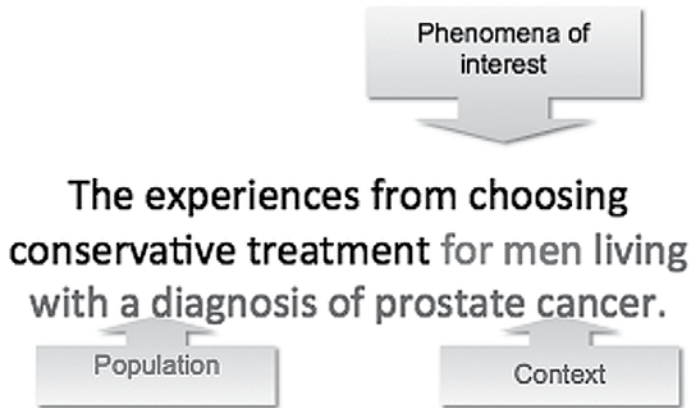


Figure 4: PICo mnemonic of experiences arising from decisions made following a diagnosis

Reviewers

Each reviewer should have post-nominal qualifications listed. Affiliations for each author need to be stated, including the affiliation with a JBI Collaborating Centre. An email address for the corresponding author needs to be provided.

Review question

The question/s guide and direct the development of the specific review criteria. Clarity in the review questions assists in developing a protocol, facilitates more effective searching, and provides a structure for the development of the full review report.

- ***As with the title, the question will incorporate the PICo elements, but will be framed as a question instead of as a statement.***

A qualitative review will have a primary question. If that question sufficiently addresses the PICo, there is no need for 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 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:

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?

Background

The Joanna Briggs Institute places significant emphasis on a clear and meaningful background section for every systematic review. 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 background should describe and situate the phenomena of interest under review, including the population and context. More specifically, the background should clearly describe the phenomena of interest and the context within which it is situated for an international readership. The purpose of the background is to:

- Situate the PICO
- Provide context to the review
- Define key terms and list operational definitions
- Put the inclusion criteria into context
- Refer to existing international literature to support and inform the inclusion criteria
- Justify the conduct of the review.

The background section should cover the main elements of the topic under review. The background is not a literature review, nor should it be longer than the discussion.

Citing research findings to support the conduct of a review is helpful. However, the purpose of the review is to provide conclusive synthesized evidence. Therefore, findings from single studies should not be considered authoritative. Avoid synthesizing findings from multiple authors in the background given this is exactly what your review will achieve.

The following example illustrates how best to cite research in the background:

Avoid this:

'Young women were found to take up cigarette smoking as an expression of independence or a sign of self confidence.'

This is what the review will determine. This type of statement should be reworded to make it clear that it is not the reviewer's conclusion but that of a third party, for example:

'Smith indicates young women were found to take up cigarette smoking as an expression of independence or a sign of self confidence'.

The background section should conclude with a statement that a preliminary search for existing systematic reviews on the topic have been/will be conducted (state the databases searched e.g. JBI Library, Cochrane Library, CINAHL, PubMed, PROSPERO where relevant). If there is an existing systematic review, it should be specified how the proposed review will differ. The Vancouver referencing style should be used throughout the protocol with superscript numbers without brackets used for in-text citations.



Questions to consider:

Does the background cover all the population, phenomenon of interest and the context for the systematic review? Are operational definitions provided? Do systematic reviews already exist on the topic? Why is this review important?

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.

Types of participants

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

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

- Age ranges (29-75)
- 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).
- Describe the population clearly and avoid ambiguity that may confound study selection. 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 question and the phenomena of interest. In the example of men diagnosed with prostate cancer, the phenomena of interest are their experiences of having chosen conservative treatment. How the phenomena relate to the topic under review should be 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 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).

Outcomes

There is no requirement for an outcome statement in qualitative reviews as the expressed phenomena of interest is the outcome; therefore this section should be left out of the protocol.

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 CReMS software offers standardized text consisting of statements regarding the types of studies considered for inclusion in a JBI qualitative review. Any of the following three 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.

How the PICo elements come together in the inclusion criteria and are operationalized is illustrated below.

Inclusion criteria

Types of participants

This review will consider studies with a focus on 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.)

Types of interventions/phenomena of interest

The qualitative component of this review will consider as phenomena of interest the actual experience of horizontal/lateral violence by licensed nurses and student nurses.

Context

This review will consider research on the experience of lateral/horizontal violence in the profession of nursing and the efficacy/effectiveness of programs/strategies that are designed to decrease its prevalence or mitigate its negative effects in any setting where licensed or student nurses practise.

Types of outcomes

The qualitative component of this review will include experiential accounts of being a nurse or student nurse who has experienced lateral/horizontal violence.

Types of studies

The qualitative component of 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.

Rittenmeyer L, Huffman D, Block M, Mathaler M, Misner S, Moore E, Wegner G, Kleefisch K. A comprehensive systematic review on lateral/horizontal violence in the profession of nursing. The JBI Database of Systematic Reviews and Implementation Reports. 2012;10(42suppl): S13-S29.

Search strategy

This section details how the reviewers plan to search for relevant papers. The process describing searching has been standardized in JBI's CReMS and is illustrated below.

A JBI review should consider papers published in both commercial (black literature) and in non-commercially operated databases (grey literature). 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). The databases to be searched must be listed along with the initial keywords to be used for the search. Appropriate databases to search should be included, including specification from the outset of the platform used to search a particular database.

In this section, some discussion of the nuances of searching for the type of evidence, e.g. where most appropriate to locate qualitative evidence, will be provided. This should include:

- databases that will be searched,
- the key words from the database thesaurus and free text words,
- the date range for searching, and
- the languages to be included.

- ***Please note: If the best available evidence for your question is text and opinion rather than qualitative research, the text and opinion studies should be analyzed using NOTARI. Such reviews become a text and opinion review rather than a qualitative review of textual evidence, and therefore the review title, question and criteria should be reviewed against the expectations of a NOTARI review.***

Within a systematic review 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.
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 CReMS as follows:

The search strategy aims to find both published and unpublished studies. A three-step search strategy will be utilized in this review. An initial limited search of MEDLINE and CINAHL will be undertaken followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe article. A second search using all identified keywords and index terms will then be undertaken across all included databases. Thirdly, the reference list of all identified reports and articles will be searched for additional studies. Studies published in #insert language(s)# will be considered for inclusion in this review. Studies published #insert dates# will be considered for inclusion in this review.

The databases to be searched include: #insert text# The search for unpublished studies will include: #insert text# Initial keywords to be used will be: #insert text#

This standardized text is editable, and includes fields for reviewers to specify content relevant to their available resources. Reviewers are required to state the databases to be searched, the initial key words that will be used to develop full search strategies and, if including unpublished studies, what sources will be accessed.

- ***Please note: 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 each review protocol as part of Phase 2.***

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 center.

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.

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.

It may also be useful to communicate with other JBI entities to identify databases not readily available outside specific jurisdictions for more comprehensive searching. JBI entities that do not have access to a range of electronic databases to facilitate searching of published and grey literature are encouraged to contact JBI regarding online access to the University of Adelaide Barr Smith Library.

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 JBI entities regarding translation.

- ***Therefore, literature searching should be based on the principal of inclusiveness, with the widest reasonable range of databases that are considered appropriate to the focus of the review. In addition to databases of published research, there are online sources of gray or unpublished literature that should be considered.***

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 and refers to papers that have not been commercially published and 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. Some early work has been undertaken to examine searching, and suggests a combination of Thesaurus terms, and specific method terms be used to construct search strategies. The help of an experienced research librarian/information scientist is recommended.

Assessment criteria

There are a variety of checklists and tools available to assess studies. The QARI checklist can be found in Appendix II, with an explanation for these criteria in Appendix III. Most checklists use a series of criteria that can be scored as being met, not met or unclear or not applicable. It is JBI policy that all study types must be critically appraised using the standard critical appraisal instruments for specific study designs, built into the analytical modules of the SUMARI software. The protocol must therefore describe how the primary studies will be assessed and detail any exclusion criteria. The appropriate JBI critical appraisal instruments should also be included as appendices to the protocol. Optional standardized set text is provided to help the reviewer.

It is editable and states:

Qualitative papers 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 the Joanna Briggs Institute Qualitative Assessment and Review Instrument (JBI-QARI). Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer.

Reviewers may wish to add or edit the set text; however the QARI critical appraisal tool is required for all JBI entities conducting reviews of qualitative evidence through JBI. There are 10 criteria for appraisal in the QARI module. They relate not to validity or bias in the process-orientated methods related to reviews of effects, but to establishing the nature and appropriateness of the methodological approach, specific methods and the representation of the voices or meanings of study participants.

The QARI critical appraisal tool is in Appendix II and has been designed with the intention that there will be at least two reviewers (a primary and a secondary) independently conducting the critical appraisal. Both reviewers are blinded to the assessment of each other and once both reviewers have completed their appraisal; the primary reviewer compares the two appraisals and makes a decision on whether to include a study or not. The two reviewers should discuss cases where there is a lack of consensus in terms of whether a study should be included, or how it should be rated; it is appropriate to seek assistance from a third reviewer as required.

Data extraction

The QARI data extraction tool is in Appendix IV. In qualitative reviews, the data consists of statements and text of interest to the review as published in primary studies. It is necessary to extract data from the primary research regarding the participants, the phenomenon of interest and the results. It is JBI policy that data extraction for all study types must be carried out using the standard data extraction instruments for specific study designs, built into the analytical modules of the SUMARI software. The protocol must therefore describe how data will be extracted and include the appropriate JBI data extraction instruments in appendices to the protocol.

As with critical appraisal, optional set text is provided to assist the reviewer. The set text is editable and indicates the types of content considered necessary to the write up of a systematic review; it states:

Qualitative data will be extracted from papers included in the review using the standardized data extraction tool from JBI-QARI. The data extracted will include specific details about the phenomena of interest, populations, study methods and outcomes of significance to the review question and specific objectives.

The data extraction template for a JBI qualitative review incorporates methodology, method, phenomena of interest, setting, geographical location, culture, participants, method of data analysis used in primary study, the author's conclusions and comments the reviewer might wish to record about the paper at that point in time.

Extraction Details: Bousfield C - Journal of Advanced Nursing (1997)

* denotes field which will appear in report appendix

| | |
|--------------------------|---|
| Methodology: | Phenomonology |
| Method: * | Interview |
| Phenomena of Interest: * | Characteristics of good leadership |
| Setting: | Acute Care |
| Geographical: | United Kingdom |
| Cultural: | Anglo Saxon |
| Participants: * | Nursing staff in senior clinical positions |
| Data Analysis: | thematic analysis |
| Authors Conclusion: * | leadership must be proven in practice |
| Reviewers Comments: * | conclusions appear congruent with textual reporting |
| Complete | Yes ▾ |

Update **Undo** **Cancel**

Figure 5: specific data extracted on the nature of the phenomena and, study characteristics

Q Have the QARI critical appraisal and data extraction tools been attached to the protocol? Have the authors agreed on how to apply the levels of credibility?

Data synthesis

The protocol set text also describes how the reviewers synthesize the data extracted from the included studies. Qualitative research findings should be pooled using JBI-QARI as per the set text below:

Qualitative research findings will, where possible be pooled using JBI-QARI. This will involve the aggregation or synthesis of findings to generate a set of statements that represent that aggregation, through assembling the findings rated according to their quality, and categorizing these findings on the basis of similarity in meaning. These categories are then 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 will be presented in narrative form.

Conflict of interest

A statement should be included in every review protocol being submitted to JBI that either declares the absence of any conflict of interest, or describes a specified or potential conflict of interest. Reviewers are encouraged to refer to JBI's policy on commercial funding of review activity.

Acknowledgements

The source of financial grants and other funding must be acknowledged, including the reviewers' commercial links and affiliations. The contribution of colleagues or Institutions should also be acknowledged.

References

Protocols are required to use the Vancouver style referencing. References should be numbered in the order in which they appear with superscript Arabic numerals in the order in which they appear in text. Full reference details should be listed in numerical order in the reference section. (This is automatically performed in CReMS.)

Appendices

Appendices should be placed at the end of the protocol and be numbered with Roman numerals in the order in which they appear in text. At a minimum this will include critical appraisal and data extraction tools. (This is automatically performed in CReMS.)

Appendix I: Critical appraisal instrument

The critical appraisal instrument used must be appended, i.e. JBI-QARI Critical Appraisal Checklist for Interpretive and Critical Research.

Appendix II: Data extraction instrument

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

Q *Does the protocol have any conflicts of interests and acknowledgments declared, appendices attached, and references in Vancouver referencing style?*

Once a protocol has been approved, it is published on the JBI Database of Systematic Reviews and Implementation Reports.

Protocols can be found at: <http://www.joannabriggslibrary.org/jbilibrary/index.php/jbisrir/index>

Chapter Three:

The 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 JBI-QARI and the outputs that can be expected if CReMs 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 the JBI library. 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. Please refer to the JBI Library for specific presentation requirements for systematic review reports: <http://www.joannabriggslibrary.org/jbilibrary/index.php/jbisrir/index>

All JBI systematic reviews are based on approved peer reviewed systematic reviews protocols. JBI considers peer review of systematic review protocols as an essential part of a process to enhance the quality and transparency of systematic reviews.

Layout of the report

The systematic review protocol details how the review will be conducted, what outcomes are of interest and how the data will be presented. The systematic review report should be the follow up to an approved protocol – any deviations from the protocol need to be clearly detailed in the report, to maintain transparency. CReMS software provides a detailed framework for the necessary sections of a report and automatically compiles the report which can be edited in the <Report Builder> section of CReMS. There is no word limit for a review report. Briefly, a JBI review should contain the following sections:

Title of systematic 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 'a systematic review'.

Review authors:

Each reviewer should have post-nominal qualifications listed. Affiliations for each author need to be stated, including the affiliation either with JBI, or with a JBI collaborating centre. The corresponding author's name and email address need to be provided.

Executive summary:

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 executive summary must accurately reflect and summarize the systematic review. The executive summary should include the following headings:

Background

Objectives

Inclusion criteria

- Types of participants
- Phenomena of interest
- Types of studies

Search strategy

Methodological quality

Data collection

Data synthesis

Results

Conclusions

Implications for practice

Implications for research

Following the Executive Summary, the report includes the following sections:

Background

The background section should be comprehensive and cover all 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 inclusion criteria into context. The background section should conclude with a statement that a preliminary search for previous systematic reviews on the topic was conducted (state the databases searched e.g. JBI Library, Cochrane Library, CINAHL, PubMed, PROSPERO). If there is a previous systematic review on the topic, how the proposed review differs should be specified. The Vancouver style of referencing should be used throughout the review with superscript numbers without brackets used for in-text citations.

It is recommended that all JBI systematic reviews should contain a sentence clearly indicating:

'The objectives, inclusion criteria and methods of analysis for this review were specified in advance and documented in a protocol. Ref' (The reference should be to the appropriate citation in JBISRIIR).

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.

Review objectives/review questions

As discussed previously in the protocol section, the objective(s) of the review should be clearly stated.

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 objectives. The reasons for the inclusion or exclusion of participants should be explained in the background.

Types of phenomena of interest

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

Outcomes

There is no requirement for an outcome statement in qualitative reviews.

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 objective.

Search strategy

This section details how the reviewers searched for relevant papers. A detailed search strategy for at least one of the major databases searched should be appended to the review. A JBI review should consider papers published in both commercial (black literature) and in non-commercially operated databases (grey 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.

Method of the review

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-QARI) should be used. Critical appraisal tools must be appended to the review.

Q *Has the QARI critical appraisal tool been appended to the review? Have the results of critical appraisal been discussed? Were there any differences of opinion between the reviewers and, if so, how were these resolved?*

Data extraction

Standardized data extraction tools allow the extraction of the same types of data across the included studies and are recommended for JBI systematic reviews. The review should detail what data the reviewers extracted from the included studies and the data extraction tool used must be appended to the review. 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.

Extracting data from critical and interpretive studies

Data extraction serves the same purpose across study designs – to summarize the findings of many studies into a single document. Qualitative data extraction involves transferring findings from the original paper using an approach agreed upon and standardized for the specific review. Thus, an agreed format is essential to minimise error, provide an historical record of decisions made about the data in terms of the review, and to become the data set for categorisation and synthesis. Using QARI, there is a series of standardized fields related to data extraction. These are as follows:

Methodology

A methodology usually covers the theoretical underpinnings of the research. In a review, it is useful to add further detail such as the particular perspective or approach of the author/s such as 'Critical' or 'Feminist' ethnography.

Method

The method is the way that the data was collected; multiple methods of data collection may be used in a single paper, and these should all be stated. Be sure to specify how the method was used. If for example it was an interview, what type of interview it was' consider whether open or closed questions were used, or whether it was face-to-face or by telephone.

Phenomena of interest

Phenomena of interest are the focus of a QARI review, whereas in a quantitative review, interventions are the focus. An intervention is a planned change made to the research situation by the researcher as part of the research project. As qualitative research does not rely on having an intervention (as they are traditionally thought of in quantitative research), the focus is called phenomenon/phenomena of interest, which refers to the experience, event or process that is occurring, for example: response to pain or coping with breast cancer.

Setting

This term is used to describe where the research was conducted – the specific location, for example: at home; in a nursing home; in a hospital; in a dementia specific ward in a sub-acute hospital. However, some research will have no setting at all, for example discourse analysis.

Geographical context

The geographical context is the location of the research. It is useful to be as specific as possible in describing the location, by including not just the country, but whether it was a rural or metropolitan setting, as this may impact upon the research.

Cultural context

Cultural context seeks to describe the cultural features in the study setting such as, but not limited to: time period (e.g. 16th century); ethnic groupings (e.g. indigenous people); age groupings (e.g. older people living in the community); or socio-economic groups (e.g. high socio-economic). When entering information be as specific as possible. This data should identify cultural features such as employment, lifestyle, ethnicity, age, gender, socio-economic class, location and time.

Participants

Information entered in this field should be related to the inclusion and exclusion criteria of the research, and include (but not be limited to) descriptions of age, gender, number of included subjects, ethnicity, level of functionality, and cultural background. Included in this section should be definitions of terms used to group people that may be ambiguous or unclear, for example, if the paper includes role definitions.

Data analysis

This section of the report should include the techniques used to analyze the data; a list, (though not exhaustive) of examples is provided below:

- Named software programs
- Contextual analysis
- Comparative analysis
- Thematic analysis
- Discourse analysis
- Content analysis.

Author's conclusions

This is the conclusion reached by the study author.

Reviewer's conclusions

This is the conclusion reached by the Reviewer.

Q *Has the QARI data extraction tool been appended to the review? Have all of the extracted findings been discussed and assigned levels of credibility in the review?*

Extracting findings

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 author's 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 a participant's voice, field-work observations or other supporting data.
- ***As a finding is extracted and its accompanying illustration entered in the JBI-QARI 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 three 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 among 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)
- **Unsupported** (findings not supported by data).

Q *Have all of the findings been extracted from the included studies? Do all of the findings have illustrations? Do all of the findings have levels of credibility assigned to them?*

Data synthesis

This section should detail the approach to data synthesis, and not the results of the synthesis. The review should detail how the reviewers synthesized data extracted from the included studies and detail the meta-aggregative approach and how it was applied across all included studies.

Data synthesis in a meta-aggregative review requires the reviewers to undertake a three-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 two findings per category
3. Developing one or more synthesized findings of at least two categories.

Reporting the methods of data synthesis requires reviewers to describe:

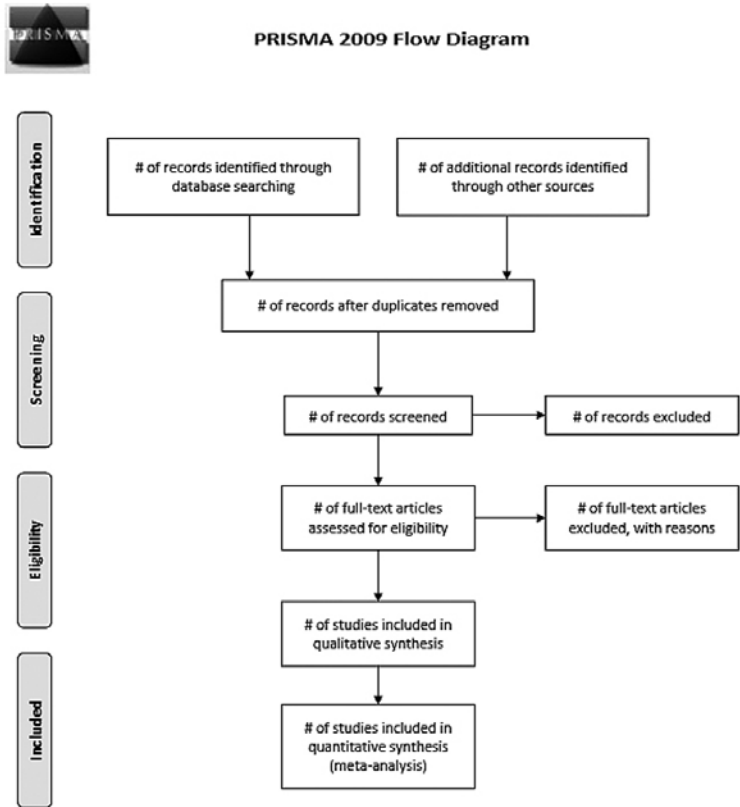
- What data was considered 'findings' in their review (i.e. was it limited to themes and metaphors, or did it include other analytic data from the papers that might have been an author observation rather than a thematic analysis)
- The process by which findings were identified (i.e. repeated reading 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 consensus process between reviewers/review group members)
- How synthesized findings and their accompanying descriptions were created and finalized.

Results

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 (see Figure 6 for example flowchart template). Flow chart of review process (from PRISMA statement), detailing flow from the search, through study selection, duplicates, full text retrieval, any additions from a third search, appraisal, extraction and synthesis.

Description of studies

This section of the results should also include an overall description of the included studies (with reference to the table of included studies in the appendices), with the aim of providing some context to the results and sufficient detail for the reader to determine if the included studies are similar enough to combine in the meta-synthesis. Specific items/points of interest from individual studies may also be highlighted here.



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(8): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

Figure 6: PRISMA flowchart detailing identification and selection of studies for inclusion in the review

Q *The PRISMA flowchart for reporting is the required format for JBI systematic reviews. The flow chart illustration below should be duplicated in the review report, and appropriate reference made to PRISMA.*

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:

Studies: Number of studies identified, number of retrieved studies, number of studies matching the preferred study methodology (i.e. grounded theory, action research), number and designs of other types of studies, number of appraised studies, number of excluded studies and overview of reasons for exclusion, and numbers of included studies.

The description of studies may also incorporate details of included studies. This additional detail may include the assessment of methodological quality, characteristics of the participants and the phenomenon/phenomena studied.

With details on the number and type of studies reported, 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.

Methodological quality

This section should focus on the 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 as an 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 a clear narrative regarding the risk of bias/rigour of included studies. Use of 'N/A' should also be justified in the text.

Table 2: Critical appraisal results for included studies using the JBI-QARI 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 |
| | | | | | | | | | | |
| Y - Yes, N - No, U - Unclear | | | | | | | | | | |

Findings of the review

Although there is no defined structure for this section, the findings of the review should flow logically from the review objection/question, i.e. they must ultimately answer the question! Findings should be extracted using JBI-QARI and a QARI-view table (e.g. a meta-aggregative flow diagram), and these should constitute part of this section.

Q *The QARI-view diagram must be accompanied by sufficient narrative to explain the categories and synthesized findings, and the similarity of meaning informing each synthesized finding to the reader of the report.*

Findings and illustrations should be located in an appendix, or may be incorporated into the body of the report. There should be a logical and informative presentation of the findings, categories and synthesized findings.

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. 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 (such as poor indexing)
- Other issues of relevance
- Implications for practice and research, including recommendations for the future
- Potential limitations of the systematic review (such as a narrow 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 objectives identified in the protocol.

Conclusions

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

Implications for practice

It should be stated how the findings of the review 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.

Implications for research

This section should include clear, specific recommendations for future research based on gaps in knowledge identified from the results of the review.

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. If the systematic review is to count towards a degree award it should also be noted.

References

All references should be listed in full using the Vancouver referencing style, in the order in which they appear in the review.

Appendices

Appropriate appendices (appraisal, extraction tools) as they appear from CReMS should be provided and referred to in the review. Appendices should be numbered using Roman numerals in the order in which they have been referred to in the body of the text. There are several required appendices for a JBI review:

Appendix I: Search strategy

A detailed search strategy for at least one of the major databases searched must be appended.

Appendix II: Critical appraisal instrument

The critical appraisal instrument used must be appended, i.e. JBI-QARI Critical Appraisal Checklist for Interpretive and Critical Research.

Appendix III: Data extraction instrument

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

Appendix IV: Table of included studies

A table of included studies is crucial to allow a snapshot of the studies included in the review.

Appendix V: List of excluded studies

At a minimum, a list of studies excluded at the critical appraisal stage must be appended and reasons for exclusion should be provided for each study (these reasons should relate to the methodological quality of the study, not study selection). Studies excluded following examination of the full-text may also 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.



"I'M THE ONE WITH THE MEDICAL DEGREE, I'LL DETERMINE
IF YOUR BACK IS BOTHERING YOU, OR NOT..."

Chapter Four:

Quantitative evidence and evidence-based practice

Quantitative evidence is generated by research based on traditional scientific methods that generate numerical data. Quantitative evidence usually seeks to establish relationships between two or more variables and then statistical models are used to assess the strength and significance of those relationships.²⁶⁻²⁹ The strength of quantitative evidence lies in its validity and reliability – the same study designs and measurements should yield the same results or answers time after time.²⁹⁻³²

The methods associated with quantitative research in healthcare have developed out of the study of natural and social sciences.³³ A review of Ulrich Tröhler's 'To Improve the Evidence of Medicine: The 18th century British Origins of a Critical Approach' (2000) suggests 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.³³ Since these beginnings, quantitative research has expanded to encompass aspects other than effectiveness, such as incidence, prevalence, association, psychometric properties, and measurement of physical characteristics, quality of life, and satisfaction with care.

The term 'evidence' in JBI systematic reviews is used to mean the basis of belief, that is, the substantiation or confirmation that is needed in order to believe that something is true.³⁴ The type of evidence needed depends on the nature of the activity and its purpose, and in JBI reviews, this has been classified accordingly as evidence of feasibility, appropriateness, meaningfulness and effectiveness.³⁵ JBI quantitative reviews focus on evidence of effectiveness. Effectiveness is the extent to which an intervention, when used appropriately, achieves the intended effect. Clinical effectiveness is about the relationship between an intervention and clinical or health outcomes.²

Quantitative research designs use two main approaches to making measurements and collecting data: those that aim to establish a causal relationship between two variables by deliberately manipulating one of them and looking at changes in the other (experimental studies), and those that imply a correlation or association between variables (observational studies). MASTARI uses checklists based on study design to critically appraise a study. The JBI checklists for quantitative evidence can be found in Appendix V and the differences between the study designs are discussed below. Appendix VI provides some discussion of the biases that the checklist items aim to address.

Research questions will utilise different study designs, each with their own features, advantages and limitations, depending on the type of question being addressed.

Experimental study design

Randomized controlled trials

Experimental study designs aim to establish a causal relationship between two variables by deliberately manipulating one of them (the intervention or independent variable) and looking at changes in the other outcome or dependant variable. There are three main characteristics of an experimental study:

- An experimental group of participants will receive the intervention of interest (e.g. a new drug)
- A second group (the control group) will receive the same conditions EXCEPT for the intervention (e.g. a placebo – identical to the new drug but with no active ingredient)
- Participants are randomly allocated to the experimental group and control groups.

By doing this, the study attempts to control as many ‘unknowns’ or potential sources of explained findings/bias as possible, in order to be sure that the observed effects are due to the intervention alone. Randomized controlled trials (RCTs) are considered the best source of experimental evidence as the participants are randomly allocated to an experimental or control arm of the study. The aim of this randomization is so that any factors that may systematically influence or confound the study (for example, gender, age or specific medical conditions) are randomly distributed so that the groups are ‘probabilistically similar to each other on average’.³⁶

RCTs also aim to limit any effect (either conscious or subconscious) that the experimenter may have on the outcome of the study by using blinding techniques. The term ‘blinding’ or ‘masking’ refers to withholding information about the interventions from people involved in the study who may potentially be influenced by this knowledge. Blinding is an important safeguard against bias, particularly when assessing subjective outcomes,^{37,38} and this is why it appears as an item on critical appraisal checklists.

RCTs provide robust evidence on whether or not a causal relationship exists between an intervention and a specific, measurable outcome, as well as the direction and strength of that outcome. Many tests of statistical significance are based on the assumptions of random sampling and allocation, and this is one of the reasons critical appraisal checklists contain items on random allocation and use of appropriate statistical methods. In reviews of effectiveness, it is common to begin with a statement that RCTs will be sought, but in their absence, other experimental study designs will be included. Other study designs may be listed in hierarchical form, giving preference to those designs which aim to minimise risk of bias (e.g. have some form of randomization or control group, or blinding), and end with those most at risk of bias (e.g. descriptive studies with no randomization, control group or blinding). The study designs of interest will depend on the nature of the question.

In addition to the risk of bias, study selection may be based on the scope of the research question. The hierarchy of study designs is reasonably consistent internationally, with widespread acceptance that RCTs provide the most robust experimental evidence but it should be noted that the RCT design may not be appropriate for all studies of effectiveness; alternatives may include non-randomized or quasi experimental studies.

Non-randomized or quasi-experimental study designs

Not all areas of research lend themselves to random allocation of participants or it may not be possible to have a control group. In these cases, the strength of evidence is thought to be less robust and the study is more prone to bias.³⁶ As such, care needs to be taken with the interpretation of results from quasi-experimental studies; however, due to the reduction in control over their design, quasi-experimental studies tend to be more flexible and are often the only practical alternative.

The approaches and methods used in quasi-experimental or non-randomized studies still aim to uncover a causal relationship between two variables; however there is a limitation to what can be conclusively determined as the researcher cannot control for all potential confounders (through randomization) that might affect the outcome and there may be several explanations for the results.

An important element of both experimental and quasi-experimental studies is the measurement of the dependent variable, which allows for comparison. Some data is quite straightforward, but other measures, such as level of self-confidence in writing ability, increase in creativity or in reading comprehension are inescapably subjective. In such cases, quasi-experimentation often involves a number of strategies to compare subjectivity, such as rating data, testing, surveying, and content analysis.

Observational study designs

Experimental studies are often not feasible due to a variety of reasons including: ethical issues, financial costs and/or difficulties in recruiting participants. The observational study design provides an alternative way of collecting information and is a much used study design in healthcare research. This type of study has no experimental features and aims to summarize associations between variables in order to generate (rather than to test) hypotheses. They are solely based on observing what happens or what has happened. Observational studies can be broadly described as being either Analytic or Descriptive.

Analytical studies

An analytic study aims to summarize associations between variables but is unable to make direct inferences about cause and effect as there are too many unknown factors that could potentially influence the data. This type of study design is often useful where it is unethical to deliberately expose participants to harm. The most commonly used analytic study designs are Cohort and Case-control studies.

Cohort study

A cohort study is a type of longitudinal study that is commonly used to study exposure-disease associations. A cohort is a group of participants who share a particular characteristic such as an exposure to a drug or being born in the same year. Cohort studies can either be prospective or retrospective. Prospective cohort studies collect data after the cohort has been identified and before the appearance of the disease/condition of interest. The appearance of the disease/condition is then counted as an event (e.g. new case of cancer). In theory, all of the individuals within the cohort have the same chance of developing the event of interest over time.

A major advantage of this study design is that data is collected on the same participants over time, reducing inter-participant variability. However this type of study is expensive to conduct and can take a long time to generate useful data. Retrospective cohort studies are much less expensive to conduct as they utilise already collected data, often in the form of medical records. Effectively in a retrospective cohort design, the exposure, latent period and development of the disease/condition have already occurred – the records of the cohort are audited backwards in time to identify particular risk factors for a disease/condition. A disadvantage of this study design is that the data was collected for purposes other than research so information relevant to the study may not have been recorded. Statistically, the prospective cohort study should be summarized by calculating relative risk and retrospective cohort studies should be summarized by calculating odds ratio.

Case-control study

The case control study also uses a retrospective study design – examining data that has already been collected, such as medical records. ‘Cases’ are those participants who have a particular disease/condition and the ‘Controls’ are matched participants who do not. The records of each are examined and compared to identify characteristics that differ and may be associated with the disease/condition of interest. One recognised disadvantage of this study design is that it does not provide any indication of the absolute risk associated with the disease of interest.

Descriptive studies

Descriptive studies aim to provide basic information such as the prevalence of a disease within a population and generally do not aim to determine relationships between variables. This type of study design is prone to biases such as selection and confounding bias due to the absence of a comparison or control. Cross-sectional studies, case reports and case series are types of descriptive studies.

Cross sectional studies

Cross sectional studies are used to describe characteristics of a population at a given point in time, and as such, provide a single snapshot of disease and other variables at one point in time. For example, cross sectional studies can be used to describe the prevalence of a disease and a risk factor at a specific point in time and can be carried out using a survey.

Cross-sectional studies may also be analytic in nature, when the data collected is 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.

Case report/case series

A case report provides a detailed description of an individual participant or case. Several case reports can be brought together as a case series.

A case series provides detailed descriptions of the exposures and outcomes of participants with a particular disease/condition of interest. This design has been very useful in identifying new diseases and rare reactions or conditions. A case series can be either prospective or retrospective, depending on when the data was collected relative to the exposure. Case report/series lack a comparator or control group but are effective as a question generating study design.

Expert Opinion

JBI regards the results of well-designed research studies grounded in any methodological position as providing more credible evidence than anecdotes or personal opinion; however, in situations where no research evidence exists, expert opinion can be seen to represent the 'best available' evidence.

Chapter Five:

Quantitative protocol and title development

Protocol design for reviews of EFFECTIVENESS

Title page

A JBI review requires at least two reviewers. The names of the reviewers, together with their post nominal qualifications, contact details and JBI affiliation, should be listed on the title page of the protocol.

Title of systematic review protocol

The title of the protocol should be as descriptive as possible and reflect all relevant information. If the review aims to examine clinical effectiveness this should be stated in the title. If specific interventions and/or patient outcomes are to be examined these should also be included in the title. Where possible the setting and target population should also be stated. For example:

'The clinical effectiveness of smoking cessation strategies for adults in acute care mental health facilities: a systematic review protocol'

This example provides potential readers of the review with a clear indication of the population, the interventions, and the outcome of interest, as well as the fact that it is a systematic review protocol. A clear title is important for indexing and to assist peer reviewers as well as end users to identify the scope and relevance of the review.

Objectives

The objectives of the review should provide a clear statement of the questions being addressed with reference to participants, interventions, comparators and outcomes. Clear objectives and specificity in the review questions assist in focusing the protocol, allow the protocol to be more effectively indexed, and provides a structure for the development of the full review report. The review objectives should be stated in full. Conventionally, a statement of the overall objective is made and elements of the review are then listed as review questions.

Review objective

'To systematically review the evidence to determine the best available evidence related to the post harvest management of Split Thickness Skin Graft donor sites.'

This broad statement can then be clarified by using focused review questions.

Review questions

Among adults in the acute postoperative phase (five days) following skin grafting, what dressings that are used in the management of the STSG donor site are the most effective in reducing:

- *healing time;*
- *rates of infection; and*
- *pain levels and promoting comfort?*

What interventions/dressings are most effective in managing delayed healing/infection in the split skin graft donor site?

What interventions are most effective in managing the healed split skin donor site?

Q ***Does the review have a concise, informative title? Are the review objectives and questions clearly stated?***

Background

JBI places significant emphasis on a comprehensive, clear and meaningful background section to every systematic review. The background should be of sufficient length to discuss all of the elements of the review (approximately 1000 words) and describe the issue under review including the target population, intervention(s) and outcome(s) that are documented in the literature. The background should provide sufficient detail to justify the conduct of the review and the choice of interventions and outcomes. Where complex or multifaceted interventions are being described, it may be important to detail the whole of the intervention for an international readership. Any topic-specific jargon or terms and specific operational definitions should also be explained. In describing the background literature, value statements about the effectiveness of interventions should be avoided. The background should avoid making statements about effectiveness unless they are specific to papers that illustrate the need for a systematic review of the body of literature related to the topic (example.g. 'the use of acupuncture is effective in increasing smoking cessation rates in hospitalized patients') if this is what the review aims to examine. If value statements are made, it should be clear that it is not the reviewer's conclusion but that of a third party, such as, 'Smith indicates that acupuncture is effective in increasing smoking cessation rates in hospitalized patients'. Such statements in the background need to be balanced by other points of view, emphasizing the need for the synthesis of potentially diverse bodies of literature. It is the responsibility of the reviewers to ensure that their review is not a duplicate of an existing review. If systematic reviews already exist on the topic, then the background should explain how this systematic review will be different (e.g. different population, type of outcomes measured).

Q ***Questions to consider:***
Does the background cover all the important elements (PICO) of the systematic review? Are operational definitions provided? Do systematic reviews already exist on the topic; if so how is this one different? Why is this review important?

Inclusion criteria for considering studies for a JBI quantitative systematic review

The PICO model aims to focus the systematic review and is used to define the properties of studies to be considered for inclusion in the review. PICO is used to construct a clear and meaningful question when searching for quantitative evidence.

- P** = Population. What are the most important characteristics of the population? (e.g. age, disease/condition or gender). In the earlier example, the PICO mnemonic describes the population (adults) within a specific setting (acute care) within a specific time frame (five days). There are no subgroups or exclusions described, hence all patients meeting the described criteria would be included in the analysis for each outcome. 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.
- I** = Intervention, factor or exposure. What is the intervention of interest? (e.g. drug therapy or exposure). In the earlier example, there is no single intervention of interest, rather the term 'dressings' is used to indicate that the review will consider all wound dressing products. Where possible, the intervention should be described in detail, particularly if it is multifaceted. Consideration should also be given to whether there is risk of exposure to the intervention in comparator groups in the included primary studies.
- C** = Comparison. What is the intervention being compared with? (e.g. placebo, standard care, another therapy or no treatment). The protocol should detail what the intervention of interest is being compared with. This can be as focused as one comparison, e.g. comparing 'dressing X with dressing Y' or as broad as 'what dressings' from the example above. This level of detail is important in determining study selection once searching is complete. For JBI reviews of effectiveness, the comparator is the one element of the PICO mnemonic that can be either left out of the question/s, or posited as a generalized statement. Systematic reviews of effectiveness based on the inclusive definition of evidence adopted by JBI often seek to answer broader questions about multifaceted interventions.
- O** = Outcome(s). How is effectiveness of the intervention measured? (e.g. reduction in mortality or morbidity, improved memory or reduced pain). The protocol should list of all the outcome measures being considered. The relevance of each outcome to the review objective should be apparent from the background section. Outcomes should be measurable and appropriate to the review objective. Outcomes might be classified as being of primary or secondary interest in relation to the review objective. It is useful to list outcomes and identify them as either primary or secondary, short-term or absolute and discuss which ones will be included.

Studies

Generally, JBI systematic reviews consider primary research studies and the main research designs used in primary studies to examine effectiveness are discussed in the previous chapter. Where appropriate however, a systematic review can draw on other systematic reviews as a source of evidence. These types of review are often called 'reviews of reviews' or 'umbrella reviews'^{39,40} and they are useful to summarize existing systematic reviews, especially in areas where much research is undertaken.

However, as the majority of JBI quantitative reviews are those that draw on primary studies of effectiveness, these types of studies will be the focus of the remainder of this section.

As previously mentioned, if there are existing systematic reviews on the topic, the purpose of conducting another and how this differs to those should be clearly explained in the background section. The appropriate JBI instruments should be used for critical appraisal and data extraction and all details should be transparent.

This section of the protocol should flow naturally from the review objective and questions. The review question will determine the methodological approach and therefore the most appropriate study designs to include in the review. Many JBI reviews will consider a hierarchy of study designs for inclusion. If this is to be the case, there should be a statement about the primary study design of interest and the range of studies that will be considered if primary studies with that design are not found. In reviews of effectiveness, it is common to begin with a statement that RCTs will be sought, but in the absence of RCTs other experimental study designs will be included. Other study designs may be listed in hierarchical form, giving preference to those designs which aim to minimise risk of bias (e.g. some form of randomization or control, or blinding), and end with those most at risk of bias (e.g. descriptive studies with no randomization, control or blinding), or which are most appropriate to the nature of the question. In addition to risk of bias, study selection may be based on the scope of the question. The hierarchy of study designs is reasonably consistent internationally, with widespread acceptance that RCTs provide the most robust evidence of effectiveness.

In the systematic review report, JBI Grades of Recommendation that describe effectiveness should be used alongside any recommendations. As different study designs use different approaches and assumptions, it is important to use the critical appraisal tool appropriate to the study design when determining methodological quality of a study for inclusion into a review. The types of studies that can be included in a JBI quantitative review is standardized in CReMS, dependant on study design and consists of the following statements.

Type of studies

1. Experimental (e.g. RCT, quasi-experimental)

This review will consider any experimental study design including randomized controlled trials, non-randomized controlled trials, quasi-experimental, before and after studies, #modify text as appropriate# for inclusion.

2. Observational (e.g. cohort/case control)

This review will consider analytical epidemiological study designs including prospective and retrospective cohort studies; case control studies and analytical cross sectional studies #modify text as appropriate# for inclusion.

3. Descriptive (e.g. case series studies)

This review will consider descriptive epidemiological study designs including case series, individual case reports and descriptive cross sectional studies #modify text as appropriate# for inclusion.

Reviewers should edit the set text to fit their review, bearing in mind the study designs that are most appropriate for answering the review question. If more than one study design is selected, for example the review will consider both experimental and observational studies, then the set text in CReMS will change appropriately to reflect this broader inclusion.

Q *Does the type of studies to be considered for inclusion in the review match with the review objective/questions?*

MAStARI example

Inclusion criteria

Types of participants

This review included studies that included adults (18 years and over) who were admitted to an acute medical setting (eg general medical unit, stroke unit, short stay unit and neuromedical unit) who were assessed using a valid assessment method as not being delirious on admission (in order to differentiate incident delirium) but who developed incident delirium during hospitalization.

The review excluded patients who were:

- a) critically ill and admitted to a specialist unit, eg ICU or Coronary Care Unit (CCU)
- b) admitted for any type of surgery (including patients who had a surgical intervention during a medical related hospitalization)
- c) admitted for alcohol-related reasons
- d) admitted to a psychiatric facility.

These patients were excluded in order to determine factors that may be exclusive to the medical in-patient setting.

Types of intervention(s)/phenomena of interest

This review considered studies that evaluated any risk factors that may have contributed to the development of delirium during in-patient hospitalization. The review looked at factors present on admission (predisposing) and also factors that may have occurred during hospitalization (precipitating) that contribute to incident delirium.

CULL, Emily Jane et al. Risk factors for incident delirium in acute medical in-patients. A systematic review. The JBI Database of Systematic Reviews and Implementation Reports, [S.l.], v. 11, n. 5, p. 62 - 111, jun. 2013. ISSN 2202-4433. Available at: <<http://www.joannabriggslibrary.org/jbilibrary/index.php/jbisrir/article/view/907/1256>>. Date accessed: 22 Jan. 2014.

Search strategy

The aim of a systematic review is to identify all relevant international research on a given topic. This is achieved by utilizing a well-designed search strategy across a breadth of resources. There is insufficient evidence to suggest a particular number of databases or whether particular databases provide sufficient topic coverage, therefore literature searching should be based on the principal of inclusiveness – with the widest reasonable range of databases included that are considered appropriate to the focus of the review. If possible, authors should always seek the advice of a research librarian in the construction of a search strategy.

The protocol should provide a detailed strategy including the search terms to be used and the resources (e.g. electronic databases and specific journals, websites, experts, etc.) to be searched. Within systematic reviews, the search strategy is often described as a three-phase process beginning with the identification of initial key words followed by an analysis of the text words contained in the title and abstract, and of the index terms used to describe relevant articles. The second phase is to construct database-specific searches for each database included in protocol, and the third phase is to review the reference lists of all studies that are retrieved for appraisal to search for additional studies. The text describing searching has been standardized in CReMS:

The search strategy aims to find both published and unpublished studies. A three-step search strategy will be utilized in this review. An initial limited search of MEDLINE and CINAHL will be undertaken followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe article. A second search using all identified keywords and index terms will then be undertaken across all included databases. Thirdly, the reference list of all identified reports and articles will be searched for additional studies. Studies published in #insert language(s)# will be considered for inclusion in this review. Studies published #insert dates# will be considered for inclusion in this review.

The databases to be searched include:

#insert text#

The search for unpublished studies will include:

#insert text#

Initial keywords to be used will be:

#insert text#

The standardized text is editable and includes fields for reviewers to specify content relevant to their available resources. Reviewers are required to state the databases to be searched, the initial key words that will be used to develop full search strategies.

- ***Details of the number of titles identified by the search are to be reported in the systematic review report so it is important to keep track of search results.***

The search strategy should also describe any limitations to the scope of searching in terms of dates, resources accessed or languages; each of these may vary depending on the nature of the topic being reviewed, or the resources available. Limiting by date may be used where the focus of the review is on a more recent intervention or innovation or if there has been a previously published systematic review on the topic and the current review is an update.

However, date limiting may exclude potentially relevant studies and should thus be used with caution, the decision preferably being endorsed by topic experts and justified in the protocol. Similarly, restricting study inclusion on the basis of language will have an impact on the comprehensiveness and completeness of the review findings. Where possible, reviewers should seek collaborative agreements with other JBI entities to ensure that minimal language restrictions are placed on the identification and inclusion of primary studies. Examples of search terms and databases that may be useful can be found in the searching material guidance which is provided in the final section of this manual.

JBI is an international collaboration with an extensive network of collaborating centres, Evidence Synthesis Groups (ESGs) and other entities around the world. This creates networking and resource opportunities for conducting reviews where literature of interest may not be in the primary language of the reviewers. 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 JBI entities regarding translation. It may also be useful to communicate with other JBI entities to identify databases not readily available outside specific jurisdictions for more comprehensive searching.

The comprehensiveness of searching and documenting the databases searched is a core component of the systematic review's credibility. In addition to databases of published research, there are several online sources of Grey or unpublished literature that should be considered. Grey or Gray literature is also known as Deep or Hidden Web material and refers to papers that have not been commercially published and 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. Rather than compete with the published literature, Grey literature has the potential to complement and communicate findings to a wider audience, as well as to reduce publication bias. However, an important thing to remember is that the group of databases should be tailored to the particular review topic.

Q *Does the search strategy detail the initial search terms and databases to be searched?
Are any restrictions clearly explained?*

Assessment criteria

The basis for inclusion (and exclusion) of studies in a systematic review needs to be transparent and clearly documented in the protocol. A systematic review aims to synthesise the best available evidence, therefore the review should aim to include the highest quality of evidence possible. Methodological quality is assessed by critical appraisal using validated tools. There are a variety of checklists and tools available to assess the validity of studies that aim to identify sources of bias and JBI checklists are based on study design. Appropriate MASTARI critical appraisal tools should be used for JBI quantitative reviews (Appendix V). These checklists use a series of criteria that can be scored as being met, not met or unclear or if deemed appropriate not applicable (N/A) to that particular study.

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 the different criteria differently, for example blinding of assessors (to prevent detection bias) may be considered to be twice as important as blinding the caregivers (to prevent performance bias).

Q ***It is important that critical appraisal tools are appropriate for the design of the study so that the questions of those tools are relevant to that study design.***

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. It is JBI policy that all study types must be critically appraised using the standard critical appraisal instruments for specific study designs, built into the analytical modules of the SUMARI software. The protocol must therefore describe how the methodological quality/validity of primary studies will be assessed; any exclusion criteria based on quality considerations; and include the appropriate JBI critical appraisal instruments in appendices to the protocol. The optional standardized set text in CReMS states:

Quantitative papers 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 the Joanna Briggs Institute Meta Analysis of Statistics Assessment and Review Instrument. Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer.

MAStARI optional set text can be extended by reviewers who wish to add or edit information. However, the assessment tools included in the analytical module MAStARI are required for all JBI entities conducting reviews through JBI.

The main object of critical appraisal is to assess the methodological quality of a study and to determine the extent to which a study has addressed the possibility of bias in its design, conduct and analysis. If a study has not excluded the possibility of bias, then its results are questionable and could well be invalid. Therefore, part of the systematic review process is to evaluate how well the potential for bias has been excluded from a study, with the aim of only including high quality studies in the resulting systematic review. A secondary benefit of critical appraisal is to take the opportunity to ensure each retrieved study has included the population, intervention and outcomes of interest specified in the review.

The most robust study design for an effectiveness study in terms of excluding bias is the double blinded randomized placebo controlled trial (RCT). Some have argued that systematic reviews on the effects of interventions should be limited to RCTs since these are protected from internal bias by design, and should exclude non-randomized studies since the effect sizes in these are almost invariably affected by confounders.²⁷

Nevertheless, there are four main forms of bias that can affect even this study design. These types of bias (as well as others) are the focus of checklist items on the JBI critical appraisal tools.

Main types of bias are: selection bias, performance bias, attrition bias and detection bias:

- **Selection bias** refers chiefly to whether or not the assignment of participants to either treatment or control groups (e.g. in a comparison of only two groups) has been made so that all potential participants have an equal chance of being assigned to either group, and that the assignment of participants is concealed from the researchers, at least until the treatment has been allocated.
- **Performance bias** refers to any systematic differences in the intervention administered to participants which may arise if either the researcher, participant, or both, are aware of what treatment (or control) has been assigned.
- **Detection bias** occurs if an assessor evaluates an outcome differently for patients depending on whether they are in the control or treatment group.
- **Attrition bias** refers to differences between control and treatment groups in terms of patients dropping out of a study, or not being followed up as diligently.

Critical appraisal tools are included in MASTARI and can be completed electronically for RCTs, quasi-experimental, case-control/cohort studies and descriptive/case series studies. A separate checklist should be used for each type of study design considered for inclusion in the review and each should be appended to the protocol (this occurs automatically in CReMS). MASTARI has been designed with the intention that there will be at least two reviewers (a primary and a secondary) independently conducting the critical appraisal. Both reviewers are initially blinded to the appraisal of the other review. Once both reviewers have completed their appraisal, the primary reviewer then compares the two appraisals. The two reviewers should discuss cases where there is a lack of consensus in terms of whether a study should be included; it is appropriate to seek assistance from a third reviewer as required.

Q *Are the critical appraisal tools appropriate to the study designs? Are copies of the critical appraisal tools appended to the protocol? Has the primary reviewer assigned a secondary reviewer to the review?*

Data extraction

Data extraction refers to the process of identifying and recording relevant details from either primary or secondary research studies that will be included in the systematic review. A standardized extraction tool is used to minimise the risk of error when extracting data and to ensure that the same data is recorded for each included study (Appendix VII). Other error-minimizing strategies include: ensuring that both reviewers have practised using the extraction tool and can apply the tool consistently. It is also recommended that reviewers extract data independently before conferring. These strategies aim to facilitate accurate and reliable data entry in to MASTARI for analysis.

Details regarding the participants, the intervention, the outcome measures and the results are to be extracted from included studies. It is JBI policy that data extraction for all study types must be carried out using the standard data extraction instruments for specific study designs, built into the analytical modules of the SUMARI software.

The protocol must therefore describe how data will be extracted and include the appropriate JBI data extraction instruments as appendices to the protocol.

Set text is included to guide the reviewer as to what should be included in each section of the protocol, and to ensure standardization across JBI reviews. However, this text is editable and reviewers should tailor the text to suit their particular review.

The editable set text for data extraction illustrates what is considered necessary for the write up of a systematic review, it states:

Quantitative data will be extracted from papers included in the review using the standardized data extraction tool from JBI-MAStARI. The data extracted will include specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives.

Studies may include several outcomes; however the review should focus on extracting information related to the research questions and outcomes of interest. Information that may impact upon the generalizability of the review findings such as study method, setting and population characteristics should also be extracted and reported. Population characteristics include factors such as age, past medical history, co-morbidities, complications or other potential confounders.

The data extracted will vary depending on the review question; however it will generally either be dichotomous or continuous in nature. Dichotomous data will include the number of participants with the exposure/intervention (n) and the total sample (N) for both control and treatment groups. Classically, this is stated as n/N; therefore there will be two columns of data for each outcome of interest.

For continuous data, the mean and standard deviation (SD), plus sample size are extracted for each specified outcome for both the control and intervention (or exposure) group. Typically, the standard deviation is expressed as:

$$\sqrt{\frac{\sum_{i=1}^n (X_i - \bar{X})^2}{N-1}}$$

Douglas G. Altman. Practical statistics for medical research. London : Chapman & Hall, 1991.

The standard error (SE) may also be reported in addition to the SD. However, if only the SE is reported, the SD can be calculated as long as the sample size (N) is known using the equation:

$$SE = \frac{SD}{\sqrt{N}}$$

In some cases it may not be possible to extract all necessary raw data from an included study for a systematic review, as sometimes only aggregated data are reported, or perhaps data from two different patient populations have been combined in the data analysis, and your review is focussed on only one of the patient populations. In these circumstances, the standard approach is to make contact with the authors of the publication and seek their assistance in providing the raw data. Most researchers are obliging when it comes to these requests providing that records are still available. If the study authors do not respond or if the data is unavailable, this should be noted in the report and the data presented in narrative summary.

In addition to the data, conclusions that study authors have drawn based on the data are also extracted. It is useful to identify the study authors' conclusions and establish whether there is agreement with conclusions made by the reviewer authors.

Q *What outcomes are anticipated? How have they been measured? What type of data is anticipated, e.g. continuous or dichotomous? Has the MASTARI data extraction tool been appended to the protocol?*

Data synthesis

The protocol should also detail how the data will be combined and reported. A synthesis can either be descriptive (narrative summary) or statistical (meta-analysis). A meta-analysis of data is desirable as it provides a statistical summary estimate of the effectiveness (called the effect size) of one intervention/treatment verses another, for a given population. By combining the result of primary research studies, a meta-analysis increases precision of the estimate, and provides a greater chance of detecting a real effect as statistically significant. The overall goal of meta-analysis in JBI systematic reviews is to combine the results of previous studies to arrive at summary conclusions about a body of research. It is used to calculate a summary estimate of effect size, to explore the reasons for differences in effects between and among studies, and to identify heterogeneity in the effects of the intervention (or differences in the risk) in different subgroups.⁴¹

In JBI systematic reviews the results of similar individual studies can be combined in the meta-analysis to determine the overall effect of a particular form of health care intervention (the treatment) compared to another standard or control intervention for a specified patient population and outcome.²

If there is large variation in either the intervention or the included population, then the summary estimate is unlikely to be valid. When systematic reviews contain very diverse primary studies a meta-analysis might be useful to answer an overall question but the use of meta-analysis to describe the size of an effect may not be meaningful if the interventions are so diverse that an effect estimate cannot be interpreted in any specific context.³⁹

Studies to be included in JBI systematic reviews with meta-analysis should be similar to each other so that generalization of results is valid. To determine if this is the case, a reviewer should examine whether the interventions being given to the 'treatment' group in each study are similar enough to allow meta-analysis, and that the control groups in each study are similar enough to warrant combination in meta-analysis.^{2,27}

The main areas where data from included studies should be comparable can be categorized as: clinical, methodological and statistical. The followings questions should be considered when deciding whether or not to combine data in a meta-analysis:^{26,27,42}

- Clinical – are the patient characteristics similar (such as age, diagnoses, co-morbidities, treatments)?
- Methodological – do the studies use the same study design and measure the same outcomes? Were outcomes measured in the same way, at the same time points, using comparable scales?
- Statistical – is there significant variance between the effect sizes?

These questions can be very difficult to answer and often involve subjective decision-making. Involvement of experienced systematic reviewers and/or researchers with a good understanding of the clinical question being investigated should help in situations where judgement is required. Such situations should be clearly described and discussed in the systematic review report. Borenstein. et al²⁷ and Barza et al.²⁶ also provide further reference material.

Another question to ask is whether it is sensible to statistically combine the results. For example, a systematic review may have a number of included studies that suggest a negative effect of a therapy and a number that suggest a positive effect; therefore a meta-analysis may conclude that overall there is no effect of the therapy. In this situation the cause of this heterogeneity should be investigated carefully; it may not be useful to combine the data in meta-analysis, and presenting the results in a narrative summary may be more appropriate.²⁷ However presentation of the results as a table or as a graphic (such as forest plot) may still be useful in conveying the results to the reader.

Statistical pooling of study data provides a summary estimate, using transparent rules specified in advance.²⁷ This allows an overall effect of a treatment/intervention to be determined. Whilst the ultimate aim of a quantitative systematic review is to combine study data in meta-analysis, this is not always appropriate or possible. Data from two or more separate studies are required to generate a synthesis.

It is important to combine the studies in an appropriate manner using methods appropriate to the specific type and nature of data that has been extracted. In the protocol, the methods by which studies will be combined should be described in as much detail as is reasonably possible. As the optional MASTARI set text below indicates, this may require describing the approaches for both dichotomous and continuous data if either or both types of data are anticipated. The set text may be extended to describe:

- Which test of statistical heterogeneity is to be used (such as Chi square)
- At which point statistical heterogeneity is considered significant
- Whether fixed or random effects models will be utilized and which specific methods of meta-analysis may be used for the anticipated types of data (i.e. continuous or dichotomous).

The set text inserted into the CReMS protocol will depend on the study design(s) that have been selected for inclusion in the review.

Data synthesis

1. Experimental (e.g. RCT, quasi-experimental)

Quantitative papers will, where possible, be pooled in statistical meta-analysis using JBI-MAStARI. All results will be subject to double data entry. Effect sizes expressed as odds ratio (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis modify text as appropriate. Heterogeneity will be assessed statistically using the standard Chi-square. 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.

2. Observational (e.g. cohort/case control)

Quantitative papers will, where possible, be pooled in statistical meta-analysis using JBI-MAStARI. All results will be subject to double data entry. Effect sizes expressed as relative risk for cohort studies and odds ratio for case control studies (for categorical data) modify text as appropriate and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis modify text as appropriate. A Random effects model will be used and heterogeneity will be assessed statistically using the standard Chi-square. 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.

3. Descriptive (e.g. case series studies)

Findings from descriptive studies will, where possible, be synthesized and presented in a tabular summary with the aid of narrative and figures where appropriate modify text as appropriate. If more than one study design was selected, the set text will change appropriately to reflect this broader inclusion.

Where possible, study results should be pooled in statistical meta-analysis using either MAStARI or another method (such as RevMan) when MAStARI is inappropriate for the type of data being examined. All numeric outcome data must be double entered to prevent data entry errors. Where statistical pooling is not possible the findings should be presented in narrative summary, although figures and tables are still encouraged.

Narrative summary

Where meta-analysis is not possible, the results should be synthesized in words and presented as a narrative summary. Elements should include raw data as presented in the included studies (e.g. weighted mean differences, standard deviations etc.) as well as information that puts the data in context – such as patient descriptions, study characteristics, and so on. Tables and figures are encouraged to aid presentation of the results.

Q *Are the methods for data synthesis clearly described? How will heterogeneity be assessed in the included studies? How will data be presented if not combined in meta-analysis?*

Conflict of interest

A statement should be included in every review protocol being submitted to JBI which either declares the absence of any conflicts of interest, or which describes a specified or potential conflict of interest. Reviewers are encouraged to refer to the JBI policy on commercial funding of review activity for what could constitute a conflict of interest.

Acknowledgments

The source of financial grants and other funding must be acknowledged, including a declaration of the authors' industrial links and affiliations. The contribution of colleagues or institutions should also be acknowledged. Personal thanks and thanks to anonymous reviewers are not appropriate.

References

Protocols are required to use the Vancouver referencing style. References should be cited using superscript Arabic numerals in the order in which they appear, with full details listed in numerical order in the reference section. Refer to the authors guidelines on the JBI library. <http://www.joannabriggslibrary.org/jbilibrary/index.php/jbisrir/about/submissions#authorGuidelines>

Appendices


Appendices should be placed at the end of the protocol and be numbered with Roman numerals in the order in which they appear in text. At a minimum this will include critical appraisal and data extraction tools. (This is automatically performed in CReMS.)

Appendix I: Critical appraisal instrument

The critical appraisal instrument used must be appended, i.e. JBI-MAStARI Critical Appraisal Checklist for Experimental Research.

Appendix II: Data extraction instrument

The data extraction instrument used must be appended, i.e. JBI-MAStARI Data Extraction Form for Experimental Research.

 ***Does the protocol have any conflicts of interests and acknowledgments declared, appendices attached, and references in the Vancouver referencing style?***

Once a protocol has been peer reviewed and approved, it will be published in the JBI Database of Systematic Reviews and Implementation Reports.

Chapter Six:

The systematic review and synthesis of quantitative data

Please refer to the JBISRIIR for specific presentation requirements for systematic review reports <http://www.joannabriggslibrary.org/jbilibrary/index.php/jbisrir/index>

All JBI systematic reviews are based on approved peer reviewed systematic reviews protocols (as discussed in chapter 5). Deviations from approved protocols are rare and should be clearly justified in the report. JBI advocates for approved peer reviewed systematic review protocols as an essential part of a process to enhance the quality and transparency of systematic reviews.

JBI systematic reviews should use American spelling. All measurements must be given in Systeme International d'Unites (SI) units. Abbreviations should be used sparingly; use only where they ease the reader's task by reducing repetition of long, technical terms. Initially use the word in full, followed by the abbreviation in parentheses. Thereafter use the abbreviation only. Drugs should be referred to by their generic names. If proprietary drugs have been used in the study, refer to these by their generic name, mentioning the proprietary name, and the name and location of the manufacturer, in parentheses.

Layout of the report

The systematic review protocol details how the review will be conducted, what outcomes are of interest and how the data will be presented. The systematic review report should be the follow up to an approved protocol – any deviations from the protocol need to be clearly detailed in the report, to maintain transparency. CReMS provides a detailed framework for the necessary sections of a report and automatically builds the report in the <Report Builder> function. CReMS automatically exports text from the protocol to <Report Builder>. Reviewers need to edit this as the protocol is written in future tense (i.e. 'Selected studies **will be** assessed for methodological quality...') and the report needs to be edited to read 'Selected studies **were** assessed for methodological quality...' Briefly, a JBI review should contain the following sections:

Title of systematic review:

This should be the same as detailed in the protocol.

Review authors:

The names, contact details and the JBI affiliation should be listed for each reviewer (which occurs automatically when using CReMS).

Executive summary:

This is generally the final section of the report to be written and should be a summary of the review in 500 words or less stating the purpose, basic procedures, main findings and principal conclusions of the review. The executive summary should not contain abbreviations or references. The following headings should be included in the executive summary:

Background:

This section should briefly describe the issue under review including the target population, interventions and outcomes that are documented in the literature. The background should be an overview of the main issues. It should provide sufficient detail to justify why the review was conducted and the choice of the various elements such as the interventions and outcomes.

Objectives:

The review objectives should be stated in full, as detailed in the protocol section.

Inclusion criteria:*Types of participants*

The report should provide details about the type participants included in the review. Useful details include: age range, condition/diagnosis or health care issue, administration of medication. Details of where the studies were conducted (e.g. rural/urban setting and country) should also be included. Decisions about the types of participants should have been explained in the background.

Types of interventions

This section should present all the interventions examined, as detailed in the protocol.

Types of outcome measures

There should be a list of the outcome measures considered, as detailed in the protocol.

Types of studies

As per the protocol section, the types of studies that were considered for the review should be included. There should be a statement about the target study type and whether or not this type was not found. The types of study identified by the search and those included should be detailed in the report.

Search strategy

A brief description of the search strategy should be included. This section should detail search activity (e.g. databases searched, initial search terms and any restrictions) for the review, as predetermined in the protocol.

Data extraction

This section should include a brief description of the types of data collected and the instrument used to extract data.

Data synthesis

This section should include a brief description of how the data was synthesized – either as a meta-analysis or as a narrative summary.

Conclusions

This section should include a brief description of the findings and conclusions of the review.

Implications for research

This section should include a brief description of how the findings of the review may lead to further research in the area – such as gaps identified in the body of knowledge.

Implications for practice

This section should include a brief description of how the findings and conclusions of the review may be applied in practice, as well as any implications that the findings may have on current practice.

Following the executive summary, the report should include the following sections:

Background

As discussed in the protocol section, JBI places significant emphasis on a comprehensive, clear and meaningful background section to every systematic review particularly given the international circulation of systematic reviews, variation in local understandings of clinical practice, health service management and client or patient experiences. It is recommended that all JBI systematic reviews should contain a sentence clearly indicating:

'The objectives, inclusion criteria and methods of analysis for this review were specified in advance and documented in a protocol. Ref' (The reference should be to the appropriate citation in JBISRIIR, 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.

Review objectives/review questions

As discussed previously in the protocol section, the objective(s) of the review should be clearly stated.

Inclusion criteria

As detailed in the protocol, the inclusion criteria used to determine consideration for inclusion should be stated. For a quantitative review aspects include: Population, Intervention/phenomenon of Interest, Comparator and Outcomes, as per the PICO mnemonic.

Search strategy

This section should include an overview of the search strategy used to identify articles considered by the review. 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 and consider the comprehensiveness and exhaustiveness of the search strategy for each included database.

Each electronic database is likely to use a different system for indexing key words within their search engines. Hence, the search strategy will be tailored to each particular database. These variations are important and need to be captured and included in the systematic review report. Additionally, if a comprehensive systematic review is being conducted through JBI-CReMS, the search strategies for each database for each approach are recorded and reported via CReMS. Commonly, these are added as appendices.

Methods of the review

Assessment of methodological quality

Critical appraisal

This section of the review should include the details of critical appraisal with the MASTARI instrument. As discussed in the section on protocol development, it is JBI policy that quantitative studies should be critically appraised using JBI critical appraisal instruments for specific study designs incorporated in to the analytical modules of the SUMARI software. The primary and secondary reviewer should discuss each item of appraisal for each study design included in their review.

In particular, discussions should focus on what is considered acceptable to the needs of the review in terms of the specific study characteristics. The reviewers should be clear on what constitutes acceptable levels of information to allocate a positive appraisal compared with a negative, or a response of 'unclear' or 'not applicable'. This discussion should take place before independently conducting the appraisal. The critical appraisal tool should be attached to the review.

Q *Has the MASTARI critical appraisal tool(s) been appended to the review? Have the results of critical appraisal been discussed? Where there any differences of opinion between the reviewers? How were any differences resolved?*

Data extraction

This section of the report should include details of the types of data extracted from the included studies, as predetermined in protocol. If no data was available for particular outcomes, that should also be discussed. The included studies may include several outcomes; however the review should focus on extracting information related to the research questions and outcomes of interest. Information that may impact upon the generalizability of the review findings such as study method, setting and population characteristics should also be extracted and reported. This is so that the data can be put into context. Population characteristics include factors such as age, past medical history, co-morbidities, complications or other potential confounders. MASTARI aims to reduce errors in data extraction by using two independent reviewers and a standardized data extraction instrument.

Data synthesis

This section should describe how the extracted data was synthesized. If the data was heterogeneous and is presented as a narrative summary, potential sources of heterogeneity should be discussed (e.g. clinical, methodological or statistical) as well as on what basis it was determined inappropriate to combine the data statistically (such as differences in populations, study designs or by Chi square test). Where meta-analysis was used, the statistical methods and the software used (MAStARI or RevMan) should be described.

Considerations for conducting a meta-analysis

Effect size

The effect size statistically describes the relationship between two variables and is represented by a square on a forest plot. This could be the impact of a new therapy on mortality rates or the effect of a new teaching method on exam scores. The effect size could be a single number such as for a prevalence study or a ratio such as with a risk ratio. Borenstein et al. 2009²⁷ describe the effect size as being the ‘currency of the systematic review’ as the aim of a meta-analysis is to summarize the effect size of each included study to obtain a summary effect. The summary effect is indicated by a graphical representation of point estimates and limits. When effect sizes are statistically combined, the methods used make certain assumptions.

Heterogeneity

When used in relation to meta-analysis, the term ‘heterogeneity’ refers to the amount of variation in the characteristics of included studies. For example, if three studies are to be included in a meta-analysis, do each of the included studies have similar sample demographics, and assess the same intervention? (Note that the method by which the outcome is measured does not need to be identical). While some variation between studies will always occur due to chance alone, heterogeneity is said to occur if there are significant differences between studies, and under these circumstances meta-analysis is not valid and should not be undertaken. But how does one tell whether or not differences are significant?

Visual inspection of the meta-analysis output, e.g. a forest plot, is the first stage of assessing heterogeneity.

Figure 7 is an example Forest Plot which shows the results of individual studies and thus indicates the magnitude of any effect between the treatment and control groups. Do the individual studies show a similar direction and magnitude of effect – i.e. are the rectangular symbols at similar positions on the X-axis? Do the confidence intervals overlap?

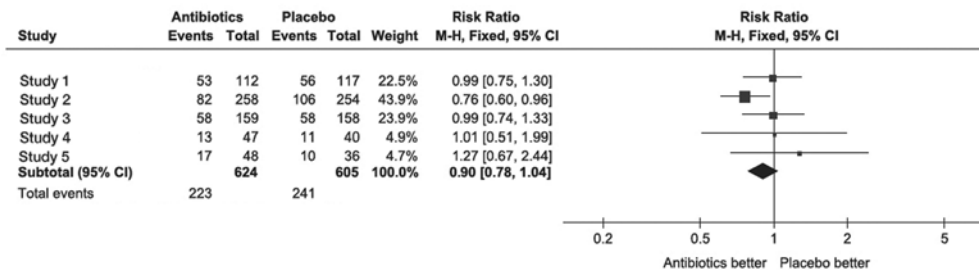


Figure 7: Example of Forest Plot

A formal statistical test of the similarity of studies is provided by the test of homogeneity.⁴³ This test calculates a probability (P value) from a Chi-square statistic calculated using estimates of the individual study weight, effect size and the overall effect size. Note, however, that this test suffers from a lack of power – and will often fail to detect a significant difference when a difference actually exists – especially when there are relatively few studies included in the meta-analysis.

Because of this low power, some review authors use a significance level of $P < 0.1$, rather than the conventional 0.05 value, in order to protect against the possibility of falsely stating that there is no heterogeneity present.⁴⁴ Often when combining the results from a series of observational studies, this is the default significance level due to the increased heterogeneity associated inherent with this study design.

Statistical combination of data

In meta-analysis, the results of similar, individual studies are combined to determine the overall effect of a particular form of health care intervention (the treatment) compared to another standard or control intervention for a specified patient population and outcome. In meta-analysis, the effect size and weight of each study are calculated. The effect size indicates the direction and magnitude of the results of a particular study (i.e. do the results favour the treatment or control, and if so, by how much), while the weight is indicative of how much information a study provides to the overall analysis when all studies are combined together.

Deeks and Altman (2001)⁴⁵ suggest three important criteria for choosing a summary statistic for meta-analysis: (i) consistency of effect across studies, (ii) mathematical properties, and (iii) ease of interpretation.

- i. Consistency of effect is important because the aim of meta-analysis is to bring together the results of several studies into a single result. The available evidence suggests that relative measures of effect such as the odds ratio (OR) and relative risk (RR) are more consistent than absolute measures^{42,45} (absolute measures of effect include the risk difference and the number needed to treat – these are not currently included as analytical options in CReMS/MAStARI and thus will not be discussed further). There is little difference between the RR and OR in terms of consistency between studies.⁴⁵
- ii. The main mathematical property required by summary statistics is the availability of a reliable variance estimate, a feature of both OR and RR. Consensus about the other two mathematical properties (reliance on which of the two outcome states [e.g. mortality/survival] is coded as the event, and the OR being the only statistic which is unbounded) has not yet been reached.⁴²
- iii. Ease of interpretation does vary between OR and RR. Most clinicians and lay readers can intuitively grasp the concept of being at risk of an outcome more easily than the odds of an outcome occurring. When meta-analysis of OR is conducted, reviewers should be careful to explain how odds ratios should be interpreted, and differences between OR and RR when outcomes are common.

Statistical assumptions in meta-analysis

Meta-analysis can be based on either one of two statistical models – fixed or random effects. The fixed effect model assumes that there is one true effect underlying the studies in the analysis and that all differences in the data are due to sampling error or chance within each study and that there is no heterogeneity between the studies.² A fixed effect model is statistically stringent and should be used when there is little heterogeneity, as determined by Chi square (or I²).

The random effects model assumes that there is a population of studies from which those analyzed in the meta-analysis were sampled, and anticipates future studies being conducted or previously unknown studies being identified. As a result, in an analysis based on a random effects model, inference relies on the assumption that the studies used in the analysis are a random sample of some hypothetical population of studies.

A random effects model allows more flexibility, assuming that there may be other factors influencing the data than error or chance, within and between studies. For example, the effect size may be influenced in studies where the participants are more educated, older or healthier or if a more intense intervention is being used. The effect size is assumed to follow a normal distribution and consequently has a mean and variance.

There is no consensus about whether fixed or random effects models should be used in meta-analysis. In many cases when heterogeneity is absent, the two methods will give similar overall results. When heterogeneity is present, the random effects estimate provides a more conservative estimate of the overall effect size, and is less likely to detect significant differences. For this reason, random effects models are sometimes employed when heterogeneity is not severe; however, the random effects model does not actually analyze the heterogeneity away and should not be considered as a substitute for a thorough investigation into the reasons for the heterogeneity.⁴⁴ Additionally, random effects models give relatively more weight to the results of smaller studies – this may not be desirable because smaller studies are typically more prone to bias and of lower quality than larger studies.^{42,45}

There are a number of meta-analytical techniques available. The selection of a particular technique is governed by three things: the study type, the nature of the data extracted and the assumptions underlying the meta-analysis. The following paragraphs introduce the tests that are available in MASTARI and when it is appropriate to use each of these tests.

When the outcome of included studies is dichotomous, MASTARI can be used to generate two overall effect sizes: odds ratios (OR) and relative risks (also known as risk ratios, RR). The choice of whether OR or RR are calculated is important and should be carefully considered.

Meta-analysis of dichotomous data

There are several different methods available to pool results of dichotomous data, depending on the data type and whether a random or fixed effects model is required: Mantel-Haenszel, Peto's and DerSimonian and Laird.

Mantel-Haenszel

Mantel-Haenszel is the MASTARI default meta-analytical method for dichotomous data using a fixed effects model. Both OR and RR can be pooled using Mantel-Haenszel methods; the calculation of study weights and effect sizes, and overall effect sizes differs slightly between OR and RR. The Mantel-Haenszel method is generally preferred in meta-analysis to another method (inverse variance) because it has been shown to be more robust when data are sparse (in terms of event rates being low and/or the number of trials being small).⁴⁵

Peto's odds ratio

Peto's odds ratio is an alternative method for meta-analysis of OR using a fixed effects model. It employs an approximation that can be inaccurate if treatment effects are very large, and when the sample sizes between treatment and control groups are unbalanced. However, the method is appropriate when event rates are very low and effect sizes are not overly large.⁴⁵

DerSimonian and Laird

DerSimonian and Laird methods are used in the meta-analysis of OR and RR using a random effects model. Although the study effect sizes and heterogeneity statistics are calculated as for the fixed effects model, the study weights and overall effect sizes in DerSimonian and Laird random effects models are calculated slightly differently to fixed models.

Meta-analysis of continuous data

When the outcomes of included studies are continuous, MASTARI can be used to generate two overall effect size calculations using the weighted mean difference (WMD) or standardized mean difference (SMD). The WMD measures the difference in means of each study when all outcome measurements are made using the same scale. It then calculates an overall difference in means between the treatment groups for all studies (this is equivalent to the effect size) based on a weighted average of all studies, which is, in turn, related to the SD. MASTARI uses the inverse variance method of calculating WMD for fixed effects models and the DerSimonian and Laird method for random effects models.

Alternatively, different studies may measure the same outcome using different scales. For example, pain can be measured on a range of different scales including non-verbal scales (e.g. 100mm visual analogue scale) and verbal scales (e.g. 5 point Likert scale). These studies can be combined in a meta-analysis that incorporates SMD. If the measurement scales operate in the same direction (e.g. an increase in pain is measured as an increase in both scales), then using SMD is straightforward. However, if two measurement scales operate in a different direction – for example a score of 10 is the worst pain imaginable on one scale but a score of 1 is the worst pain imaginable on another scale - then data from one scale needs to be reversed. This is relatively simply achieved by multiplying the mean data from one scale (for both treatment and control groups) by -1. Standard deviations do not need to be modified.

MASTARI provides two options for calculation of the SMD using fixed effects: Cohen's SMD and Hedges' SMD. Both options produce a similar result, although Hedges' SMD is generally preferred as it includes an adjustment to correct for small sample size bias.⁴² As per WMD, the DerSimonian and Laird method is used for random effects models calculations for SMD.

Review Results

Description of studies

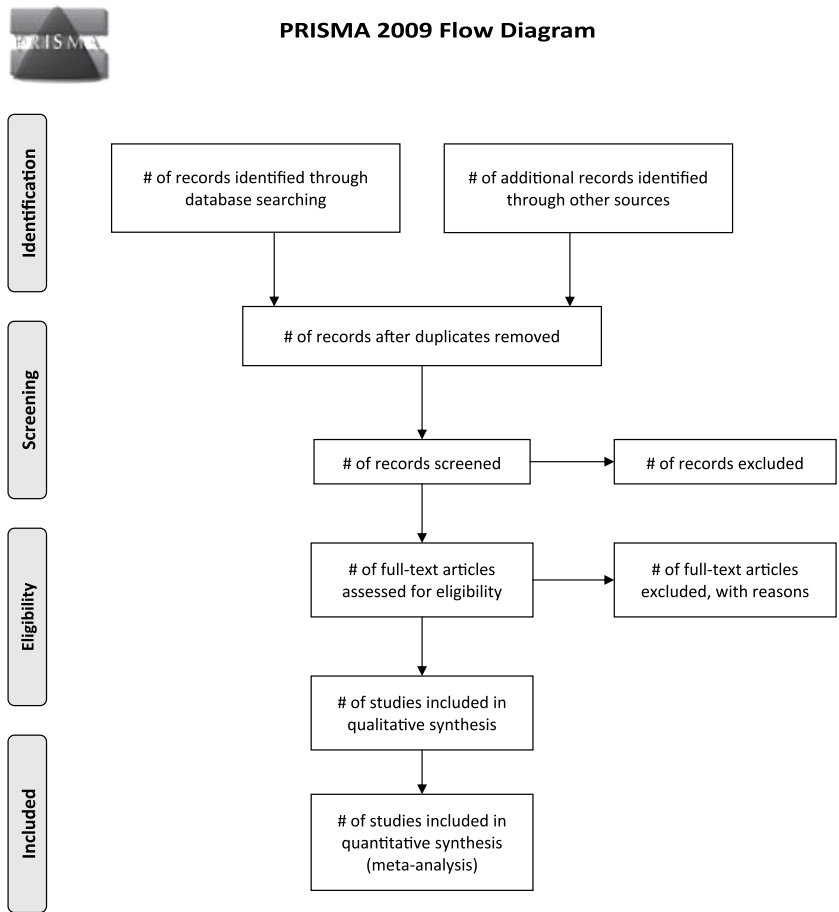
The type and number of papers identified by the search strategy and the number of papers that were included and excluded should be stated. The description should be accompanied by a flowchart such as that shown in Figure , with the following stages of identifying and retrieving studies for inclusion:

- Number of studies identified
- Number of studies retrieved for detailed examination
- Number of studies excluded on the basis of title and abstract
- Number of full text articles retrieved
- Number of studies excluded on the basis of full text
- Number of appraised studies

- Number of studies excluded studies following critical appraisal and an overview of reasons for exclusion
- Numbers of included studies.

Details of all full text articles that were retrieved for critical appraisal should be given. There should be separate appendices for details of included and excluded studies. For excluded studies, details should also be given for why they were excluded. (Note: all of this is automatically documented in CReMS as reviewers add information in MASTARI and is uploaded to <Report Builder>)

This section should include the type and number of papers identified by the search and the numbers of studies that were included and excluded from the review.



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

Figure 8: The PRISMA flowchart

The description of studies may also incorporate details of included studies. This additional detail may include the assessment of methodological quality, characteristics of the participants and types of interventions.

With detail on the number and type of studies reported, 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.

Assessment of methodological quality

This section should summarize the overall quality of the literature identified. For example:

The search strategy identified 53 potentially relevant studies, of which 23 were excluded as they were not consistent with the review objectives. Of the 30 relevant studies, 10 were excluded on the basis of methodological quality, as they scored less than six using the MASTARI checklist (the criteria should be detailed in the protocol). Of the remaining 20 included studies, 15 were randomized controlled trials and five were quasi-experimental studies.

In the example above, data from the RCTs would be combined and the data from the quasi-experimental studies could potentially be combined, assuming there was no significant heterogeneity, as discussed previously.

Review results

This section should be organized in a meaningful way based on the objectives of the review and the criteria for considering studies. There is no standardized international approach to how review findings are structured or how the findings of reviews ought to be reported. It would be logical, however, to present findings in the same order as the review questions and/or review objectives. The audience for the review should be considered when structuring and presenting the review findings.

With detail on the studies reported, 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 reviewer, in discussion with their review panel, give consideration to whether the specific review question be used to structure the results section, or whether the findings can be reported under the outcomes specified in the protocol. For reviews of effectiveness, reporting based on outcomes identified in the protocol is a common method for establishing clear structure to the results. Some reviews have taken the approach of reporting RCT-based data for all outcomes of interest, then repeating the structure for non-RCT papers.

Where a systematic review seeks to address multiple questions, the results may be structured in such a way that particular outcomes are reported according to the specific questions.

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 advice here is general in nature. In general, findings are discussed textually and then supported with meta-graphs, tables and figures as appropriate. The focus should be on presenting information in a clear and concise manner. Any large or complex diagrams/tables/figures should be included as appendices so as not to break the flow of the text.

Meta-view graphs represent a specific item of analysis that can be incorporated in to the results section of a review. However, the results are more than the meta-view graphs, and whether this section is structured based on the intervention of interest, or some other structure, the content of this section needs to present the results with clarity.

Synthesis of quantitative research findings using MASTARI

It is important to combine the studies in an appropriate manner; otherwise the conclusions that are drawn will not be valid. Where possible study results should be pooled in statistical meta-analysis using MASTARI. All results must be double entered in order to avoid data entry errors. Odds ratio or relative risks (for categorical data) and standard or weighted mean differences (for continuous data) and their 95% confidence intervals should be calculated for analysis. Heterogeneity should be assessed using the standard Chi-square. Where statistical pooling is not possible the findings can be presented in narrative summary, as previously discussed.

While using odds ratios (OR) is the traditional approach to meta-analysis for dichotomous data, the relative risk (RR) should be considered for RCTs as well as cohort or descriptive designs as risks may be easier to communicate, and better understood by a wider audience than an odds ratio.

The meta-analysis functions in the CReMS module are made up of a number of drop-down menus that allow the user to specify the required comparison (i.e. which intervention group is to be compared to which control group), the outcome to be included and the statistical tests to be used. These drop-down menus incorporate outcome and intervention descriptions and data that have previously been entered in MASTARI.

The SUMARI user guide is a recommended text for technical aspects of data synthesis.

This section of the report should describe the data type (continuous/dichotomous), the required effects model used (random/fixed), the statistical method of meta-analysis required and the size of confidence limits to be included in the calculations. The method used will depend on the data type.

For continuous data under a fixed effects model there are three options for meta-analysis included in CReMS:

- Hedge's adjusted standardized mean difference (SMD);
- Cohen's standardized mean difference (SMD); or
- Weighted mean difference (WMD).

For continuous data under a random effects model there are two options:

- DerSimonian and Laird standardized mean difference (SMD); or
- DerSimonian and Laird weighted mean difference (WMD).

For dichotomous data using a fixed effects model, there are three options:

- Mantel-Haenszel Relative Risk (RR);
- Mantel-Haenszel Odds Ratio (OR); or
- Peto Odds Ratio (OR).

There are two options for dichotomous data using a random effects model:

- the DerSimonian and Laird Odds Ratio (OR); or
- the DerSimonian and Laird Relative Risk (RR).

In terms of confidence intervals, the default setting of MASTARI is to calculate 95% confidence intervals; however this can be adjusted to either 90% or 99% as required. In the current version of the software, the preferred meta-view field defaults to 'Forest plot' as currently no other options are available.

Once all of the appropriate settings have been selected, the forest plot summarizing the results of the individual studies and their combined meta-analysis can be generated. The forest plot can be saved as a jpeg (.jpg) file using the 'Save graph to disk' button, and specifying an appropriate name and location for the file, enabling it to be embedded in a systematic review report or other document. Simply using the 'send to report button' will automatically transfer your forest plot to your review results in CReMS.

In MASTARI, if you have not previously conducted data extraction on your outcome of interest, create a new outcome. Include a title for the outcome, a description of the outcome, the units or scale that the outcome is measured in, and whether the data is dichotomous (i.e. can only take two possible entities, for example yes/no, dead/alive, disease cured/not cured) or continuous (i.e. measured on a continuum or scale using a number, for example body mass in kg, blood pressure in mm Hg, number of infections per year). Note the title of the outcome and its description for future reference. All relevant outcomes can be added at this time, and will appear in a drop down list for selection when adding interventions and data, or outcomes can be added one at a time. Complete data entry undertaken for each outcome prior to commencing extraction of subsequent outcomes.

Q *Are appropriate statistical methods used?
If in doubt, seek specialist help.*

Discussion

The aim of this section is to summarize and discuss the main findings – including the strength of the evidence, for each main outcome. It should address 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 not bring in new literature or information that has not been reported in the results section. The discussion does seek to establish a line of argument based on the findings regarding the effectiveness of an intervention, or its impact on 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.^{46,47}

Points to consider in this section include:

- Were any problems identified while 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.?

Conclusions

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
- Implications for practice and research, including recommendations for the future
- Potential limitations of the systematic review.

Implications for practice

Where possible, implications for practice should be detailed but these must be based on the documented results from the review findings and not merely the reviewer's opinion. Where evidence is of a sufficient level, appropriate recommendations should be made. Recommendations must be clear, concise and unambiguous and be assigned a JBI Grade of Recommendation.

Implications for research

As with implications for practice, all implications 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 small sample sizes or methodological weaknesses. Implications for research should avoid generalized statements calling for further research, but should be linked to specific issues. Recommendations must be clear, concise and unambiguous.

References

The references should be appropriate in content and volume and include background references and studies from the initial search. The format must be in the Vancouver referencing style, as previously discussed in the Protocol section.

Appendices

Appropriate appendices (appraisal, extraction tools) as they appear from CReMS should be provided and referred to in the review. Appendices should be numbered using Roman numerals in the order in which they have been referred to in the body of the text. There are several required appendices for a JBI review:

Appendix I: Search strategy

A detailed search strategy for at least one of the major databases searched must be appended.

Appendix II: Critical appraisal instrument

The critical appraisal instrument used must be appended, i.e. JBI-MASARI Critical Appraisal Checklist for Experimental Research.

Appendix III: Data extraction instrument

The data extraction instrument used must be appended, i.e. JBI-MASARI Data Extraction Form for Experimental Research.

Appendix IV: Table of included studies

A table of included studies is crucial to allow a snapshot of the studies included in the review.

Appendix V: List of excluded studies

At a minimum, a list of studies excluded at the critical appraisal stage must be appended and reasons for exclusion should be provided for each study (these reasons should relate to the methodological quality of the study, not study selection). Studies excluded following examination of the full-text may also 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.



Are all appendices correctly numbered and attached to the report?



“Try to get some rest. I’ll be in every few minutes to make sure you don’t.”

Chapter Seven:

Economic evidence and evidence-based practice

Economic evidence, similar to the quantitative evidence discussed in the preceding section of this manual, also deals with numerical data. As its name suggests however, this type of research introduces another important dimension to the evidence used to inform decisions made across healthcare, that is, the dollar value. A health economic evaluation looks to compare both the health effects and the costs of two or more alternative health interventions.⁴⁸ To do this, the study designs encountered are often similar to those for 'quantitative' evidence already described (Section 3) with the added inclusion of cost measurement. Studies that incorporate sometimes complex modelling of data are also frequently encountered whilst addressing economic evidence.

In any society, resources available (including dollars!) have alternative uses. In order to make the best decisions about alternative courses of action evidence is needed on the health benefits and also on the types and amount of resources needed for these courses of action. Health economic evaluations are particularly useful to inform health policy decisions attempting to achieve equality in health care provision to all members of society and are commonly used to justify the existence and development of health services, new health technologies and also, clinical guideline development.⁴⁹

The generalizability of economic data has been widely debated by health economists. Problems arising from factors such as differences in time of measurement, epidemiology of disease, resource availability and currencies to name a few can all impact on the transferability of economic evidence from one place to another.

Consideration of economic evidence and the different methods available to evaluate this form of evidence relies on understanding some basic principles of health economics. The remainder of this chapter will introduce some of the main differences in methods of economic evaluation and then consider issues inherent to all of these methods used to evaluate economics in healthcare such as the range of different costs and benefits which may be incurred across healthcare and differences in how they are measured; differences in perspective on these costs, whether from the patient, physician, hospital or society as a whole and different categorisation of costs.

Methods for economic evaluation

Economic studies can be distinguished from each other on the basis of the method of analysis or approach employed. These methods can be either full or partial. Types of full economic evaluation include cost-effectiveness analysis (CEA), cost-utility analysis (CUA) and cost-benefit analysis (CBA), whilst cost-minimisation analysis (CMA) is only considered to be a partial economic analysis. Each of these different methods will be discussed briefly.

Cost-minimisation analysis

Cost-minimisation analysis is only considered to be a partial analysis as the outcomes of the intervention or program being compared are assumed to be equivalent and only differences in costs of the interventions are investigated. The preferred option is the cheapest. Clearly, strength of any CMA relies on the assumption that outcomes are indeed equivalent. For example, it would not be appropriate to compare different classes of medications using cost-minimisation analysis if there are noted differences in outcomes.

Cost-effectiveness analysis

Studies which compare not just the costs of different interventions or programs, but also the outcomes or effects often employ CEA. This is similar in principle to a CBA; however the defining feature being that in a CEA the outcome is measured as you may expect for any study of effectiveness (e.g. mmHg, cholesterol levels etc.), whilst in a CBA the outcome is measured in monetary terms (see below).^{50,51} In a cost effectiveness study results are presented as a ratio of incremental cost to incremental effect, or, in other words, the relative costs to achieve a given unit of effects.⁵² One disadvantage of CEA is that programs with different types of outcomes cannot be compared.

Cost-utility analysis

Studies investigating the cost utility can often be identified by the outcome the study or analysis reports – quality adjusted life years, or QALYs. Whilst costs are still measured in monetary units, the QALY measure is the product of two dimensions of life, both quality and length.⁵¹

Cost-benefit analysis

As mentioned above, the distinguishing feature of a cost benefit study or analysis is that both the intervention and also the outcome are measured in dollars. In a CBA all costs and benefits are measured in monetary terms and then combined into a summary measure, for example the Net Present Value (NPV) and the Benefit-Cost Ratio (BCR). A limitation of this type of study is the difficulty of measuring the value of all health outcomes, for example life, in dollars! Table 3 compares the four basic types of economic evaluation studies.

- ***There are four basic types of economic evaluation studies: cost-minimisation analysis (CMA), cost-effectiveness analysis (CEA), cost-utility analysis (CUA), cost-benefit analysis (CBA).***

Table 3: A summary of the different types of economic evaluation, together with the costs measured and specific advantages and disadvantages associated with each type

| Type of Economic Evaluation | Costs Measures | Benefits/Consequences Measures | Comments |
|--|--|---|---|
| Cost-Minimisation Analysis (CMA) | Costs measured in monetary units (e.g., dollars) | Not measured | CMA is not a form of full economic evaluation; the assumption is that the benefits/consequences are the same; the preferred option is the cheapest |
| Cost-Effectiveness Analysis (CEA) | Costs measured in monetary units (e.g., dollars) | Benefits measured in natural units (e.g., mmHg, cholesterol levels, symptom-free days, years of life saved) | results are expressed for example as dollars per case averted, dollars per injury averted; different incremental summary economic measures reported (e.g., incremental cost-effectiveness ratio ICER) |
| Cost-Utility Analysis (CUA) | Costs measured in monetary units (e.g., dollars) | Benefits expressed in summary measures as combined quantity and quality measures (e.g., QALY, DALY etc) | two dimensions of effects measured (quality and length of life); results are expressed for example as cost per QALY |
| Cost-Benefit Analysis (CBA) | Costs measured in monetary units (e.g., dollars) | Benefits are measured in monetary units (e.g., dollars) | it is difficult to measure the value of all health outcomes in monetary units (e.g., dollars); summary measures for CBA are the Net Present Value (NPV) and the Benefit-Cost Ratio (BCR) |

Perspective

Irrespective of the type or method of economic evaluation study there are some economic principles that must be considered. One important consideration is perspective – put simply, the benefits and costs of using an intervention in health care depends on whose perspective it is. Economic studies will present perspective to make it clear whose or which costs are being considered. Different perspectives may include those of patients, physicians, hospitals, insurance companies or even that of society (by combining all healthcare perspectives), just to name a few! The choice of perspective will influence the types of costs and outcome measures considered relevant for inclusion in the economic study.

Costs

The measure of cost may seem simple at first, but in health care analyses it is an important and often multi-dimensional concept which includes identification of costs (which costs are included or not and why), measurement of the factors that result in the costs (expressed in the natural units used for measurement), and valorization of every unit from whose perspective it is.⁴⁸ Another important consideration is cost and how it is categorized. Economic studies use a range of costs, hence it is important to be able to distinguish between the different types of costs that are used. Costs are typically categorized as 'direct medical', 'direct non-medical' and 'indirect costs'. Direct medical costs are those incurred by health services, such as physician time, drugs, medical devices and the like. Direct non-medical costs include things like administration, child care, travel costs and utilities whilst indirect costs would include for example the time off work a patient has had to take to visit the doctor or whilst ill.

Another category of costs are those labelled 'intangible' such as pain, suffering or anxiety; these costs are often quantified by measures of 'willingness-to-pay'. Further cost categories encountered in the literature may include health care sector costs, patient and family costs, productivity costs and more. Costs presented in economic studies can also be referred to simply as variable or fixed. These are terms more commonly used amongst financial circles and in the case of variable costs, they refer to those that vary depending on the number of cases treated, such as drugs administered. Fixed costs on the other hand do not fluctuate and are unlikely to vary in the short-medium term irrespective of the number of cases, e.g. the cost of a building. Semi-fixed costs have components of both and would tend to increase only when there is a large increase in the number of cases treated.

When comparing costs and benefits, another key principle in economics is that of discounting. Discounting is necessary for direct comparison of costs and benefits during different periods of time. It is necessary to consider in economic studies due to the underlying economic principle that society places greater value on benefits gained immediately, rather than those in the future. To reflect this preference, costs and benefits gained in the future are discounted when they are being compared with the present. The rationale for the choice of the discount rate should be provided.

Chapter Eight:

Economic protocol and title development

JB I economic evaluation reviews are conducted through the ACTUARI module of the SUMARI software.

The ACTUARI module is designed to manage, appraise, extract and analyze economic data as part of a systematic review of evidence. ACTUARI has been designed as a web-based database and incorporates a critical appraisal scale; data extraction forms; and a data analysis function. The ACTUARI software is one analytical module of the SUMARI software. SUMARI is the Joanna Briggs Institute's software for the systematic review of literature.

Systematic reviews are often conducted to address information needs for a particular constituency or jurisdiction, yet the final review and subsequent guidance is disseminated internationally. Therefore, the request for JBI reviewers is to develop protocols for systematic review appropriate to an international audience.

A search of at least the Cochrane Library, Joanna Briggs Institute Library of Systematic Reviews, MEDLINE and NHS EED databases will assist to establish whether or not a recent systematic review report exists on the economic evaluation topic of interest.

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 the date of last update longer than three years ago?
- Do the methods reflect the specific inclusion and exclusion criteria of interest for your topic?
- Is there a specific gap in terms of population or intervention or outcomes that has not been addressed in the identified review?

These questions may not be the deciding factor in continuing with a review topic, but do present some contextual factors that need considering before embarking on a systematic review process.

Once a topic has been selected, and the decision to conduct a systematic review verified by the lack of existing systematic reviews within the topic area, the systematic review title should be registered with JBI.

A protocol for a review of economic evaluation evidence should be developed as for a review of effectiveness evidence. The protocol should establish in advance the methods that will be used throughout the systematic review process. Decisions about the review question, inclusion criteria, search strategy, study selection, data extraction, quality assessment, data synthesis and reporting should be addressed. Specifying the methods in advance reduces the risk of introducing bias into the review.

Q JBI systematic reviews of economic evidence are required to use the ACTUARI software. Do systematic reviews already exist on the topic of interest? How is the current review different?

Protocol design for reviews of Economic Evidence

Title page

A JBI review requires at least two reviewers. The names of the reviewers, together with their post nominal qualifications, contact details and JBI affiliation should be listed on the title page of the protocol.

Title of the systematic review protocol

The title of the systematic review protocol should be as descriptive as is reasonable and should reflect the systematic review type to be conducted. If the review is examining economic effectiveness this should be stated in the title of the protocol. If specific interventions and patient outcomes are to be examined these should also be included in the title. Where possible the setting and target population should be stated. Reviews of economic effectiveness may also incorporate a review of clinical effectiveness. Both elements can readily be incorporated in the title. For example:⁵³

'Self-monitoring of blood glucose in type 2 diabetes mellitus: systematic review of economic evidence.'

This example provides potential readers of the review with a clear indication of population, the interventions, and the outcome of interest, as well as the fact that it is a systematic review. A clear title is important for indexing and to assist peer reviewers as well as end users to identify the scope and relevance of the review.

- ***The clearer and more specific a title of a systematic review is, the more readily users of electronic databases will be able to make decisions about the systematic review and its applicability to their information needs.***

Objectives

The objectives of the review should provide a clear statement of the questions being addressed with reference to participants, interventions, comparators and outcomes. Clear objectives and specificity in the review questions assist in focusing the protocol, allow the protocol to be more effectively indexed, and provides a structure for the development of the full review report. The review objectives should be stated in full. Conventionally, a statement of the overall objective is made and elements of the review are then listed as review questions. For example:⁵³

'To perform a systematic review of economic evaluations of self-monitoring of blood glucose in patients with type 2 diabetes mellitus.'

This broad statement can then be clarified by using focussed review questions. For example:⁵³

The objectives of this review were to:

- *systematically review the cost-effectiveness of self-monitoring of blood glucose in the treatment of type 2 diabetes mellitus*
- *where possible, determine the cost-effectiveness of self-monitoring of blood glucose in differing treatment subgroups*
- *inform practice and policy regarding the cost-effective use of self-monitoring of blood glucose in type 2 diabetes mellitus.*

The review question can be framed in terms of the Population, Intervention(s), Comparator(s) and Outcomes of the studies that will be included in the review. These elements of the review question together with the study design will be used in order to determine the specific inclusion criteria for the review.

There is a range of mnemonics available to guide the structuring of systematic review questions, the most common for JBI reviews being PICO. The PICO mnemonic begins with identification of the Population, the Intervention being investigated and the Comparator and ends with a specific Outcome of interest to the review. Use of mnemonics can assist in clarifying the structure of review titles and questions, but is not a requirement of JBI systematic reviews.

In addition to clarifying the focus of a systematic review topic through the development of a review question, it is recommended that reviewers establish whether or not a systematic review has already been conducted to answer their specific review questions, and whether there is a body of literature available for their review questions.

Q *Does the review have a concise, informative title? Are the review objectives and questions clearly stated?*

Background

The Joanna Briggs Institute places significant emphasis on a comprehensive, clear and meaningful background section to every systematic review. The background should communicate the contextual factors and conceptual issues relevant to the review. It should explain why the review is required and provide the rationale underpinning the inclusion/exclusion criteria and the review question.

The background should also describe the issue under review including the target population, interventions and outcomes that are documented in the literature. The background should provide sufficient detail on each of the elements to justify the conduct of the review and the choice of various elements such as interventions and outcomes. Where complex or multifaceted interventions are being described, it may be important to detail the whole of the intervention for an international readership.

It is often as important to justify why elements are not to be included into the review. In describing the background literature value statements about effects or impact or value of interventions should be avoided. The background section of the review protocol should provide statements based on relevant literature and should provide clear and explicit literature references.

The background should avoid making statements about cost-effectiveness (or cost-benefit or cost-utility) unless they are specific to papers that illustrate the need for a systematic review of the body of literature related to the topic. For example the background section should avoid a statement like 'Use of specialised wound clinics in community centres is cost-effective compared to hospital based treatment'. This is what the review will determine. If this type of statement is made it should be clear that it is not the reviewer's conclusion but that of a third party, such as 'The study by Smith et al., 2010 indicates that use of specialised wound clinics in community centres is cost-effective compared to hospital based treatment'. Such statements in the background need to be balanced by other view points, emphasizing the need for the synthesis of potentially diverse bodies of literature.

A statement should also be provided that clarifies whether or not a systematic review has previously been conducted and/or a rationale for performing another review should one already exist.

Q **Questions to consider:**
Does the background cover all the important elements (PICO) of the systematic review? Are operational definitions provided? Do systematic reviews already exist on the topic, if so how is this one different? Why is this review important?

Inclusion criteria

The inclusion criteria should be set out in the protocol to ensure that the boundaries of the review question are clearly defined. All elements should be specified in detail. Complex issues may require detailed consideration of terms. Reviewers need to be clear about definitions used. Conceptual and operational definitions will usually be helpful.

The inclusion criteria should capture all studies of interest. If the criteria are too narrowly defined there is a risk of missing potentially relevant studies. If the criteria are too broad the review may contain information which is hard to compare and synthesise. Inclusion criteria need to be practical to apply.

The PICO model aims to focus the systematic review and is used to define the properties of studies to be considered for inclusion in the review. PICO is used to construct a clear and meaningful question when searching for quantitative evidence.

P = *Population (type of participants)*

When expanding the title and objectives/questions through the criteria for inclusion, reviewers will need to consider whether the whole population of people with a specific condition should be included, or if the population will be limited to specific subsets. Specific reference to population characteristics (participants' gender, age, disease severity, co-morbidities, socio-economic status, ethnicity, geographical area) either for inclusion or exclusion should be based on a clear, scientific justification rather than based on unsubstantiated clinical, theoretical or personal reasoning.

The included population should be relevant to the population to which the review findings will be applied. Explicit inclusion criteria should be defined in terms of the disease or condition of interest. If the inclusion criteria are broad it may be useful to investigate subgroups of participants. Where analysis of participant subgroups is planned this should be specified in the protocol. For example:⁵³

'The population of interest for this review consisted of adult patients diagnosed with type 2 diabetes mellitus. Those patients with type 1 diabetes mellitus were excluded from the review on the basis that SMBG is recommended as standard practice for all type 1 diabetes mellitus patients. Where the data permitted, relevant subgroups of interest were also explored, such as co morbidities (e.g. presence of heart disease or hypertension) and the treatment regime of the patient i.e. diet and exercise, oral anti-diabetic agents (OADs) and insulin treated patients).'

I = Intervention (types of interventions)

Where possible, the intervention should be described in detail, particularly if it is multifaceted. The nature of the intervention(s) explored in the review may be framed in very broad terms or may be more specific. Elements usually specified include the nature/type of the intervention, the person(s) delivering the intervention(s) and the setting in which the intervention is delivered.

Important details for types of interventions are: explicit and clear description of interventions, dosage, intensity, mode of delivery, types of personnel who deliver it, frequency of delivery, duration of delivery, timing of delivery, critical doses/intensity, co-interventions. For example:⁵³

"Studies which examined SMBG, as part of a wider program to control blood glucose, as well as studies which investigated SMBG as a single interventional program, were considered."

C = Comparator (types of comparisons)

Stating a particular comparator limits the scope of a review, assisting with ensuring a clear focus for determining inclusion and exclusion once searching and appraisal is complete. However, when a broader question is being considered, particularly one where multiple interventions exist, limiting the types of comparators may not be appropriate or desirable.

Where an intervention has not been subject to previous economic evaluation, the comparator can reasonably be identified based on either a known gold standard, or an approach, which is considered to be 'current practice'.

Important details for comparators are: explicit and clear description of interventions, dosage, intensity, mode of delivery, types of personnel who deliver it, frequency of delivery, duration of delivery, timing of delivery, critical doses/intensity and co-interventions.

O = Outcome (types of outcomes)

The types of outcomes and the timing of outcomes measurements are key decisions in development of a systematic review protocol. There should be a list of all the outcome measures to be considered. Note that outcome measures might be primary or secondary. The background should provide enough information to justify the outcomes included and potentially those that were not included. The outcomes need to be measurable and appropriate to the review objective. It is useful to list outcomes and identify them as primary or secondary, short-term or long-term, relative or absolute.

In terms of costing data, the outcome may be described in relation to the type of review. Therefore the outcomes may be described in relation to cost-minimisation analysis, cost-effectiveness analysis, cost-benefit analysis or cost-utility analysis (these being the economic models incorporated in the analytical module ACTUARI). For example:⁵³

'The main outcome measures were in terms of cost-effectiveness and cost-utility i.e. cost per life year saved or cost per quality adjusted life year saved (QALY) which is determined not only by the quantity but quality of additional life years. Studies that use other methods to formally combine cost and outcome data e.g. an average cost-effectiveness ratio, were also included.'

ACTUARI Example

Inclusion criteria Types of participants

The population of interest for this review consisted of adult patients diagnosed with T2DM. Those patients with type 1 DM were excluded from the review on the basis that SMBG is recommended as standard practice for all type 1 DM patients. Where the data permitted, relevant subgroups of interest were also explored, such as co morbidities (e.g. presence of heart disease or hypertension) and the treatment regime of the patient i.e. diet and exercise, oral antidiabetic agents (OADs) and insulin treated patients).

Types of intervention(s)/phenomena of interest

Studies which examined SMBG, as part of a wider programme to control blood glucose, as well as studies which investigated SMBG as a single interventional programme, were considered.

Types of studies

Studies involving SMBG compared to no SMBG in the management of blood glucose in T2DM, to be included, must have made a formal attempt to relate cost to outcome data in a cost-effectiveness or cost utility analysis.

Types of outcomes

The main outcome measures were in terms of cost-effectiveness and cost-utility i.e. cost per life year saved or cost per quality adjusted life year saved (QALY) which is determined not only by the quantity but quality of additional life years. Studies that use other methods to formally combine cost and outcome data e.g. an average cost-effectiveness ratio, were also included.

DE VERTEUIL, Robyn; TAN, Woan Shin. Self-monitoring of blood glucose in type 2 diabetes mellitus: systematic review of economic evidence. JBI Library of Systematic Reviews, [S.l.], v. 8, n. 7, p. 302 - 342, apr. 2010. ISSN 1838-2142. Available at: <<http://www.joannabriggslibrary.org/jbilibrary/index.php/jbisrir/article/view/116/167>>. Date accessed: 22 Jan. 2014.

Types of studies

This section should flow naturally from the criteria that have been established to this point, and particularly from the objective and questions the review seeks to address. For JBI reviews of health economic evaluation evidence, there are specific study designs of interest to specific economic questions.

These include:

Cost-minimisation studies: intended to identify the least costly intervention where multiple interventions have demonstrated similar benefit

Cost-effectiveness studies: where interventions achieve similar outcomes but have unknown or potentially different resource implications

Cost-utility studies: seek to establish benefit as measured by quantity and quality of life (QALYs)

Cost-benefit studies: seek to identify a specific monetary ration (gain/loss or cost/benefit) for an intervention

The reviewers should specify if they will include in the systematic review only one specific study design (for example, only cost-minimisation studies) or two (cost-effectiveness and cost-utility) or more than two study design types. The reviewers should also clarify the types of studies they will include in the systematic review: comparative prospective economic evaluation studies, comparative retrospective economic evaluation studies, health economic evaluation modelling studies. For economic evaluation modelling studies the reviewers should specify the types of modelling studies they will include in the systematic review.

Search strategy

Systematic reviews are international sources of evidence; particular nuances of local context should be informed by and balanced against the best available international evidence.

The protocol should provide a detailed search strategy that will be used to identify all relevant international research within an agreed time frame. This should include databases that will be searched, and the search terms that will be used. In addition to this, it should also specify what types of study design for economic evaluation studies (for example, CEA, etc.) will be considered for inclusion in the review.

Within JBI systematic reviews, the search strategy is described as a three-phase process that begins with identifying initial key words followed by an analysis of the text words contained in the title and abstract, and of the index terms used to describe relevant articles. The second phase is to construct database-specific searches for each database included in the protocol, and the third phase is to review the reference lists of all studies that are retrieved for appraisal to search for additional studies.

The text describing searching has been standardized in JBI CReMS as follows:

The search strategy aims to find both published and unpublished studies. A three-step search strategy will be utilized in this review. An initial limited search of MEDLINE and CINAHL will be undertaken followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe article. A second search using all identified keywords and index terms will then be undertaken across all included databases. Thirdly, the reference list of all identified reports and articles will be searched for additional studies. Studies published in #insert language(s)# will be considered for inclusion in this review. Studies published #insert dates# will be considered for inclusion in this review.

- **The standardized text is editable and includes fields for reviewers to specify content relevant to their available resources.**

Reviewers are required to state the databases to be searched, the initial key words that will be used to develop full search strategies and if including unpublished studies what sources will be accessed. The search strategy should also describe any limitations to the scope of searching in terms of dates, resources accessed or languages; each of these may vary depending on the nature of the topic being reviewed, or the resources available to each reviewer.

Limiting by date may be needed where the focus of the review is on a more recent intervention or innovation.

However, date limiting may exclude seminal early studies in the field and should thus be used with caution, the decision preferably be endorsed by topic experts, and justified in the protocol.

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

The comprehensiveness of searching and the documentation of the databases searched is a core component of the systematic review's credibility. In addition to databases of published research, there are several online sources of grey or unpublished literature that should be considered.

Grey literature is a term that refers to papers, reports, technical notes or other documents produced and published by governmental agencies, academic institutions and other groups that are not distributed or indexed by commercial publishers. Many of these documents are difficult to locate and obtain. Rather than compete with the published literature, grey literature has the potential to complement and communicate findings to a wider audience.

The Joanna Briggs Institute is an international collaboration with an extensive network of centres and other entities around the world. This creates networking and resource opportunities for conducting reviews where literature of interest may not be in the primary language of the reviewers. 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 JBI entities regarding translation.

It may also be useful to communicate with other JBI entities to identify databases not readily available outside specific jurisdictions for more comprehensive searching.

JBI entities that do not have access to a range of electronic databases to facilitate searching of published and grey literature are encouraged to contact JBI, which enables them to access an increased range of resources.

Obtaining the input of an experienced librarian to develop the search strategy is recommended.

- ***Details of the number of titles identified by the search are to be reported in the systematic review report so it is important to keep track of search results.***

Assessment criteria

The systematic review protocol should provide details of the method of study appraisal to be used. Details of how the study appraisal is to be used in the review process should be specified.

The protocol should specify the process of appraisal of study quality, the number of reviewers involved and how disagreements will be resolved. The protocol should specify any exclusion criteria based on quality considerations.

It is JBI policy that all study types must be critically appraised using the standard critical appraisal instruments for specific study designs, built into the analytical modules of the SUMARI software.

As with other types of reviews, the JBI approach to reviews of economic evidence incorporates a standardized approach to critical appraisal, using the ACTUARI software. The protocol must therefore describe how the validity of primary studies will be assessed.

The systematic review protocol of economic evidence must include a copy of the ACTUARI critical appraisal checklist (Appendix VIII) as an appendix. The checklist is a series of criteria that can be scored as being met, not met or unclear.

The standardized set text in CReMS states:

Economic papers 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 the Joanna Briggs Institute Analysis of Cost, Technology and Utilisation Assessment and Review Instrument (JBI-ACTUARI). Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer.

■ ***The ACTUARI set text can be extended by reviewers who wish to add or edit information.***

The assessment tools included in the analytical module ACTUARI are required for all JBI entities conducting reviews through JBI. A separate checklist should be used for each type of study design considered for inclusion in the review (when appropriate) and each should be appended to the protocol (this occurs automatically in CReMS). ACTUARI has been designed with the intention that there will be at least two reviewers (a primary and a secondary) independently conducting the critical appraisal. Both reviewers are initially blinded to the appraisal of the other review. Once both reviewers have completed their appraisal, the primary reviewer then compares the two appraisals. The two reviewers should discuss cases where there is a lack of consensus in terms of whether a study should be included; it is appropriate to seek assistance from a third reviewer as required. A discussion of each checklist items can be found in Appendix IX and provides clarification of the objective of each of those items.

The main object of critical appraisal is to assess a study's quality and determine the extent to which a study has excluded the possibility of bias in its design, conduct and analysis.

If a study has not excluded the possibility of bias, then its results are questionable and could well be invalid. Therefore, part of the systematic review process is to evaluate how well the potential for bias has been excluded from a study, with the aim of only including high quality studies in the resulting systematic review.

Q ***Are copies of the critical appraisal tools appended to the protocol? Has the primary reviewer assigned a secondary reviewer to the review?***

Data extraction

The systematic review protocol should outline the information that will be extracted from studies identified for inclusion in the review. The protocol should state the procedure for data extraction including the number of researchers who will extract the data and how discrepancies will be resolved. The protocol should specify whether authors of primary studies will be contacted to provide missing or additional data.

As with other types of reviews, the JBI approach to reviews of economic evidence incorporates a standardized approach and tool to data extraction from ACTUARI software. The standardized data extraction can be found in Appendix X.

The JBI systematic review protocol of economic evidence must include in appendices to the protocol the JBI data extraction form for economic evaluation studies. The set text for data extraction section of the protocol for systematic reviews of economic evidence in CReMS is the following:

Economic data will be extracted from papers included in the review using the standardized data extraction tool from JBI-ACTUARI. The data extracted will include specific details about the interventions, populations, cost, currency, study methods and outcomes of significance to the review question and specific objectives.

In addition to the standardized text from CReMS, reviewers should consider describing how papers will be extracted, and how differences between reviewers were to be resolved.

Q What outcomes are anticipated? How have they been measured? What type of data is anticipated? Has the ACTUARI data extraction tool been appended to the protocol?

Data synthesis

The protocol should describe the methods of data synthesis. In CReMS, the standardized text gives an overview of synthesis as follows:

'Economic findings will, where possible be synthesized and presented in a tabular summary. Where this is not possible, findings will be presented in narrative form.'

However, reviewers should seek to address the synthesis of clinical as well as cost effectiveness data in economic reviews which incorporate both. Additional statements can be added to CReMS and may include descriptions of how data will be presented, including a description of the measurement of estimate of effects and the stated percentage for the confidence interval. Specific reference to continuous and dichotomous data synthesis methods is useful.

Synthesis of economic effectiveness data does not follow the same pattern as synthesis of clinical effectiveness data. While clinical data is synthesized and given a weighting, economic data is more commonly subject to one or more of three options for synthesis. Economic results can be described in this section of the protocol as being subject to:

- narrative summary
- sorting in tables by comparisons or outcomes (as deemed appropriate by reviewers)
- tabulated in a permutation matrix.

In the ACTUARI analytical module, this is described as a dominance rating; each outcome of interest is allocated a position in a grid (which extends from A to I) depending on whether the intervention should be preferred over its comparator. CReMS does not specify these three methods of managing the results. Reviewers, however, are encouraged to describe them in their protocol as a cascade of options, which will in part depend on the quantity, quality and nature of the economic papers they identify. The permutation matrix has three possible outcomes and these are determined by the reviewers' rating of the costs of an intervention of interest balanced against the health outcomes:

- Strong dominance is considered appropriate for decisions clearly in favour of either the treatment or control intervention from both the clinical and economic effectiveness points of view.

- Weak dominance is utilized where the data support either clinical or economic effectiveness, but not both positions.
- Non-dominance is allocated where the intervention of interest is less effective or more costly.

The decision or dominance matrix illustrates the data, making visualization and interpretation by readers clearer and easier.

Q *Are the methods for data synthesis clearly described? How will data be presented?*

Conflict of interests

A statement should be included in every systematic review protocol being submitted to JBI which either declares the absence of any conflict of interest, or which describes a specified conflict of interest. Reviewers are encouraged to refer to the Institute's policy on commercial funding of systematic review activity.

Acknowledgments

The source of financial grants and other funding must be acknowledged, including a declaration of the authors' commercial links and affiliations. The contribution of colleagues or institutions should also be acknowledged.

References

Protocols are required to use the Vancouver referencing style. References should be numbered in the order in which they appear with superscript Arabic numerals in the order in which they appear in text. Full reference details should be listed in numerical order in the reference section. Refer to the author guidelines on the JBI Database of Systematic Reviews and Implementation Reports here: <http://www.joannabriggslibrary.org/jbilibrary/index.php/jbisrir/index>

Appendices

Appendices should be placed at the end of the protocol and be numbered with Roman numerals in the order in which they appear in text. At a minimum this will include critical appraisal and data extraction tools. (This is automatically performed in CReMS.)

Appendix I: Critical appraisal instrument

The critical appraisal instrument used must be appended, i.e. JBI-ACTURAI Critical Appraisal Checklist for Economic Evidence.

Appendix II: Data extraction instrument

The data extraction instrument used must be appended, i.e. JBI-ACTURAI Data Extraction Form for Economic Evidence.

Q *Does the protocol have any conflicts of interests and acknowledgments declared, appendices attached, and references in Vancouver referencing style?*

Once a protocol has been approved, it is published on the JBI Database for Systematic Reviews and Implementation Reports.

Chapter Nine:

The systematic review and synthesis of economic data

Please refer also to the JBI Library for specific presentation requirements for systematic review reports <http://www.joannabriggslibrary.org/jbilibrary/index.php/jbisrir/index>

All JBI systematic reviews are based on approved peer reviewed systematic reviews protocols, as discussed in Chapter 8. Deviations from approved protocols are rare and should be clearly justified in the report. JBI advocates for approved peer reviewed systematic review protocols as an essential part of a process to enhance the quality and transparency of systematic reviews.

Layout of the report

The systematic review protocol details how the review will be conducted, what outcomes are of interest and how the data will be presented. The systematic review report should follow the approved protocol – any deviations from the protocol need to be clearly detailed in the report in order to maintain transparency. CReMS provides a detailed framework for the necessary sections of a report and automatically builds the report in the <Report Builder> function. CReMS automatically exports text from the protocol to <Report Builder>. Reviewers need to edit this as the protocol is written in future tens (i.e. 'Selected studies **will be** assessed for methodological quality...') and the report needs to be edited to read 'Selected studies **were** assessed for methodological quality...' Briefly, a JBI review should contain the following sections:

Title of systematic review

This should be the same as detailed in the protocol.

Review authors

The names, contact details and the JBI affiliation should be listed for each reviewer (which occurs automatically when using CReMS).

Executive summary

This is generally the final section of the report to be written and should be a summary of the review in 500 words or less stating the purpose, basic procedures, main findings and principal conclusions of the review. The executive summary should not contain abbreviations or references. The following headings should be included in the executive summary:

Background:

This section should briefly describe the issue under review including the target population, interventions and outcomes that are documented in the literature. The background should be an overview of the main issues. It should provide sufficient detail to justify why the review was conducted and the choice of the various elements such as the interventions and outcomes.

Objectives:

The review objectives should be stated in full, as detailed in the protocol section.

Inclusion criteria

Types of participants

The report should provide details about the type participants included in the review. Useful details include: age range, condition/diagnosis or health care issue, administration of medication. Details of where the studies were conducted (e.g. rural/urban setting and country) should also be included. Again the decisions about the types of participants should have been explained in the background.

Types of interventions

This section should present all the interventions examined, as detailed in the protocol.

Types of outcome measures

There should be a list of the outcome measures considered, as detailed in the protocol.

Types of studies

As per the protocol section, the types of studies that were considered for the review should be included. There should be a statement about the target study type and whether or not this type was not found. The types of study identified by the search and those included should be detailed in the report.

Search strategy

A brief description of the search strategy should be included. This section should detail search activity (e.g. databases searched, initial search terms and any restrictions) for the review, as predetermined in the protocol.

Data collection

This section should include a brief description of the types of data collected and the instrument used to extract data.

Data synthesis

This section should include a brief description of how the data was synthesized, where is a meta-analysis of as a narrative summary.

Conclusions

This section should include a brief description of the findings and conclusions of the review.

Implications for practice

This section should include a brief description of how the findings and conclusions of the review may be applied in practice, as well as any implications that the findings may have on current practice.

Implications for research

This section should include a brief description of how the findings of the review may lead to further research in the area – such as gaps identified in the body of knowledge.

Following the executive summary, the report should include the following sections:

Background

As discussed in the protocol section, JBI places significant emphasis on a comprehensive, clear and meaningful background section to every systematic review particularly given the international circulation of systematic reviews, variation in local understandings of clinical practice, health service management and client or patient experiences. This section should be an overview of the main issues and include any definitions or explanation of any technical terms used in the review. It is recommended that all JBI systematic reviews should contain a sentence clearly indicating:

'The objectives, inclusion criteria and methods of analysis for this review were specified in advance and documented in a protocol. Ref' (The reference should be to the appropriate citation in JBISRIIR, 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.

Review objectives/review questions

As discussed previously in the protocol section, the objective(s) of the review should be clearly stated.

Inclusion criteria

As detailed in the protocol, the inclusion criteria used to determine consideration for inclusion should be stated.

Search strategy

This section should include an overview of the search strategy used to identify articles considered by the review. The documentation of search strategies is a key element of the scientific validity of an economic systematic review. It enables readers to look at and evaluate the steps taken, decisions made and consider the comprehensiveness and exhaustiveness of the search strategy for each included database.

Each electronic database is likely to use a different system for indexing key words within their search engines. Hence, the search strategy will be tailored to each particular database. These variations are important and need to be captured and included in the systematic review report. Additionally, if a comprehensive systematic review is being conducted through CReMS, the search strategies for each database for each approach are recorded and reported via CReMS. Commonly, these are added as appendices.

Q ***Where there any deviations from the search strategy detailed in the approved protocol? Any details, together with an explanation should be included in the search strategy section of the review report.***

Methods of the Review

Assessment of methodological quality

Critical appraisal

This section of the review should include the details of critical appraisal of included studies using the ACTUARI checklist.

The main object of critical appraisal is to assess the methodological quality of a study and determine the extent to which a study has excluded the possibility of bias in its design, conduct and analysis. If a study has not excluded the possibility of bias, then its results are questionable and could well be invalid. Therefore, part of the systematic review process is to evaluate how well the potential for bias has been excluded from a study, with the aim of only including high quality studies in the resulting systematic review. A secondary although no less strategic benefit of critical appraisal is to take the opportunity to ensure that each retrieved study has included the population, intervention and outcomes of interest specified in the review.

It is JBI policy that economic reviews submitted to JBI should use the ACTUARI critical appraisal checklist, as discussed in Chapter 8. The checklist uses a series of criteria that can be scored as being met, not met or unclear, and can be found in Appendix VIII. 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 the different criteria differently. These decisions about the scoring system and the cut-off for inclusion should be made in advance, and be agreed upon by all participating reviewers before critical appraisal commences.

There are specific guidelines for various economic evaluation studies/methods⁴⁸ including models, retrospective studies and prospective studies. There are guidelines focusing specifically on decision-making models and Markov analyses for health economic evaluations.

Q *Has the ACTUARI critical appraisal tool been appended to the review? Have the results of critical appraisal been discussed? Were there any differences of opinion between the reviewers? How were any differences resolved?*

ACTUARI critical appraisal checklist items are discussed further in Appendix IX.

Data extraction

The ACTUARI data extraction tool lists a range of fields which describe the study: economic evaluation method, interventions, comparator, setting, geographical context, participants, source of effectiveness data, author's conclusion, reviewer's comments and a field for whether the extraction details are 'complete'. The standardized ACTUARI data extraction form can be found in Appendix X. More details about the extraction details fields are provided below:

Economic evaluation method

There are four options available in ACTUARI. The four options are: cost-minimisation, cost-effectiveness, cost-utility, and cost-benefit. If the authors of the economic evaluation studies have defined the study type incorrectly, the correct type of economic evaluation should be provided by the systematic reviewer and the correction should be justified.

Interventions and comparator

The 'interventions' field relates to the new treatment (or intervention) whose costs or effectiveness is being compared to the standard (or control, or 'comparator' treatment). There are different types of interventions: primary prevention, secondary prevention, screening, diagnosis, treatment, rehabilitation, palliative care. Important details for types of interventions and types of comparators are: explicit and clear description of interventions, dosage, intensity, mode of delivery, types of personnel who deliver it, frequency of delivery, duration of delivery, timing of delivery, critical doses/intensity, co-interventions.

Setting

Specify the practice setting (outpatient care, inpatient care, home care, community care, etc.) and the level of health care (primary care, secondary care, tertiary care).

Geographical context

The geographical field relates to the region (city, state, country) in which the study took place.

Participants/population

Important details for types of participants are: specific disease/conditions, stage of the disease, severity of the disease, co-morbidities, age, gender, ethnicity, previous treatments received, condition, explicit standardized criteria for diagnosis, setting (hospital, community, outpatient), who should make the diagnosis of the specific disease, and other important characteristics of participants (such as their response to the treatment). Summarize any inclusion/exclusion criteria reported by the authors. Where studies include economic models the study population may be hypothetical but defined by the authors.

Source of effectiveness

There are four options for sources of effectiveness data available in ACTUARI. They refer to the original location of the information from which the effectiveness of the intervention compared to the comparator was derived: Single Study (same participants); Single Study (different participants); Multiple Studies (meta-analysis); Multiple Studies (no meta-analysis). Selection of a particular type of source document determines which data extraction fields become available in ACTUARI in the next phase of extraction.

Author's conclusion

Summarize the main findings of the study from the author's perspective.

Reviewer's comments

Summarize your interpretation of the study and its significance. Once this data has been extracted and entered, ACTUARI takes users to a second data extraction page specific to the methods described under 'Source of effectiveness data'. There are two primary sections in this last step in data extraction. The first relates to the clinical effectiveness component of the study, the second to the data on economic effectiveness.

Clinical effectiveness

This section relates to evidence on the clinical effectiveness of the intervention versus the comparator, or control group. The five fields in this section are designed for numbers and free text relating to the study design, for instance: randomized controlled study, cohort study, case control, interrupted time series; the study date (in years); sample size (in numbers, combining both treatment and comparator groups if relevant); type of analysis used (e.g. intention to treat analysis, logistic regression etc.); and the clinical outcome results (survival, survival at one year, survival at five years, stroke avoided, fracture avoided, pain intensity, frequency of vomiting, frequency of pain, etc.). If either single study method was chosen, data extraction includes the date of publication for the study. If either multiple study option was chosen, the extraction field requests the date range that was searched; note that this is not the date range of included studies, but the date range for the search strategy used to identify all studies prior to appraisal.

Economic effectiveness

There are ten fields in the economic effectiveness results section. The first relates to the date (year) when the economic data were collected; the next relates to any linkages between data collected on effectiveness and cost – for example, were the data collected on the same or different participants? The third field requires a list of the measurements (or units) of benefits that were used in the economic evaluation – were benefits measured in only dollar terms, or in terms of health outcomes? The fourth, fifth and sixth fields relate to costs examined in the study: direct costs of the intervention/program being evaluated, indirect costs and the currency used to measure the costs. The seventh field relates to the results of any sensitivity analysis conducted as part of the study (a sensitivity analysis would be conducted to determine whether the economic model and its conclusions are robust to changes in the underlying assumptions of the model). The eighth field relates to listing the estimated benefits to using the intervention instead of the comparator. The ninth field requires a summary of the cost results findings, and the tenth is a summary of the synthesis of the costs and results.

Outcomes matrix for an economic evaluation

The outcome matrix is a three by three matrix of possible outcomes of an economic evaluation. The final decision about the clinical effectiveness and costs of the intervention under examination is entered here, using data extracted on both the clinical effectiveness and costs of the intervention.

In comparing the clinical effectiveness of two alternatives there are three possibilities: the intervention of interest is more effective than the comparator (i.e. a '+'), the intervention is equally effective (i.e. a '0') or the intervention is less effective (i.e. a '-').

Similarly, in terms of costs, there are three possibilities: the intervention is more expensive (i.e. a '+'), the intervention and comparator's costs are the same (i.e. a '0'), or the intervention is less expensive (i.e. a '-').

In the analytical module ACTUARI, there is a dominance rating; each outcome of interest is allocated a position in a grid (which extends from A to I) depending on whether the intervention should be preferred over its comparator.

Each of the comparisons between intervention and comparator can only be classed as one of nine options (Figure A – I). For example, an intervention that was shown to be more effective and less expensive would be scored as 'G', whereas an intervention that was less effective and of equal cost would be scored as 'F'.

| Key | Effectiveness | Cost |
|-----|---------------|--------|
| + | Better | Higher |
| 0 | Equal | Equal |
| - | Poorer | Lower |

| | | | |
|---|---|---|---|
| | + | 0 | - |
| + | A | B | C |
| 0 | D | E | F |
| - | G | H | I |

Figure 9: Data synthesis and results reporting in systematic reviews of economic evaluation studies

Synthesis of economic data

Synthesis of economic data does not follow the same pattern as synthesis of clinical effectiveness data. While clinical data is synthesized and given a weighting, economic data is more commonly subject to one or more of three options for synthesis. CReMS set text describes how an economic synthesis should be structured:

Economic findings will, where possible be synthesized and presented in a tabular summary. Where this is not possible, findings will be presented in narrative form.

Essentially, there are three options for the synthesis or summation of economic data in ACTUARI: results are presented in a narrative summary; table of results sorted by comparisons (if appropriate); results can be further summarized using a hierarchical decision matrix.

Examples of narrative summary of economic evidence (from Lister-Sharp et al.⁵⁴):

Example 1:

'For studies comparing docetaxel with paclitaxel, the range of cost–utility ratios for QALYs gained was £1990–£5233. The low estimate was for the UK²⁰ and the high value was for the USA.⁵⁶ Two studies did not present an incremental analysis. One showed docetaxel to be the dominant strategy over paclitaxel, while the other found vinorelbine to be dominant over either taxane.'^{55,59}

Example 2:

'In the three studies comparing docetaxel to vinorelbine, the one UK study showed the cost of docetaxel per QALY gained was £14,050.20. Although the efficacy rates used were not the result of a direct-comparison clinical study, the economic evaluation was otherwise of a relatively high quality.'

Example 3:

'Two of the three UK economic evaluations of taxanes in advanced breast cancer compared docetaxel to paclitaxel and found a range of incremental cost per QALY gained of £1990–£2431. One also compared docetaxel with vinorelbine and found the incremental cost per QALY gained to be £14,050.'

Examples of tables of results**Example 1 of a template for Tables for Results**

| Study (Year) | Type of study | Primary outcome | Location of Study | Funding for the Study |
|--------------|---------------|-----------------|-------------------|-----------------------|
|--------------|---------------|-----------------|-------------------|-----------------------|

Example 2 of a template for Tables of Results

| Study (Year) | Outcomes | Results | Study Design (for effectiveness evidence) | Sample Population | Co-morbidities | Age range |
|--------------|----------|---------|---|-------------------|----------------|-----------|
|--------------|----------|---------|---|-------------------|----------------|-----------|

Example 3 of a template for Tables of Results

| Study | Intervention And Comparator | Incremental Outcome | Perspective | Time Horizon | Economic evaluation model | Outcomes |
|-------|-----------------------------|---------------------|-------------|--------------|---------------------------|----------|
|-------|-----------------------------|---------------------|-------------|--------------|---------------------------|----------|

Example 4 of a template for Tables of Results (Economic Models)

| Study (Year) | Country | Type of economic evaluation | Type of model | Time Horizon | Model Cycles Length (months or years) | Intervention and comparators | Results |
|--------------|---------|-----------------------------|---------------|--------------|---------------------------------------|------------------------------|---------|
|--------------|---------|-----------------------------|---------------|--------------|---------------------------------------|------------------------------|---------|

Example 5 of a template for Tables of Results (Sources of data for Economic models)

| | | | | | |
|--------------|--------------------|----------------|--------------------------|-----------------------|----------------------|
| Study (Year) | Effectiveness Data | Utilities Data | Model Probabilities Data | Short-term costs data | Long-term costs data |
|--------------|--------------------|----------------|--------------------------|-----------------------|----------------------|

Example 6 of a template for template for Tables of Results (CUA, cost per DALY averted)

| | | | |
|-----------------------------|--|---|---|
| Description of Intervention | Average cost per DALY averted (AUD\$) No age weight Undiscounted | Average cost per DALY averted (AUD\$) Discounted | Average cost per DALY averted (AUD\$) Age weighted Discounted |
|-----------------------------|--|---|---|

Decision matrix

The **decision matrix** has three possible outcomes and these are determined by the reviewers' rating of the costs of an intervention of interest balanced against the health outcomes:

- *Strong dominance* is considered appropriate for decisions clearly in favour of either the treatment or control intervention from both the clinical effectiveness and costs points of view.
- *Weak dominance* is considered where the data support either clinical effectiveness or costs, but not both positions.
- *Non-dominance* is considered where the intervention of interest is less effective or more costly.

The decision or dominance matrix illustrates the data, making visualization and interpretation by readers clearer and easier.

From the data extraction, particularly the outcome specific data per included paper, reviewers are able to generate a matrix as shown in Figure , which lists the comparison of interest, the score from the three by three matrix for each study ('the dominance rating') and the study citation.

| Cost | Studies | No.of Studies | Clinical effectiveness | Decision |
|------|---------|---------------|------------------------|---------------------------|
| + | | | - | } Don't use |
| 0 | | | - | |
| + | | | 0 | |
| - | | | - | Further analysis required |
| 0 | | | 0 | |
| + | 1,3,5 | 3 | + | |
| - | | | 0 | } Use |
| 0 | | | + | |
| - | 2,6 | 2 | + | |

Figure 10: Decision matrix for economic evidence

In contrast to meta-analysis of quantitative evidence of effectiveness, a decision matrix is not weighted. The synthesis in ACTUARI brings together the individual studies in a visual/tabular format.

The allocation to specific points in the decision matrix during extraction dictates where in the table a study will appear in terms of establishing whether the intervention should be used, subject to further research, or not used.

Review Results

The results section of a systematic review report has three subsections: Description of studies, Methodological quality, and Review findings. In the Description of studies subsection the types and numbers of papers identified and the number of papers that were included and excluded should be stated. A flow diagram is recommended. The Methodological quality subsection should be a summary of the overall quality of the literature identified. The Results subsection must be organized in a meaningful way based on the objectives of the review and the criteria for considering studies.

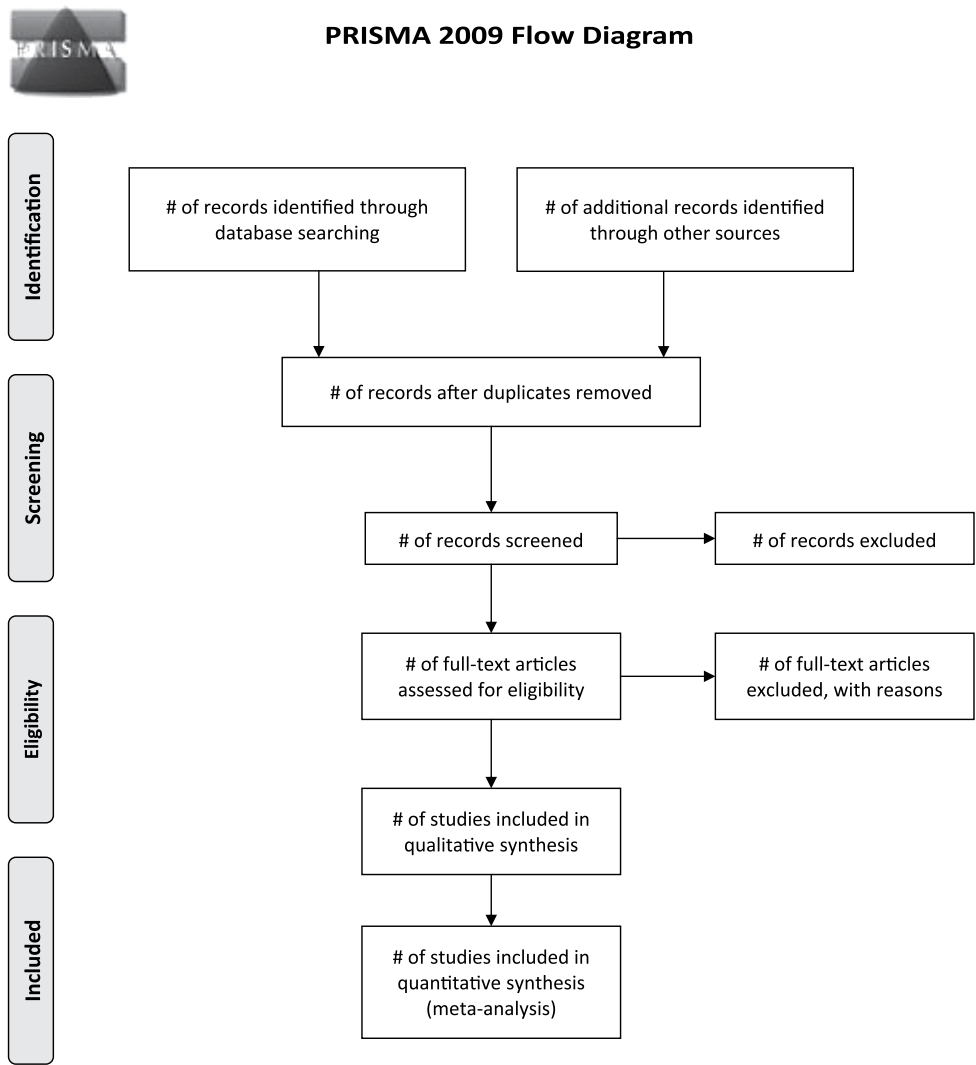
There is no standardized international approach to structuring how the results of systematic reviews of economic evaluation evidence should be reported. The method of synthesis described in the protocol will have some bearing on the structure of the results report. Additionally, the audience for the review should be considered when structuring and writing up the review results.

Graphs represent a specific item of analysis that can be incorporated in to the results section of a review. However, the results are more than graphs, and whether it is structured based on the intervention of interest, or some other structure, the content of the review results section needs to present the results with clarity using the available tools (tables, figures, matrix) supported by textual descriptions.

There is no clear international standard or agreement on the structure or key components of the Review findings section of a systematic review report. Furthermore given the level of variation evident in published systematic reviews the issues described in this section should be considered guidance for consideration rather than a prescription.

The following information is provided on identified studies, retrieved studies, and included studies in the review results section of the systematic review report: numbers of studies identified, numbers of retrieved studies, numbers of studies matching a specified type of study design (i.e. cost-minimisation, cost-effectiveness, cost-utility, cost-benefit), numbers of appraised studies, numbers of excluded studies and overview of reasons for exclusion, numbers of included studies.

The findings of the search are commonly written in narrative style, and illustrated with a flow diagram as shown in Figure 11 below.



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

Figure 11: A typical flowchart to detail study identification

The description of studies must also incorporate details on included studies. This additional detail may involve writing up the characteristics of the participants, types of interventions and extend to the effectiveness of interventions, or descriptions of instruments for measuring particular outcomes.

Methodological quality subsection of a systematic review report should be a summary of the overall quality of the literature identified.

With detail on the studies reported, 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, consider whether the specific review question be used to structure the results section, or whether the findings can be reported under the outcomes 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 structured according 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 use of tables, graphs and in text reference to specific appendices is encouraged.

Discussion

The aim of this section is to summarize and discuss the main findings – including the strength of the evidence, for each main outcome. It should address 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 not bring in new literature or information that has not been reported in the results section. The discussion does seek to establish a line of argument based on the findings regarding the effectiveness of an intervention, or its impact on the outcomes identified in the protocol. The application and relevance of the findings to relevant stakeholders (e.g. health care providers, patients and policy makers) should also be discussed in this section.^{46,47}

Points to consider in this section include:

- Were 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.?

Conclusions

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
- Implications for practice and research, including recommendations for the future
- Potential limitations of the systematic review.

Implications for practice

Where possible, implications for practice should be detailed but these must be based on the documented results from the review findings and not merely the reviewer's opinion. Where evidence is of a sufficient level, appropriate recommendations should be made. Recommendations must be clear, concise and unambiguous and be assigned a JBI Grade of Recommendation.

Implications for research

As with implications for practice, all implications 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 small sample sizes or methodological weaknesses. Implications for research should avoid generalized statements calling for further research, but should be linked to specific issues. Recommendations must be clear, concise and unambiguous.

References

The references should be appropriate in content and volume and include background references and studies from the initial search. The format must be in the Vancouver referencing style, as previously discussed in the Protocol section.

Appendices

Appropriate appendices (appraisal, extraction tools) as they appear from CReMS should be provided and referred to in the review. Appendices should be numbered using Roman numerals in the order in which they have been referred to in the body of the text. There are several required appendices for a JBI review:

Appendix I: Search strategy

A detailed search strategy for at least one of the major databases searched must be appended.

Appendix II: Critical appraisal instrument

The critical appraisal instrument used must be appended, i.e. JBI-ACTUARI Critical Appraisal Checklist for Economic Evidence.

Appendix III: Data extraction instrument

The data extraction instrument used must be appended, i.e. JBI-ACTUARI Data Extraction Form for Economic Evidence.

Appendix IV: Table of included studies

A table of included studies is crucial to allow a snapshot of the studies included in the review.

Appendix V: List of excluded studies

At a minimum, a list of studies excluded at the critical appraisal stage must be appended and reasons for exclusion should be provided for each study (these reasons should relate to the methodological quality of the study, not study selection). Studies excluded following examination of the full-text may also 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.



Are all appendices correctly numbered and attached to the report?

Conflicts of interest

A statement should be included in every review protocol being submitted to JBI which either declares the absence of any conflict of interest, or which describes a specified or potential conflict of interest. Reviewers are encouraged to refer to the JBI's policy on commercial funding of review activity.

Acknowledgements

The source of financial grants and other funding must be acknowledged, including a frank declaration of the reviewers' commercial links and affiliations. The contribution of colleagues or Institutions should also be acknowledged.



"My diabetic research shows that test subjects are 98% more likely to take their diabetic pills if the pills are covered in chocolate."

**Text and opinion-
based evidence**

Chapter Ten:

Protocol development for reviews of textual, non-research evidence

Expert opinion has a role to play in evidence-based health care, as it can be used to either complement empirical evidence or, in the absence of research studies, stand alone as the best available evidence. While rightly claimed not to be a product of 'good' science, expert opinion is empirically derived and mediated through the cognitive processes of practitioners who have been typically trained in scientific method. This is not to say that the superior quality of evidence derived from rigorous research is to be denied; rather, that in its absence, it is not appropriate to discount expert opinion as non-evidence.²

Opinion-based evidence refers to expert opinions, comments, assumptions or assertions that appear in various journals, magazines, monographs and reports.^{2,55-57} An important feature of using opinion in evidence based practice *'is to be explicit when opinion is used so that readers understand the basis for the recommendations and can make their own judgment about validity'*.⁵⁷

The synthesis of text and opinion

The synthesis of expert opinion findings within the systematic review process is not well recognised in mainstream² evidence-based practice and it is acknowledged that efforts to appraise often conflicting opinions are tentative. However, in the absence of research studies, the use of a transparent systematic process to identify the best available evidence drawn from text and opinion can provide practical guidance to practitioners and policy makers.

The nature of textual or opinion based reviews is that they do not rely upon evidence in the form of primary research and, therefore, elements of the protocol will vary from reviews drawing on primary research as the types of papers of interest. However, the principals of developing a clearly documented protocol, incorporating a priori criteria and methods are – as for any systematic review – considered essential.

Protocol design for reviews of textual evidence

Title page

A JBI review requires at least two reviewers. The names of the reviewers, together with their post nominal qualifications, contact details and JBI affiliation, should be listed on the title page of the protocol.

Protocol title

While a number of mnemonics have been discussed in the sections on quantitative and qualitative protocol development, and can be used for opinion and text, not all elements necessarily apply to every text or opinion-based review, and use of mnemonics should be considered a guide rather than a policy.

Background

The background should describe and situate the elements of the review, regardless of whether a particular mnemonic is used or not. The background should provide sufficient detail on each of the important elements of the review question to justify the conduct of the review and the choice of the various elements of the review.

The Joanna Briggs Institute places significant emphasis on an extensive, comprehensive, clear and meaningful background section to every systematic review. Given the international circulation of systematic reviews, variations in local understandings of clinical practice, health service management and client or patient experiences need to be clearly stated. It is often as important to justify why elements are not to be included.

Review objectives/questions

The objectives guide and direct the development of the specific review criteria. Clarity in the objectives and specificity in the review questions assists in developing a protocol, facilitates more effective searching, and provides a structure for the development of the full review report. The review objectives must be stated in full. Conventionally, a statement of the overall objective is made and elements of the review are then listed as review questions. With reviews of text and opinion, consideration needs to be given to the phrasing of objectives and specific questions as causal relationships are not established through evidence of this nature, hence cause and effect type questions should be avoided.



Questions to consider:

Does the background cover all the population, phenomenon of interest and the context for the systematic review? Are operational definitions provided? Do systematic reviews already exist on the topic? Why is this review important? Are the review objectives/questions clearly defined?

Inclusion criteria

Population/type of participants

Describe the population, giving attention to whether specific characteristics of interest, such as age, gender, 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 not to imply that aspects of population pertinent to quantitative reviews such as sampling methods, sample sizes or homogeneity are either significant or appropriate in a review of text and opinion.

Intervention/phenomena of interest

Is there a specific intervention or phenomena of interest? As with other types of reviews, interventions may be broad areas of practice management, or specific, singular interventions. However, reviews of text or opinion 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.

Comparator

The use of a comparator is not required for a review of text and opinion based literature. In circumstances where it is considered appropriate, as with the intervention, its nature and characteristics should be described.

Outcome

As with the comparator, a specific outcome statement is not required. In circumstances where it is considered appropriate, as with the intervention, its nature and characteristics should be described.

NOTARI example of inclusion criteria

Inclusion criteria

Types of participants

Pregnant and birthing women who received care from a skilled birth attendant within Cambodia, Thailand, Malaysia and Sri Lanka.

Phenomena of interest

The review considered publications that described: 1. The health system/service delivery structures and underlying policy; 2. The maternity care provided by a skilled birth attendant.

Types of publications

This review considered government reports, expert opinion, discussion papers, position papers, and other forms of text, published in the English language. Technical reports, statistical reports and epidemiological reports were excluded.

Types of outcomes

The primary outcome of interest in this review was: Impact on maternal mortality rates. Secondary outcomes of interest to this review included:

- a) Changes to health system structures related to pregnancy and childbirth (including resources/finances)
- b) Change in cultural practices related to pregnancy and birth
- c) Empowerment of women and their position in society (and what impact this has had with respect to their choice of pregnancy and birth care).

MCARTHUR, Alexa; LOCKWOOD, Craig. Maternal mortality in Cambodia, Thailand, Malaysia and Sri Lanka: a systematic review of local and national policy and practice initiatives. The JBI Database of Systematic Reviews and Implementation Reports, [S.l.], v. 11, n. 4, p. 115 - 186, may. 2013. ISSN 2202-4433. Available at: <<http://www.joannabriggslibrary.org/jbilibrary/index.php/jbisir/article/view/971/1219>>. Date accessed: 22 Jan. 2014.

Search strategy

This section should flow naturally from the criteria that have been established to this point, and particularly from the objective and questions the review seeks to address. As reviews of opinion 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'.

As with all types of systematic reviews conducted through JBI, the search strategy does need to reflect current international standards for best practice in literature searching. CReMS includes the following editable statement on searching:

The search strategy aims to find both published and unpublished studies. A three-step search strategy will be utilized in this review. An initial limited search of MEDLINE and CINAHL will be undertaken followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe article. A second search using all identified keywords and index terms will then be undertaken across all included databases. Thirdly, the reference list of all identified reports and articles will be searched for additional studies. Studies published in #insert language(s)# will be considered for inclusion in this review. Studies published #insert dates# will be considered for inclusion in this review.

The databases to be searched include:

#insert text#

The search for unpublished studies will include:

#insert text#

Initial keywords to be used will be:

#insert text#

The protocol should also include a list of databases to be searched. If unpublished papers are to be included, the specific strategies to identify them are also described, and lists of key words per database are also recorded.

Assessment of methodological quality

Expert opinion – whether expressed by an individual, by a learned body or by a group of experts in the form of a consensus guideline – draws on the experience of practitioners. Thus, validity in this context relates to the soundness of opinion in terms of its logic and its ability to convince, the authority of the source and the quality of the opinion that renders it supportable. Whilst expert opinion is rightly claimed to not be a product of 'good' science, it is empirically derived and mediated through the cognitive processes of practitioners who have typically been trained in scientific methods. CReMS provides optional editable set text that states:

Textual papers selected for retrieval will be assessed by two independent reviewers for authenticity prior to inclusion in the review using standardized critical appraisal instruments from the Joanna Briggs Institute Narrative, Opinion and Text Assessment and Review Instrument (JBI-NOTARI). Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer.

The focus then of appraisal is on authenticity: specifically, authenticity of the opinion, its source, the possible motivating factors and how alternate opinions are addressed. The items of appraisal are standardized for this type of literature, while the methods are the same as for appraisal of any type of literature. Standardized appraisal criteria 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 paper. Once both primary and secondary reviewers have conducted appraisal, any discrepancies in opinion are discussed and a mutual decision agreed upon. The NOTARI critical appraisal checklist is in Appendix XI. An explanation for each criteria is included in Appendix XII.



Is the NOTARI critical appraisal tool appended to the protocol?

Data extraction

The section of the protocol should detail what data is to be extracted and the tool that will be used for extracting that data. JBI reviewers of textual data are required to use the NOTARI data extraction tool which can be found in Appendix XIII. Data extraction serves the same purpose across evidence types - as in the previous modules that considered quantitative, qualitative and economic evidence, extraction aims to facilitate the accurate retrieval of important data that can be identified from many papers and summarized into a single document.

An extraction is a summary of the main details of the publication and should be conducted after carefully reading the publication. Data extraction incorporates several fields relating to the type of text, its authors and participants, then the content of the paper in the form of conclusions.

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

Types of text

The type of opinion that is being appraised, for example, an expert opinion, a guideline, a Best Practice Information Sheet.

Those represented

To whom the paper refers or relates.

Stated allegiance/position

A short statement summarizing the main thrust of the publication.

Setting

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.

Geographical context

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

Cultural context

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.

Logic of argument

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?

Author's conclusion

The main finding(s) of the publication.

Reviewer's comments

A summary of the strengths and weaknesses of the paper.

Textual data extraction involves transferring conclusions from the original publication using an approach agreed upon and standardized for the specific review. Thus, an agreed format is essential to minimise error, provide an historical record of decisions made about the data in terms of the review, and to become the data set for categorisation and synthesis. Specifically, the reviewer is seeking to extract the Conclusions drawn by the author or speaker and the argument that supports the conclusion. The supporting argument is usually a quotation from the source document and is cited by page number with the Conclusion if using NOTARI.

Many text and opinion based reports do not report 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 NOTARI.

The editable set text in NOTARI states:

Textual data will be extracted from papers included in the review using the standardized data extraction tool from JBI-NOTARI. The data extracted will include specific details about the phenomena of interest, populations, study methods and outcomes of significance to the review question and specific objectives.

Data synthesis

This section of the protocol should include details of how the extracted data will be synthesized. The aim of meta-aggregation is to: firstly, assemble conclusions; secondly, categorise 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.

NOTARI describes a particular approach to the synthesis of textual papers. As with meta-aggregation in QARI, synthesis in NOTARI is a three-step analytical process undertaken within the module:

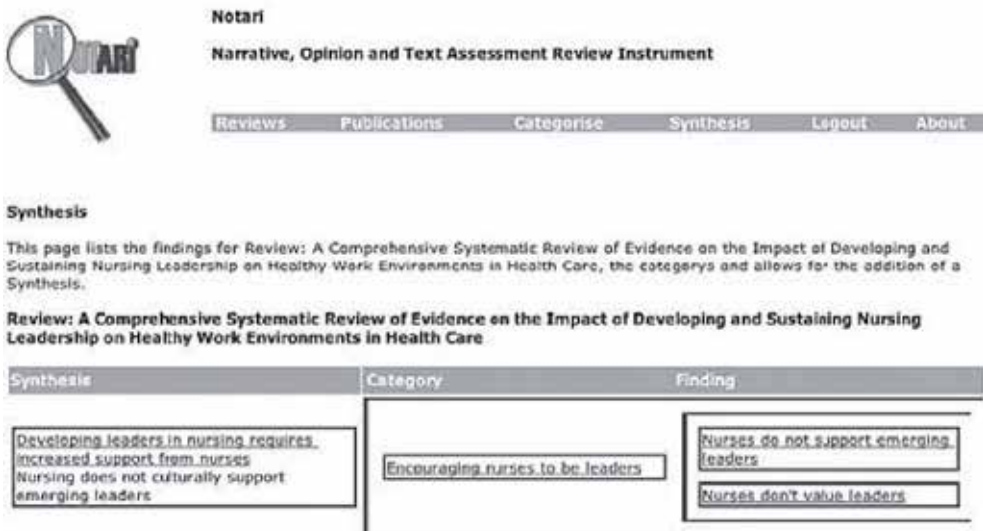
Textual papers will, where possible be pooled using JBI-NOTARI. This will involve the aggregation or synthesis of conclusions to generate a set of statements that represent that aggregation, through assembling and categorizing these conclusions on the basis of similarity in meaning.

These categories are then 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 conclusions will be presented in narrative form.

The aim of synthesis is for the reviewer to establish synthesized findings by bringing together key conclusions drawn from all of the included papers. 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 NOTARI. Conclusions should be extracted as verbatim statements from the author. Once all information on a review is collected (see section on extraction) in the form of extractions and conclusions, the conclusions can be allocated by the reviewer on the basis of similarity to user defined 'categories'. Categories are groups of conclusions that reflect similar relationships between similar phenomena, variables or circumstances that may inform practice.

Categorizing is the first step in aggregating conclusions and moves from a focus on individual papers to the conclusions as a whole. To do this, the reviewer needs to read all of the conclusions from all the papers to identify categories.

To synthesise the categories, the reviewer needs to consider the full list of categories and identify categories of sufficient similarity in meaning to generate synthesized findings. A synthesis is defined as a group of categorized conclusions that allows for the generation of recommendations for practice. This process is illustrated in Figure 12.



Notari
Narrative, Opinion and Text Assessment Review Instrument

Reviews Publications Categorise Synthesis Layout About

Synthesis

This page lists the findings for Review: A Comprehensive Systematic Review of Evidence on the Impact of Developing and Sustaining Nursing Leadership on Healthy Work Environments in Health Care, the categories and allows for the addition of a Synthesis.

Review: A Comprehensive Systematic Review of Evidence on the Impact of Developing and Sustaining Nursing Leadership on Healthy Work Environments in Health Care

| Synthesis | Category | Finding |
|--|----------------------------------|--|
| Developing leaders in nursing requires increased support from nurses Nursing does not culturally support emerging leaders | Encouraging nurses to be leaders | Nurses do not support emerging leaders Nurses don't value leaders |

Figure 12: NOTARI-view graph of a JBI-NOTARI aggregation

Conflict of Interest

A statement should be included in every review protocol being submitted to JBI which either declares the absence of any conflict of interest, or which describes a specified or potential conflict of interest. Reviewers are encouraged to refer to JBI's policy on commercial funding of review activity.

Acknowledgements

The source of financial grants and other funding must be acknowledged, including a frank declaration of the reviewers' commercial links and affiliations. The contribution of colleagues or institutions should also be acknowledged.

References

Protocols are required to use the Vancouver referencing style. References should be numbered in the order in which they appear with superscript Arabic numerals in the order in which they appear in text. Full reference details should be listed in numerical order in the reference section.

More information about the Vancouver referencing style is detailed in the International Committee of Medical Journal Editors' revised 'Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication', and can be found at <http://www.ICMJE.org/>

Appendices

Appendices should be placed at the end of the protocol and be numbered with Roman numerals in the order in which they appear in text. At a minimum this will include critical appraisal and data extraction tools. (This is automatically performed in CReMS.)

Appendix I: Critical appraisal instrument

The critical appraisal instrument used must be appended, i.e. JBI-NOTARI Critical Appraisal Checklist for Text and Opinion.

Appendix II: Data extraction instrument

The data extraction instrument used must be appended, i.e. JBI-NOTARI Data Extraction Form for Text and Opinion.

Q *Does the protocol have any conflicts of interests and acknowledgments declared, appendices attached, and references in the Vancouver referencing style?*

Once a protocol has been approved, it is published on the JBI Library. Protocols can be found at: <http://www.joannabriggslibrary.org/jbilibrary/index.php/jbisrir/index>

Chapter Eleven:

The systematic review and synthesis of text and opinion data

Please refer to the JBI Library for specific presentation requirements for systematic review reports <http://www.joannabriggslibrary.org/jbilibrary/index.php/jbisrir/index>

All JBI systematic reviews are based on approved peer reviewed systematic review protocols. Deviations from approved protocols are rare and should be clearly justified in the report. JBI advocates approved peer reviewing of systematic review protocols as an essential part of a process to enhance the quality and transparency of systematic reviews.

Layout of the report

The systematic review protocol details how the review will be conducted, what outcomes are of interest and how the data will be presented. The systematic review report should be the follow up to an approved protocol – any deviations from the protocol need to be clearly detailed in the report, to maintain transparency. CReMS software provides a detailed framework for the necessary sections of a report. Briefly, a JBI review should contain the following sections:

Title of systematic review:

This should be the same as detailed in the protocol.

Review authors:

The names, contact details and the JBI affiliation should be listed for each reviewer

Executive summary:

This section should be a summary of the review in 500 words or fewer stating the purpose, basic procedures, main findings and principal conclusions of the study. The executive summary should not contain abbreviations or references. The following headings should be included in the Executive Summary:

Background:

This section should briefly describe the issue under review including the target population, phenomena of interest, interventions and outcomes that are documented in the literature. The background should be an overview of the main issues. It should provide sufficient detail to justify why the review was conducted and the choice of the various elements such as the interventions/ phenomena of interest and outcomes.

Objectives:

The review objectives should be stated in full, as detailed in the protocol section.

Inclusion criteria:

Types of participants

The report should provide details about the type of participants included in the review. Useful details include: age range, condition/diagnosis or health care issue, administration of medication.

Types of interventions or phenomena of interest

This section should present all the interventions/phenomena of interests relevant to your review question. Any comparators can also be discussed.

Types of outcome measures

There should be a list of the outcome measures considered if applicable for these types of reviews.

Types of publications

As per the protocol section, the types of publications that were considered for the review should be included. There should be a statement about the target publication type and whether or not this type was not found. The types of publication identified by the search and those included should be detailed in the report.

Search strategy

A brief description of the search strategy should be included. This section should detail search activity (e.g. databases searched, initial search terms and any restrictions) for the review, as predetermined in the protocol.

Data collection

This section should include a brief description of the types of data collected and the instrument used to extract data.

Data synthesis

This section should include a brief description of how the data was synthesized, whether in a meta-aggregation or as a narrative summary.

Conclusions

This section should include a brief description of the findings and conclusions of the review.

Implications for practice

This section should include a brief description of how the findings and conclusions of the review may be applied in practice, as well as any implications that the findings may have on current practice.

Implications for research

This section should include a brief description of how the findings of the review may lead to further research in the area, such as gaps identified in the body of knowledge.

Following the executive summary, the report should include the following sections:

Background

As discussed in the protocol section, JBI places significant emphasis on a comprehensive, clear and meaningful background section to every systematic review particularly given the international circulation of systematic reviews, variation in local understandings of clinical practice, health service management and client or patient experiences. It is recommended that all JBI systematic reviews should contain a sentence clearly indicating:

'The objectives, inclusion criteria and methods of analysis for this review were specified in advance and documented in a protocol. Ref' (The reference should be to the appropriate citation in JBI SRIR).

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.

Review objectives/questions

As discussed previously in the protocol section, the objective(s) of the review should be clearly stated. Conventionally a statement of the overall objective should be made and elements of the review then listed as review questions.

Inclusion criteria

As detailed in the protocol, the inclusion criteria used to determine consideration for inclusion should be stated.

Types of text and opinion papers

This section should flow from the background. There should be a statement about the target type of text and opinion, e.g. medical, nursing.

Types of participants

There should be details about the type of individuals targeted including characteristics (e.g. age range), condition/diagnosis or health care issue (e.g. administration of medication in rural areas and the setting[s] in which the individuals are being managed). Again the decisions about the types of participants should have been justified in the background.

Types of interventions/phenomena of interest

There should be a list of all the interventions or phenomena of interest examined. In some cases it may be appropriate to list categories of interventions. For example, 'pharmaceutical and non-pharmaceutical interventions for smoking cessation'. This section should be concise as the background section provides the opportunity to describe the main aspects.

Types of outcome measures

Specific statements of outcome measures are not usually required in a systematic review of text and opinion.

Search strategy

Developing a search strategy for opinion and text-based evidence

There are a range of databases that are relevant to finding expert opinion based literature. Examples include CINAHL, Pubmed, CRD database from the NHS Centre for Reviews and Dissemination, University of York, PsychINFO, National Guideline Clearing House and Cochrane Library.

Search terms for text and opinion papers

Search filters are pre-tested strategies that identify articles based on criteria such as specified words in the title, abstract and keywords e.g. testimony, expert opinion. They can be of use to restrict the number of articles identified from the vast amount of literature in the major databases. Search filters look for sources according to relevance, not the quality of the article or citation itself. Quality judgments are performed separately and require skills in critical appraisal.

Databases and terms for identifying expert opinion

A research librarian should be able to assist with development of a search strategy for textual evidence. Examples of databases and example search terms for finding expert opinion based literature can be found in the final section of this manual.

Methods of the review

Assessment of methodological quality

This section of the review should include the results of critical appraisal with the NOTARI instrument. As discussed in the section on protocol development, it is JBI policy that textual evidence should be critically appraised using the NOTARI software. The primary and secondary reviewer should discuss each item of appraisal for each study design 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 text and opinion. 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 appraisal as each publication in a review should be assessed independently by both reviewers. The critical appraisal tool should be attached to the review.

Critical appraisal of text or expert opinion

The focus on limiting bias to establish validity in the appraisal of quantitative studies is not possible when dealing with text and opinion. 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. The optional editable NOTARI set text states:

Textual papers selected for retrieval will be assessed by two independent reviewers for authenticity prior to inclusion in the review using standardized critical appraisal instruments from the Joanna Briggs Institute Narrative, Opinion and Text Assessment and Review Instrument (JBI-NOTARI). Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer.

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.²

Q *Has the NOTARI critical appraisal tool been appended to the review? Have the results of critical appraisal been discussed? Where there any differences of opinion between the reviewers?*

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. In SUMARI, elements of data extraction are undertaken through the analytical modules and the data extracted is automatically transferred to CReMS. For reviews of text and opinion, synthesis is conducted in the NOTARI analytical module, and the final report is generated in CReMS.

Extracting data from text and opinion

As detailed in the protocol section, this section of the review should include details of the types of data extracted for inclusion in the review. An extraction in NOTARI includes nine fields relating to the type of text, its authors and participants, and the content of the paper. The editable NOTARI set text states:

Textual data will be extracted from papers included in the review using the standardized data extraction tool from JBI-NOTARI). The data extracted will include specific details about the phenomena of interest, populations, study methods and outcomes of significance to the review question and specific objectives.

Either the primary or secondary reviewer can perform the extraction.

1. Types of text

The type of opinion being reported, for example an expert opinion, a newspaper article, or a guideline.

2. Those represented

To whom the paper refers.

3. Stated allegiance/position

A short statement summarizing the main thrust of the publication.

4. Setting

Setting is the specific location, for example nursing home, hospital or dementia-specific ward in a sub-acute hospital.

5. Geographical context

The geographical context is the location of the opinion. Be as specific as possible, for example Poland, Austria, or rural New Zealand.

6. Cultural context

The cultural context refers to the cultural features in the publication setting, such as, but not limited to: time period (16th century); ethnic groupings (indigenous nationalities); age groupings (e.g. older people living in the community); or socio-economic groups (e.g. working class). When entering information be as specific as possible. This data should identify cultural features such as employment, lifestyle, ethnicity, age, gender, socio-economic class, and time period.

7. Logic of argument

An assessment of the clarity of the argument's presentation and logic. Is other evidence provided to support assumptions and conclusions?

8. Data analysis

This section of the report should include any techniques that may have been used to analyze the data, e.g. named software program.

9. Author's conclusion

Use this field to describe the main finding of the publication.

10. Reviewer's comments

Use this field to summarize the strengths and weaknesses of the paper.

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 give consideration to whether the findings can be reported under the outcomes 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.

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 use of tables, graphs and in text reference to specific appendices is encouraged. Additionally, and significantly, the report structure should give consideration to the needs of the journal, for JBI systematic reviews, the preferred journal is the International Journal of Evidence-Based Health Care. Details about this journal are available online.

Q *Has the NOTARI data extraction tool been appended to the review? Have all of the extracted findings been discussed and assigned levels of credibility in the review?*

Data analysis

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.

Data synthesis

This section of the report should include how the findings were synthesized. Where meta-aggregation is possible, textual findings should be pooled using NOTARI. 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 NOTARI. Conclusions should be extracted as verbatim statements from the author.

The processes for categorisation and formulating synthesized findings mirror that of QARI. For a more detailed discussion of synthesis reviewers are encouraged to read the section on data synthesis for qualitative studies.

Data synthesis should involve the aggregation or synthesis of findings to generate a set of statements that represent that aggregation, through assembling the findings rated according to their credibility, and categorizing these findings 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. The editable NOTARI set text states:

Textual papers will, where possible be pooled using JBI-NOTARI. This will involve the aggregation or synthesis of conclusions to generate a set of statements that represent that aggregation, through assembling and categorizing these conclusions on the basis of similarity in meaning. These categories are then 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 conclusions will be presented in narrative form.

The set text in CReMS describes the process by which these options are implemented in the protocol development section as follows:

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 (findings) to categories
- how to aggregate categories into synthesized findings.

In NOTARI, 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 validity 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 NOTARI analytical module for the meta-synthesis of opinion and text.

This process involves categorizing and re-categorizing the conclusions of two or more studies to develop synthesized findings. In order to pursue this, reviewers, before carrying out data synthesis, need to establish their own rules on:

- How to assign conclusions to categories.
- How to aggregate categories into synthesized findings.

Reviewers should also document these decisions and their rationale in the systematic review report.

Many text- and opinion-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 NOTARI.

Each conclusion/finding should be assigned a level of credibility, based on the congruency of the finding 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 - 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.

Unsupported - is when the findings are not supported by the data

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 finding.

Categorisation is the first step in aggregating conclusions and moves from a focus on individual papers to consideration of all conclusions for all papers included in the review. Categorisation is based on similarity in meaning as determined by the reviewers. Once categories have been established, they are read and re-read in light of the findings, their illustrations and in discussion between reviewers to establish synthesized findings. NOTARI sorts the data into a meta-synthesis table or 'NOTARI-view', when allocation of categories to synthesized findings (a set of statements that adequately represent the data) is completed. These statements can be used as a basis for evidence-based practice.

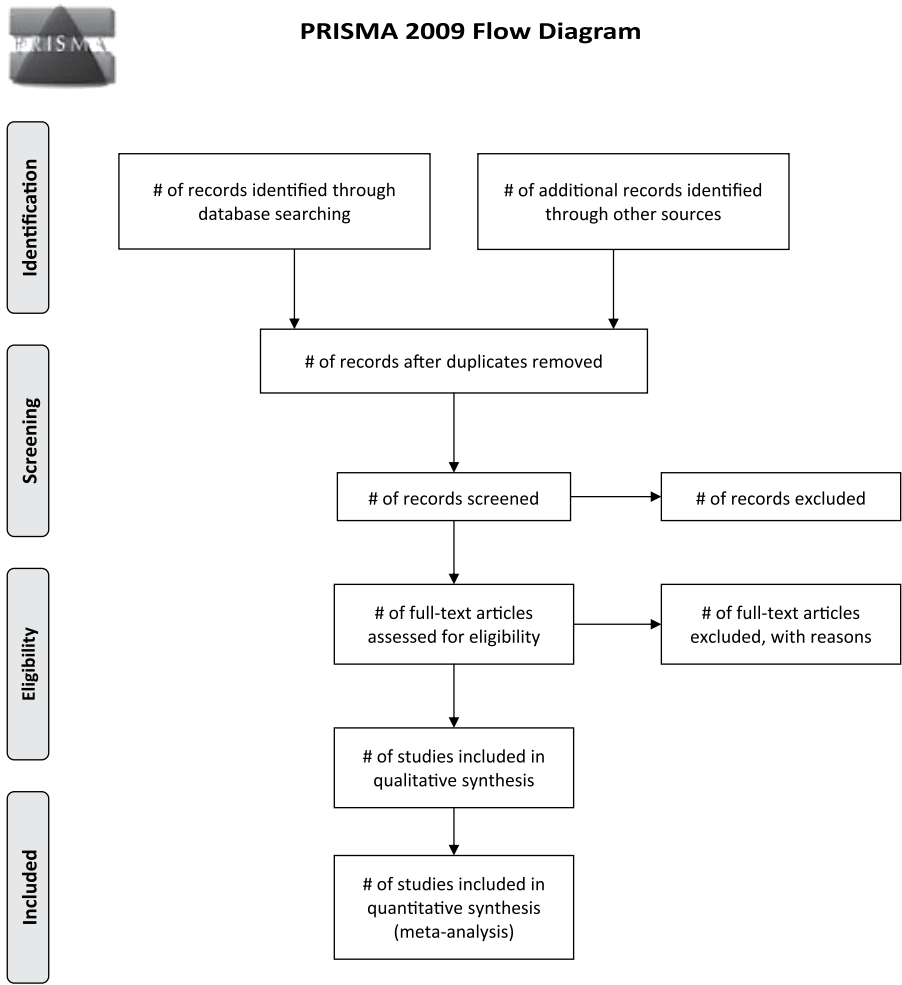


Have all of the conclusions been extracted from the included papers? Do all of the conclusions have illustrations? Do all of the conclusions have levels of credibility assigned to them?

Results

Description of publications

This section should include the type and number of papers identified by the search and the number of studies that were included and excluded from the review. A flowchart of this is shown in Figure 13.



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

Figure 13: A flowchart of search results

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:

Papers: Number of studies identified, number of retrieved papers, number of appraised papers, number of excluded papers and overview of reasons for exclusion, and number of included 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.

Review findings

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. NOTARI-view graphs represent a specific item of analysis that can be incorporated into the results section of a review. However, the results are more than the NOTARI-view graphs, 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 (NOTARI-view graphs, tables, figures) 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.

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 research within the area of interest (such as poor indexing)
- Other issues of relevance
- Implications for practice and research, including recommendations for the future
- 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.

Conclusions

Implications for practice

Where evidence is of a sufficient level, appropriate recommendations should be made. The implications must be based on the documented results, not reviewer opinion. Recommendations must be clear, concise and unambiguous, and assigned a JBI Grade of Recommendation.

Implications for research

All implications 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. Implications for research should avoid generalized statements calling for further research, but should be linked to specific issues (such as longer follow up periods). Recommendations must be clear, concise and unambiguous.

Conflict of interest

A statement should be included in every review protocol being submitted to JBI which either declares the absence of any conflict of interest, or which describes a specified or potential conflict of interest. Reviewers are encouraged to refer to the JBI's policy on commercial funding of review activity.

Acknowledgements

The source of financial grants and other funding must be acknowledged, including a frank declaration of the reviewers' commercial links and affiliations. The contribution of colleagues or institutions should also be acknowledged.

References

Protocols are required to use the Vancouver referencing style. References should be numbered in the order in which they appear with superscript Arabic numerals in the order in which they appear in text. Full reference details should be listed in numerical order in the reference section. Refer to the JBI Library for further information. <http://www.joannabriggslibrary.org/jbilibrary/index.php/jbisrir/index>

Appendices

Appropriate appendices (appraisal, extraction tools) as they appear from CReMS should be provided and referred to in the review. Appendices should be numbered using Roman numerals in the order in which they have been referred to in the body of the text. There are several required appendices for a JBI review:

Appendix I: Search strategy

A detailed search strategy for at least one of the major databases searched must be appended.

Appendix II: Critical appraisal instrument

The critical appraisal instrument used must be appended, i.e. JBI-NOTARI Critical Appraisal Checklist for Text and Opinion.

Appendix III: Data extraction instrument

The data extraction instrument used must be appended, i.e. JBI-NOTARI Data Extraction Form for Text and Opinion.

Appendix IV: Table of included studies

A table of included studies is crucial to allow a snapshot of the studies included in the review.

Appendix V: List of excluded studies

At a minimum, a list of studies excluded at the critical appraisal stage must be appended and reasons for exclusion should be provided for each study (these reasons should relate to the methodological quality of the study, not study selection). Studies excluded following examination of the full-text may also 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.



"It's just a sprain. But let me put a cast on it so you won't look like an idiot for screaming like a freakin' schoolgirl."

Chapter Twelve:

Publication of JBI reviews

The process for publishing a review that has been conducted using the JBI approach to the systematic review of literature involves the submission of a protocol and a review manuscript to the online journal *the JBI Database of Systematic Reviews and Implementation Reports* (<http://www.joannabriggslibrary.org/jbilibrary/index.php/jbisrir/index>). Following submission, manuscripts are subjected to both blind peer review and editorial review prior to approval and publication in the journal. The JBI Database of Systematic Reviews and Implementation Reports publishes systematic reviews undertaken by the Joanna Briggs Institute and its international collaborating centres and groups.

Centres undertaking systematic reviews as their core focus are required to submit their systematic review reports to the JBI Database of Systematic Reviews and Implementation Reports for consideration as output for their Centre. This output is used to determine the Centre's status and funding eligibility on an annual basis.

The JBI DATABASE of Systematic Reviews AND IMPLEMENTATION REPORTS

JBI has published systematic review reports (SRRs) in various formats since 1998. Initially, SRRs were published as in-house booklets in PDF and made available to members via the JBI website. In 2003, JBI Reports, a quarterly Blackwell Publishing journal, was launched and all JBI SRRs were published in this journal. Subsequently, this journal became the International Journal of Evidence-Based Healthcare, published by Wiley-Blackwell electronically and in hard copy.

In 2009 the JBI Library of Systematic Reviews was established that housed all JBI SSRs in PDF that have been published since inception. The Library was available to members/JBI CONNECT+ subscribers via the JBI website (<http://www.joannabriggs.org/>) and each SRR was assigned a volume and issue number. At the end of 2012, the JBI Database of Systematic Reviews and Implementation Reports was launched as an international, online journal with a new ISSN number and presenting all JBI systematic reviews published to date. All JBI systematic reviews are also available to subscribers to JBI@OVID (http://www.ovid.com/webapp/wcs/stores/servlet/content_landing_JBI_13051_-1_13151)

Publication of a review report in the JBI Database of Systematic Reviews and Implementation Reports and its availability via JBI CONNECT+ and JBI@OVID occurs only when a review report has satisfied the submission requirements (<http://www.joannabriggslibrary.org/jbilibrary/index.php/jbisrir/about/submissions#onlineSubmissions>) and completed the editorial processes of the journal. An Exclusive Licence Form (ELF) must be included with submissions to the journal. The Receiving Editor may contact the corresponding author if they have any issues related to the submission. To avoid delay it is recommended authors adhere to the submission guidelines (<http://www.joannabriggslibrary.org/jbilibrary/index.php/jbisrir/about/submissions#onlineSubmissions>).

Please note: Only systematic reviews that have had their protocols previously published in the JBI Database of Systematic Reviews and Implementation Reports are eligible to be published in the journal.

Editor-in-Chief

Edoardo Aromataris

The Joanna Briggs Institute, School of Translational Health Science, Faculty of Health Sciences, The University of Adelaide, Adelaide, South Australia, Australia

International Editorial Board

Details of the Editorial Board can be found at:

<http://www.joannabriggslibrary.org/jbilibrary/index.php/jbisrir/about/displayMembership/2>

The Synthesis Science Unit

The JBI has established a strong international outreach program and there are now international Joanna Briggs Institute Collaborating Centres located in Europe, Africa, Asia, Canada, North and South America and Australasia. The Institute has strong links within these countries and across these regions.

At the twenty-sixth meeting of the Joanna Briggs Institute Committee of Collaborating Centres, in Durban, South Africa on 9–11 August 2006, the Committee of Directors endorsed a suggestion that a Support Unit – aiming to assist systematic reviewers to develop protocols and complete reviews (including helping those in developing and other countries with searching and document retrieval when access to databases and full text papers is less than optimal) – be established.

Although the Collaborating Centres, Evidence Synthesis Groups and the Critical Appraisal Network represent the Institute's central collaborative work, the Joanna Briggs Institute is increasing collaborative activity with other international groups and entities, including the Cochrane Collaboration and the Campbell Collaboration. The need for a unit that focuses on facilitating collaboration in general, and improving systematic review quality and output (through Cochrane Review Groups or the Institute) specifically is well supported by both the Committee of Collaborating Centre Directors and the Institute's executive. It was therefore proposed that a Collaboration Support Unit be established to advance the JBI's mission – to improve the health status of the global population through the delivery of health care that is based on the best available evidence – by supporting: Collaborating Centres of the Joanna Briggs Collaboration; JBI Evidence Synthesis and Critical Appraisal Networks; the Cochrane entities to which JBI contributes; collaborative links with the Campbell Collaboration; and other collaborative enterprises. In 2011 the Collaboration Support Unit became the Synthesis Science Unit (SSU).

Objectives

The objectives of the SSU, in relation to protocols and systematic reviews developed by JBI, the Collaboration or ESGs are to:

- i. Support Collaborating Centres and Evidence Synthesis Groups to develop high quality Systematic Review Protocols and Systematic Review Reports
- ii. Develop Best Practice Information Sheets for publication in the JBI Database of Best Practice Information Sheets and Technical Reports (<http://www.joannabriggslibrary.org/jbilibrary/index.php/JBIBPTR/index>).

Support Collaborating Centres and Evidence Synthesis Groups to develop high quality Systematic Review Protocols and Systematic Review Reports

Specifically, the SSU supports quality improvement and increased output of systematic reviews by providing constructive feedback to reviewers, and assists in response to direct queries from reviewers in improving protocols, search strategies and reporting.

If requested by a JBI reviewer preparing a manuscript for publication in the JBI Database of Systematic Reviews and Implementation Reports, SSU staff will also offer additional assistance where possible – such as re-designing search strategies, conducting searches and assisting with the retrieval of documents – to groups with limited access to electronic databases and the international literature.

Essentially, the goal of the Unit is to increase both the quality and output of systematic reviews by providing support, advice and assistance, rather than acting as critics requiring reviewers to interpret and act upon critique.

Reviewer training and accreditation

JBI reviews can only be conducted by accredited JBI reviewers – who must complete systematic review training through a registered Cochrane entity or an approved JBI trainer. The conduct of the formal JBI Comprehensive Systematic Review Training Program (CSRTP) is the responsibility of the Joanna Briggs Institute and its Centres.

The CSRTP consists of the following four modules:

Module 1: Introduction to Evidence-based Healthcare and the Systematic Review of Evidence (1 day)

Module 2: The appraisal, extraction and pooling of quantitative data from experimental, non-experimental, diagnostic and prognostic studies (2 days)

Module 3: The appraisal, extraction and pooling of qualitative data from qualitative studies, narrative and text from opinion papers (2 days)

Module 4: The appraisal, extraction and pooling of data from economic studies (2 days)

Module 1 is compulsory for all participants and it is the decision of participants which subsequent modules they participate in (modules 1, 2 and 3 are the most commonly taught). Core staff of a Centre are eligible to receive training at no cost.

Reviewers who have completed the JBI CSRTP and the four day Train-the-Trainer Program may be granted a license to deliver the JBI CSRTP. Reviewers who are interested in the Train-the-Trainer Program must be affiliated with a Collaborating Centre.

Licensed trainers are required to:

- Successfully complete the JBI Train-the-Trainer program
- Promote and deliver the CSRTP as designed by JBI and without variation
- Register all participants with JBI
- Notify JBI of the successful completion of each module and request accreditation of the participant as a JBI reviewer
- Submit an annual training report to JBI using the pro-forma provided.

Accredited trainers, in being granted a license to become approved providers of JBI education and training, are expected to:

- Sign a Train-the-Trainer agreement with the JBI
- Maintain a high level of professionalism
- Maintain their knowledge and skills in teaching and in the content of JBI programs
- Promote JBI and other evidence-based practice groups
- Promote the establishment of JBI Evidence Synthesis Groups
- Encourage participants to conduct JBI Systematic Reviews using JBI or Cochrane software.

The presence of accredited JBI Trainers in Centres enables Centres to:

- Improve consistency and quality in Centres' systematic reviews by being able to train core staff on-site
- Decrease training costs by delivering training rather than covering the costs of sending core staff to JBI Adelaide
- Build the Centre's profile by offering JBI accredited training to those other than core staff
- Increase Centres' systematic review output by promoting and training ESGs in other schools and departments of the parent organisation, health agencies and other universities in the Centre's country/state/constituency
- Establish the Centre as a source of expertise in evidence synthesis
- Offer an alternative to the conduct of primary research to academic staff/faculty who need to research and publish by equipping them to conduct and publish systematic reviews
- Increase the availability of high quality, summarized evidence through training systematic reviewers

The role of Centres and of Evidence Synthesis Groups (ESGs)

Joanna Briggs Institute Collaborating Centres

The Joanna Briggs Collaboration (JBC) is a group of self-governing collaborative centres, coordinated through the leadership of The Joanna Briggs Institute. Collaborating Centres accept the terms of the JBI Memorandum of Understanding. Some Centres have a geographic jurisdiction while others have a specialist jurisdiction. Centres can focus on conducting systematic reviews, developing and maintaining specialty nodes of JBI COnNECT+ or assisting in translating JBI resources into languages other than English.

The legitimate operations of Collaborating Centres who focus on systematic reviews include, but are not limited to:

- Conducting and publishing systematic reviews
- Conducting evaluation cycles/implementation projects (leading and/or participating)
- Membership services, for example, education and training
- Promoting the Collaboration and membership within their jurisdiction
- Providing locally agreed services.

Collaborating Centres conduct at least one systematic review per year on a topic that informs health care practice relevant to the information needs of practitioners within their jurisdiction or professional stream.

It is anticipated that Centres will actively engage with their constituents by requesting and vetting topics for reviews with them, and engaging specific constituents in systematic review panels. Furthermore, they will hold regular review panel meetings throughout the conduct of each systematic review to report progress, seek feedback and discuss issues that arise during the conduct of the review.

Centres are also in a position to significantly increase their capacity to produce reviews when aligned with higher degree departments that incorporate the conduct of a systematic review in their research programs. These may include Honours, Masters and Doctoral programs. Higher degree students who conduct reviews using the JBI approach, which includes registering the title with JBI, are able to submit their manuscripts to the JBI Database of Systematic Reviews and Implementation Reports and the review is considered Centre output by association. The review remains the intellectual property of the student.

Evidence Synthesis Groups

Evidence Synthesis Groups (ESGs) are self-governing, self-funding collaborators who accept the terms of the JBI Letter of Agreement. Evidence Synthesis Groups must consist of at least three members who are graduates with research training. All members must have successfully completed a JBI CS RTP and one member of the group must be named as Group Convener. Evidence Synthesis Groups conduct Systematic Reviews following the JBI approach (or, in the case of reviews and effectiveness, the approach adopted by the Cochrane Collaboration).

Academics within Health Sciences faculties in universities and colleges are increasingly required to engage in research and to demonstrate scholarship by adding to the knowledge base of their field and generating research outputs such as refereed publications. Rigorously designed and executed systematic reviews of evidence are credible examples of scholarly research and are published in most high impact, refereed journals across the health sciences field.

A program of research that focuses on rigorous evidence review obviates the need for the extensive resource demands of clinical studies, makes a practical contribution to practice and health outcomes, and leads to recognised research output such as refereed publications. The systematic review process requires high levels of research expertise from diverse research traditions and provides a framework for establishing a team-based, programmatic approach to research and scholarship. Where appropriate, JBI recommends that ESGs be affiliated with a Collaborating Centre, and make themselves known to Collaborating Centres, particularly those within a shared regional or professional jurisdiction.

Companion publications

While a core function of JBI, the JBC and ESGs is to develop and produce systematic reviews, the intended result of this review activity is to improve global health by providing practitioners with the best available evidence concerning the feasibility, appropriateness, meaningfulness and effectiveness of health care practice, interventions and experiences. To maximise the exposure to best practice, systematic reviews produced through JBI, or entities known for the production of high quality reviews are re-written as Best Practice Information Sheets. Each Best Practice Information Sheet is accompanied by a Technical Report. Further information on these documents is provided below.

Best Practice Information Sheets

Best Practice Information Sheets (BPIS) follow a set format and are designed by JBI in Adelaide and published online in the *JBI Database of Best Practice Information Sheets and Technical Reports* (<http://www.joannabriggslibrary.org/jbilibrary/index.php/JBIBPTR/index>). Best Practice information sheets are based on systematic reviews published in the *JBI Database of Systematic Reviews and Implementation Reports*.

Best Practice Information Sheets are considered current for a maximum of three years. Updates of BPISs may also be published electronically.

Each BPIS developed by staff of the JBI is sent via the peer review process of the *JBI Database of Best Practice Information Sheets and Technical Reports* the authors of the review and for blind peer review. The BPIS drafts are then posted on the JBI Public Engagement webpages for open comment by the public for 21 days (<http://joannabriggs.org/bpis/jbi-BPIS.html>) and incorporation of feedback/comments received prior to being forwarded to the Communication Science team for final development and publication in electronic form.

Where possible JBI Centres/Groups are also encouraged to translate BPIS into languages other than English. The Centre/Group should notify the SSU of their intent and a template will be provided. All translated BPIS are uploaded onto the Joanna Briggs Institute's website.

Technical reports

A technical report is developed alongside the BPIS to detail the development process between the systematic review and the guideline for health professionals.

Technical reports contain all details of reviewers and review panel members, as well as all references used. Technical reports are produced by the primary author of the BPIS.

Chapter Thirteen:

An introduction to searching

There is insufficient evidence to suggest that searching a particular number or even particular databases will identify all of the evidence on a particular topic, therefore JBI recommend that a search should be as broad and as inclusive as possible. The following section offers some suggestions for search terms and databases that may be helpful in constructing a search strategy.

Search filters are pre-tested strategies that identify articles based on criteria such as specified words in the title, abstract and keywords. They can be of use to restrict the number of articles identified by a search from the vast amounts of literature indexed in the major medical databases. Search filters look for sources of evidence based on matching specific criteria, such as certain predefined words in the title or abstract of an article. Search filters have strengths and weaknesses:

- (i) Strengths: they are easy to implement and can be pre-stored or developed as an interface.
- (ii) Limitations: database-specific, platform-specific, time-specific, not all empirically tested and therefore not reproducible, assume that articles are appropriately indexed by authors and databases.

Key to search terms used in this section

- ab = words in abstract
- exp = before an index term indicates that the term was exploded
- hw = word in subject heading
- mp = free text search for a term
- pt = publication type • *sh = subject heading
- ti = words in title
- tw = textwords in title/abstract
- ? = in middle of term indicates use of a wildcard
- / = MeSH subject heading (and includes all subheadings being selected)
- \$ = truncation symbol
- adj = two terms where they appear adjacent to one another (so adj4, for example, is within four words)

Generic medical/science databases

One of the most widely searched databases is PubMed, but often MEDLINE and PubMed are used interchangeably. There are in fact some important differences. PubMed is updated more quickly than MEDLINE and, PubMed indexes more journal titles and includes the database 'Old MEDLINE' as well.

MEDLINE (Medical Literature Analysis and Retrieval System Online) is the US National Library of Medicine's® (NLM) main bibliographic database with references to journal articles in biomedicine and the life sciences. This is the main component of **PubMed**, which provides access to MEDLINE and some other resources, including articles published in MEDLINE journals which are beyond the scope of MEDLINE, such as general chemistry articles. Approximately 5200 journals published in the United States and more than 80 other countries have been selected and are currently indexed for MEDLINE. A distinctive feature of MEDLINE is that the records are indexed with NLM's controlled vocabulary, the Medical Subject Headings (MeSH®).

In addition to MEDLINE citations, PubMed also contains:

- process citations which provide a record for an article before it is indexed with MeSH and added to MEDLINE or converted to out-of-scope status.
- that precede the date that a journal was selected for MEDLINE indexing (when supplied electronically by the publisher).
- OLDMEDLINE citations that have not yet been updated with current vocabulary and converted to MEDLINE status.
- to articles that are out-of-scope (e.g. covering plate tectonics or astrophysics) from certain MEDLINE journals, primarily general science and general chemistry journals, for which the life sciences articles are indexed with MeSH for MEDLINE.
- Some life science journals that submit full text to PubMed Central® and may not yet have been recommended for inclusion in MEDLINE although they have undergone a review by NLM, and some physics journals that were part of a prototype PubMed in the early to mid-1990s.
- Citations to author manuscripts of articles published by National Institutes of Health-funded researchers.

One of the ways users can limit their retrieval to MEDLINE citations in PubMed is by selecting MEDLINE from the Subsets menu on the Limits screen.

Other PubMed services include:

- Links to many sites providing full text articles and other related resources
- Clinical queries and Special queries search filters
- Links to other citations or information, such as those to related articles
- Single citation matcher
- The ability to store collections of citations, and save and automatically update searches
- A spell checker
- Filters to group search results.

NLM distributes all but approximately 2% of all citations in PubMed to those who formally lease MEDLINE from NLM.

MEDLINE® is the NLM's premier bibliographic database that contains approximately 18 million references to journal articles in life sciences with a concentration on biomedicine.

Ovid is a search platform that is available to subscribers. PubMed is provided free of charge by the National Library of Medicine. PubMed includes MEDLINE, as well as Pre-MEDLINE and select online publications provided directly from publishers. Below is a brief list of selected features.

| Selected Ovid features | Selected PubMed features |
|---|---|
| Common search interface for 11 databases in a variety of convenient groupings. | Access to MEDLINE and PREMEDLINE. Links to NCBI to search Entrez Gene and other genetics databases. |
| Ability to rerun your search strategy in other Ovid databases. | Searches seamlessly across MEDLINE and PREMEDLINE. Can switch to other NCBI databases via a drop-down menu. |
| Article Linker box connects user to over 30,000 full text online journals available via Health Sciences Library subscriptions. Ovid also provides links to many online full text articles via a 'Full Text' link. | Users can switch from 'summary' to 'abstract' display and click on the Article Linker box to access the Health Sciences Library's online journals. PubMed also provides Links to publisher sites for electronic journals (may require subscription for full-text). |
| Full text of approximately 270 clinical medical journals. | Users can switch from 'summary' to 'abstract' and click on the display button to access many of the Health Sciences Library's online journals, denoted by the 'Article Linker' box. PubMed also provides Links to publisher sites for electronic journals (may require subscription for full-text). |
| Can limit to over 15 different specific subject or journal subsets, e.g. AIDS, bioethics, cancer, complementary medicine, dentistry, history of medicine, nursing, toxicology. | Can limit to any of 13 journal subsets. |
| Use 'Find Similar' to automatically retrieve citations on similar topics. | 'See Related Articles' creates a search to find articles related to a selected article |
| Search strategy recovery not available once the user has logged off. | Search strategies are retained in History for eight hours. |
| Can save searches for subsequent use or may request periodic e-mail updates (Auto Alerts) to a search. | Can register for My NCBI to save searches, set up e-mail updates, and customise filters for displaying results. |

| | |
|---|---|
| Ability to e-mail results to yourself or others. | Ability to e-mail results to yourself or others via the 'Send To' e-mail feature |
| Common limits may be applied from the initial search screen. | Limits link is available on the initial search screen. |
| Search terms automatically map to MeSH headings. | Search terms map to MeSH headings and are also searched as text words. |
| MeSH terms are not automatically exploded. | MeSH terms are automatically exploded. |
| MEDLINE updated weekly; PREMEDLINE updated daily. | PREMEDLINE updated daily. |
| 'Clinical Queries' and 'Expert Searches' may be used for quality filtering in MEDLINE and CINAHL. | 'Clinical Queries' may be used to retrieve quality research articles. Systematic Reviews and Medical Genetics searches are also available on the 'Clinical Queries' page. |
| 'Find Citation' feature can be used to locate a citation when you have incomplete information. | 'Citation Matcher' feature can be used to find citations when you have incomplete information. |
| Three- to 32-week time lag from journal publication to Ovid MEDLINE access. | One- to eight-week time lag from journal publication to PubMed access. |

Grouping terms together using parentheses

Parentheses (or brackets) may be used to control a search query. Without parentheses, a search is executed from left to right. Words that you enclose in parentheses are searched first. Why is this important? Parentheses allow you to control and define the way the search will be executed. The left phrase in parentheses is searched first; then based upon those results the second phrase in parentheses is searched.

Grey or Gray Literature, Deep Web searching

Developing a search strategy for grey literature

Since the mid-1980s and particularly since the explosion of the Internet and the opportunity to publish electronically all kinds of information, there has been an 'information revolution'. This revolution is making it increasingly impossible for people to read everything on any particular subject. In this case medicine, health care, nursing or any other evidence-based practices are no exception. There is such a huge amount of data being written, published and cited that Internet search engines and medical specialist databases such as MEDLINE, EMBASE, CINAHL, Cochrane Library, PsycINFO, cannot hope to catalogue or index everything. There are bound to be valuable sources of medical evidence, which can nonetheless prove useful when doing systematic reviews, but have not been 'captured' by commercial electronic publishers.

Grey (or gray – alternative spelling) literature includes documents such as:

- technical reports from government, business, or academic institutions
- conference papers and proceedings
- preprints
- theses and dissertations
- newsletters
- raw data such as census and economic results or ongoing research results

The US Interagency on Gray Literature Working Group (1995) defined grey literature (or 'greylit' as it is sometimes referred to in the information management business) as: 'foreign or domestic open source material that usually is available through specialised channels and may not enter normal channels or system of publication, distribution, bibliographical control or acquisition by booksellers or subscription agents'.⁵⁸

Furthermore, grey literature has been defined as:

That which is produced on all levels of government, academics, business and industry in print and electronic formats, but which is not controlled by commercial publishers moves the field of grey literature beyond established borders into new frontiers, where lines of demarcation between conventional/non-conventional and published/unpublished literature cease to obstruct further development and expansion. At the same time, this new definition challenges commercial publishers to rethink their position on grey literature.²

When building a search strategy for grey literature, it is important to select terms specifically for each source. In using mainstream databases, or Google-type searches (including GoogleScholar), it is best to draw from a list of keywords and variations developed prior to starting the search. To be consistent and systematic throughout the process, using the same keywords and strategy is recommended. It is important to create a strategy, compile a list of keywords, wildcard combinations and identify organizations that produce grey literature. If controlled vocabularies are used, record the index terms, qualifiers, keywords, truncation, and wildcards.

Searching the medical grey literature can be time-consuming because there is no 'one-stop shopping' database or search engine that indexes materials the way, for example as CINAHL does for nursing and allied health or MEDLINE does for the biomedical sciences. The Mednar database indexes qualitative grey literature articles and may be useful:

<http://mednar.com/mednar/>

as maybe the Qualitative times website:

<http://www.qualitativeresearch.uga.edu/QualPage/>

It should be remembered that your access to bibliographic databases may depend on the subscriptions taken by your library service and the search interface may also vary depending on the database vendor, for example Ovid, EBSCO, ProQuest, etc. or whether you access MEDLINE via the free PubMed interface:

The following search engines are very useful for finding health-based scientific literature:

www.scirus.com

www.metacrawler.com

www.disref.com.au/

www.hon.ch/Medhunt/Medhunt.html

[www.medworld_stanford.edu/medbot/](http://www.medworld.stanford.edu/medbot/)

<http://sumsearch.uthscsa.edu/cgi-bin/SUMSearch.exe/>

www.intute.ac.uk/healthandlifesciences/omnilost.html

www.mdchoice.com/index.asp

www.science.gov/

<http://www.eHealthcareBot.com/>

<http://medworld.stanford.edu/medbot/>

<http://omnimedicalsearch.com/>

<http://www.ingentaconnect.com/>

<http://www.medical-zone.com/>

Scirus (www.scirus.com), for example, is a science-specific search engine with access to over 410 million science-related web pages (as of February 2011), and it indexes sites that other search engines do not. Its medical sites include ArXiv.org, Biomed Central, Cogprints, DiVa, LexisNexis, and PsyDok. PsyDok is a disciplinary Open Access repository for psychological documents. PsyDok is operated by Saarland University and State Library (SULB), which also hosts the special subject collection psychology and the virtual library psychology. PsyDok is a free, full-text e-print archive of published, peer-reviewed journal post-prints plus pre-publications, reports, manuals, grey literature, books, journals, proceedings, dissertations and similar document types.

Search the World Wide Web for higher level – usually government-affiliated – funding bodies, for instance Australia's NHMRC (National Health and Medical Research Council) or MSAC (Medical Services Advisory Committee) for pointers to reports such as clinical trials or reviews from funded research programmes.

Be aware that there are health information gateways or portals on the Internet containing links to well organized websites containing primary research documents, clinical guidelines, other sources and further links. For example:

World Health Organisation, <http://www.who.int/library/>

National Institute on Alcohol Abuse and Alcoholism, <http://www.niaaa.nih.gov/>

Canadian Health Network, <http://www.canadian-health-network.ca/customtools/homee.html>

Health Insite, <http://www.healthinsite.gov.au/>

MedlinePlus, <http://www.nlm.nih.gov/medlineplus>

National Guidelines Clearinghouse, <http://www.guideline.gov/index.asp>

National Electronic Library for Health (UK), <http://www.nelh.nhs.uk/>

Partners in Information Access for the Public Health Workforce, <http://phpartners.org/guide.html>

Clinical guidelines sites

Identify universities, colleges, institutes, collaborative research centres (CRCs) nationally and internationally that have profiles or even specialisations in your area of interest, and check their library websites – they should provide a range of relevant resources and web links already listed. For example, theses or dissertations are generally included on universities' library pages because these have to be catalogued by library technicians according to subject heading, author, title, etc. University library pages will also have links to other universities' theses collections, for example:

- Dissertation Abstracts
- Theses Canada Portal
- Networked Digital Library of Theses and Dissertations (NDLTD)
- Index to Theses

Search academic libraries' Online Public Access Catalogues (OPACS), which are excellent sources of grey literature in that these catalogues provide access to local and regional materials, are sources for bibliographic verification, they index dissertations, government and technical reports, particularly if the authors are affiliated with the parent organisation or agency as scholars or researchers

Authors, if in academic positions, sometimes have their own web pages. Find home pages for specific researchers, either by navigating through their institution's home page or by Internet.

Contact others working in the same/similar area to see if they already have reference lists they are prepared to share or names of others working in the same/related fields, for example contact authors of Cochrane protocols that are not yet completed. This is especially useful for clinicians because they know who works in their specific area of interest.

Identify any conference series in the area of interest. You will find these in academic or national libraries due to the legal deposit rule.

Many national libraries collect grey literature created in their countries under legal deposit requirements. Their catalogues are usually available on the Internet. Some also contain holdings of other libraries of that country, as in the Australian National Library's Libraries Australia: <http://librariesaustralia.nla.gov.au/apps/kss> If you want to conduct an international search, be aware of the existence of WORLDCAT, a service which aims to link the catalogues of all major libraries under one umbrella. <http://www.worldcat.org/>

The media often reports recent medical or clinical trials so check newspaper sites on the Internet. Take note (if you can) of who conducted the trial, where, when, the methodology used, and nature of experimental group or groups so you can locate the original source.

Set up 'auto alerts' if possible on key databases so that you can learn about new relevant material as it becomes available.

Join a relevant web discussion group/list and post questions and areas of interest; your contacts may identify leads for you to follow.

Grey literature is increasingly referenced in journal articles, so reference lists should be checked via hand-searching. Hand searching is recommended for systematic reviews because of the hazards associated with missed studies. Hand searching is also a method of finding recent publications not yet indexed by or cited by other researchers.

Finding grey literature on a government website

Generally, most health or medicine-related government-sponsored or maintained websites will go to the trouble of showing:

- (a) How or if their documents are organized alphabetically, topically or thematically
- (b) How individual documents are structured, i.e. contents pages, text, executive summary, etc.
- (c) Database-type search strategies to find them
- (d) Links to other web sites or other documents that are related to the documents that they produce
- (e) When their collection of grey literature has been updated
- (f) Documents in PDF or Microsoft Word downloadable form.

A brief grey literature case study

Consider a search on the topic: 'Acupuncture in the management of drug and alcohol dependence'. With this query you may wish to explore the effectiveness of acupuncture in the management of drug and alcohol dependence. The goal of this study is to uncover as many randomized controlled trials (RCTs) as possible, and to perform a meta-analysis on the data.

Step One – Mainstream database search

Do your initial research in the mainstream databases, such as:

PudMed

EMBASE

CINAHL

Cochrane Library

BIOSIS (Biological Abstracts)

PsycINFO

Sociological Abstracts

AMED – Allied and Complementary Medicine Database.

There may be a fair bit of duplication between some of these but you should also note down (perhaps as two separate columns) two things: (a) the keywords or terms used in acupuncture-related medical treatment not forgetting to check if the database uses a thesaurus or controlled vocabulary of indexing terms; and (b) the names of institutions, organizations, agencies, research groups mentioned.

The terminology that you could use in various combinations when searching, (including wildcards and truncation, which may vary from database to database and should therefore be checked), may include the following:

acupuncture, meridian, acupressure, electroacupuncture, shiatsu, drug, polydrug, substance, alcohol, tranquilize, tranquilizer, narcotic, opiate, solvent, inhalant, street drug, prescri*, non-prescri*, nonprescri*, abuse, use, usin*, misus*, utliz*, utilis*, depend, addict, illegal, illicit, habit, withdraw, behavio*, abstinen*, abstain*, abstention, rehab, intox*, detox*, dual, diagnosis, disorder. [Note - in the example, the * has been used to indicate either a wildcard or truncation symbol.]

Step Two - Contacting directories and organizations

Do a Yahoo or Google Search using keywords Acupuncture, Alternative Medicine, Alternative Medicine databases, Acupuncture Organizations, in combination with the terms from your initial database search. Remember that Google.com 'Advanced Search' is best for this part of the search as it allows you to 'limit' your inquiry in many ways (go to http://www.google.com.au/advanced_search?hl=en).

For our topic, here are a few organizations that are relevant to your search:

- ETOH - Alcohol and Alcohol Problems Science Database, referred to as ETOH, <http://etoh.niaaa.nih.gov/Databases.htm>
- National Institute on Alcohol Abuse and Alcoholism (NIAAA), <http://www.niaaa.nih.gov/>
- National Institute on Drug Abuse (NIDA), <http://www.nida.nih.gov/>
- Canadian Centre on Substance Abuse (CCSA),
<http://www.ccsa.ca/CCSA/EN/TopNav/Home/>
- National Center for Complementary and Alternative Medicine (NCCAM),
<http://nccam.nih.gov/health/acupuncture/>
- National Acupuncture Detoxification Association (NADA), <http://www.acudetox.com>

Step Three – Finding and searching specialised databases for grey literature

Contacting relevant organizations noted in your mainstream database search is a good way to assess what resources exist in the form of special databases, library catalogues, etc. Some websites have resources providing a 'jumping-off' point for your search deeper into the World Wide Web. Finding the web sites in Step Two and 'digging deeper' into them will enable you to discover the documents they have, and their links to more precise sites with databases that specialize in acupuncture issues. Examples of these are as follows:

- HTA Database, <http://144.32.150.197/scripts/WEBC.EXE/NHSCRD/start>
- The Traditional Chinese Drug Database (TCDBASE), <http://www.cintcm.com/index.htm>
- Drug Database (Alcohol and other Drugs Council of Australia),
<http://203.48.73.10/liberty3/gateway/gateway.exe?application=Liberty3&displayform=opac/main>
- Canadian Centre for Substance Abuse,
http://www.ccsa.ca/CCSA/EN/Addiction_Databases/LibraryCollectionForm.htm
- Combined Health Information Database (CHID), <http://chid.nih.gov/search/>

Grey literature differs from other published literature for the following reasons:

- It is not formally part of 'traditional publishing models'. Producers, to name a few, include research groups, non-profit organizations, universities and government departments.
- In many cases high-quality research it is still waiting to be published and/or indexed.
- It is not widely disseminated but nonetheless important in that an infrastructure does exist to disseminate this material and make it visible.
- Some organizations create their own reports, studies of trials, guidelines, etc.
- Specialised strategies are still needed to facilitate identification and retrieval.

Librarians try to adopt pro-active approaches to finding this material, though web-based searching, self-archiving and open access are helping to facilitate access. If you have access to a library service, your librarian should be able to assist you in your quest for uncovering the grey literature in your area of interest.

Intute is a free online service providing access to the very best web resources for education and research. All material is evaluated and selected by a network of subject specialists to create the Intute database.

<http://www.intute.ac.uk/> This database includes pre-vetted resources by subject-specialists in areas of health, science, tech, social sciences, and arts/ humanities. Intute has brilliant search options: you can browse by MeSH or by keywords. It is like a happy and fun version of the internet – someone else has already gone ahead and removed the rubbish so you don't have to wade through it.

With millions of resources available on the Internet, it is difficult to find relevant and appropriate material even if you have good search skills and use advanced search engines.

Issues of trust, quality, and search skills are very real and significant concerns – particularly in a learning context. Academics, teachers, students and researchers are faced with a complex environment, with different routes into numerous different resources, different user interfaces, search mechanisms and authentication processes.

The Intute database makes it possible to discover the best and most relevant resources in one easily accessible place. You can explore and discover trusted information, assured that it has been evaluated by specialists for its quality and relevance.

<http://mednar.com/mednar/> Mednar is a one-stop federated search engine and is therefore non-indexing, designed for professional medical researchers to quickly access information from a multitude of credible sources. Researchers can take advantage of Mednar's many tools to narrow their searches, drill down into topics, de-duplicates, ranks and clusters results as well as discover new information sources. Comprehensively searches multiple databases in real time, instead of crawling and indexing static content like Google or many meta-search engines, Mednar queries select high quality databases to search simultaneously. It utilizes the native search tools available at each of the ⁴⁷ related sites/databases. If you follow the search links, you will find a search box at all of the sources.

<http://worldwidescience.org/index.html> Another Deep Web search mechanism, *WorldWideScience.org* is a global science gateway connecting you to national and international scientific databases and portals.

WorldWideScience.org accelerates scientific discovery and progress by providing one-stop searching of global science sources. The WorldWideScience Alliance, a multilateral partnership, consists of participating member countries and provides the governance structure for WorldWideScience.org.

It is very good for a global perspective, and includes OpenSIGLE, Chinese, Indian, African, Korean and other sources. The database interface has only been in existence since June 2007.

Thesis/dissertations

ProQuest Dissertations & Theses Database (PQDT)

With more than 2.3 million entries, the ProQuest Dissertations & Theses (PQDT) database is the most comprehensive collection of dissertations and theses in the world. Graduate students customarily consult the database to make sure their proposed thesis or dissertation topics have not already been written about. Students, faculty, and other researchers search it for titles related to their scholarly interests. Of the millions of graduate works listed, we offer over 1.9 million in full text format. PQDT is a subscription database, so consult your library for availability.

Dissertation Abstracts Online (DIALOG) is a definitive subject, title, and author guide to virtually every American dissertation accepted at an accredited institution since 1861. Selected Masters theses have been included since 1962. In addition, since 1988, the database includes citations for dissertations from 50 British universities that have been collected by and filmed at *The British Document Supply Centre. Beginning with DAIC Volume 49, Number 2 (Spring 1988)*, citations and abstracts from Section C, Worldwide Dissertations (formerly European Dissertations), have been included in the file.

Abstracts are included for doctoral records from July 1980 (Dissertation Abstracts International, Volume 41, Number 1) to the present. Abstracts are included for masters theses from Spring 1988 (Masters Abstracts, Volume 26, Number 1) to the present.

Individual, degree-granting institutions submit copies of dissertations and theses completed to University Microfilms International (UMI). Citations for these dissertations are included in the database and in University Microfilms International print publications: *Dissertation Abstracts International (DAI)*, *American Doctoral Dissertations (ADD)*, *Comprehensive Dissertation Index (CDI)*, and *Masters Abstracts International (MAI)*. A list of cooperating institutions can be found in the preface to any volume of *Comprehensive Dissertation Index*, *Dissertation Abstracts International*, or *Masters Abstracts International*.

Developing a search strategy for Qualitative evidence

Predefined search strategies have been written for qualitative research;⁵⁹ however the usefulness on such an approach relies on the author identifying the research as being qualitative and the publisher indexing the work as being qualitative.

Qualitative databases

British Nursing Index: From the partnership of Bournemouth University, Poole Hospital NHS Trust, Salisbury Hospital NHS Trust and the Royal College of Nursing comes the most extensive and up-to-date UK nursing and midwifery index. It covers all the major British publications and other English language titles with unrivalled currency making it the essential nursing and midwifery database. The database provides references to journal articles from all the major British nursing and midwifery titles and other English language titles.

BNI is an essential resource for nurses, midwives, health visitors and community staff.

Academic Search™ Premier (Ebscohost) Academic Search™ Premier : This contains indexing and abstracts for more than 8300 journals, with full text for more than 4500 of those titles. PDF backfiles to 1975 or further are available for well over one hundred journals, and searchable cited references are provided for more than 1000 titles. The database contains unmatched full text coverage in biology, chemistry, engineering, physics, psychology, religion and theology, etc.

HealthSource®:Nursing/Academic Edition (Ebscohost): This resource provides nearly 550 scholarly full text journals focusing on many medical disciplines. Coverage of nursing and allied health is particularly strong, including full text from *Creative Nursing*, *Issues in Comprehensive Pediatric Nursing*, *Issues in Mental Health Nursing*, *Journal of Advanced Nursing*, *Journal of Child & Adolescent Psychiatric Nursing*, *Journal of Clinical Nursing*, *Journal of Community Health Nursing*, *Journal of Nursing Management*, *Nursing Ethics*, *Nursing Forum*, *Nursing Inquiry*, and many more.

In addition, this database includes the *Lexi-PAL Drug Guide* which covers 1300 generic drug patient education sheets with more than 4700 brand names.

Sociological Abstracts (formerly SocioFile) ex ProQuest CSA Sociological Abstracts and indexes the international literature in sociology and related disciplines in the social and behavioral sciences. The database provides abstracts of journal articles and citations to book reviews drawn from over 1800+ serials publications, and also provides abstracts of books, book chapters, dissertations, and conference papers. Records published by Sociological Abstracts in print during the database's first 11 years, 1952-1962, have been added to the database as of November 2005, extending the depth of the backfile of this authoritative resource.

Many records from key journals in sociology, added to the database since 2002, also include the references cited in the bibliography of the source article. Each individual reference may also have links to an abstract and/or to other papers that cite that reference; these links increase the possibility of finding more potentially relevant articles. These references are linked both within Sociological Abstracts and across other social science databases available on CSA Illumina.

Academic OneFile Gale Academic OneFile is the premier source for peer-reviewed, full-text articles from the world's leading journals and reference sources. With extensive coverage of the physical sciences, technology, medicine, social sciences, the arts, theology, literature and other subjects, Academic OneFile is both authoritative and comprehensive. With millions of articles available in both pdf and html full-text with no restrictions, researchers are able to find accurate information quickly.

In addition to all of the traditional services available through *InfoTrac*, Gale is proud to announce a number of new services offered through collaboration with Scientific/ISI. Mutual subscribers of *Academic OneFile*, *Scientific's Web of Science®* and *Journal Citation Reports®* will be provided seamless access to cited references, digital object identifier (DOI) links, and additional article-level metadata, as well as access to current and historical information on a selected journal's impact factor. Further, scientific customers will be able to access the full-text of an article right from their InfoTrac subscription. This close collaboration will allow for fully integrated and seamless access to the best in academic, full-text content and the indexing around it. *Academic OneFile* also includes a linking arrangement with JSTOR for archival access to a number of periodicals, as well as full OpenURL compliance for e-journal and subscription access.

Scopus

Scopus is the largest abstract and citation database of research literature and quality web sources. It is designed to find information scientists need. Quick, easy and comprehensive, Scopus provides superior support of the literature research process. Updated daily, Scopus offers:

- Over 16,000 peer-reviewed journals from more than 4000 publishers
 - over 1200 Open Access journals
 - 520 conference proceedings
 - 650 trade publications
 - 315 book series
- 36 million records
- Results from 431 million scientific web pages
- 23 million patent records from five patent offices
- “Articles-in-Press” from over 3000 journals
- Seamless links to full-text articles and other library resources
- Innovative tools that give an at-a-glance overview of search results and refine them to the most relevant hits
- Alerts to keep you up-to-date on new articles matching your search query, or by favorite author.

Scopus is the easiest way to get to relevant content fast. Tools to sort, refine and quickly identify results help you focus on the outcome of your work. You can spend less time mastering databases and more time on research.

Subject heading/keyword-related strategies

The following terms/terminology listed below should be considered (but also brainstorm from these to find similar natural language terms and synonyms) for all the other databases that describe qualitative evidence. In particular, it is recommended that the terms listed below, derived from CINAHL, be applied to all the databases not already included in the search filters.

EbscoHost: CINAHL

The following are examples of subject headings (in bold) for qualitative evidence should be used by clicking on to the prompt ‘CINAHL Headings’:

Qualitative studies – term used to find ‘qualitative research’ or ‘qualitative study’. Investigations which use sensory methods such as listening or observing to gather and organise data into patterns or themes.

Qualitative validity – term used to find ‘qualitative validities’. The extent to which the research findings from qualitative processes represent reality; the degree to which internal procedures used in the research process distort reality.

Confirmability (research) – Review of the qualitative research process used to affirm that the data support the findings, interpretations, and recommendations; confirmability audit.

Content analysis or field studies – A methodological approach that utilizes a set of procedures for analyzing written, verbal, or visual materials in a systematic and objective fashion, with the goal of quantitatively and qualitatively measuring variables.

Grounded theory – A qualitative method developed by Glaser and Strauss to unite theory construction and data analysis.

Multimethod studies – Studies which combine quantitative and qualitative methods.

Structured categories – A method where qualitative behaviors and events occurring within the observational setting are arranged systematically or quantitatively.

Transferability – Potential to extend the findings of a qualitative research study to comparable social situations after evaluation of similarities and differences between the comparison and study group(s).

Unstructured categories or variable - A qualitative or quantitative entity within the population under study that can vary or take on different values and can be classified into two or more categories.

Phenomenology – Method of study to discover and understand the meaning of human life experiences.

Reviewers may use the following methodological index terms (but NOT limit themselves to these) as either subject headings or text words (or a combination of both) that appear in citations' title or abstract. Use Advanced, Basic, exact phrase, field restrictions (e.g. publication or theory/ research type) search strategies according to database.

- ethnographic research
- phenomenological research
- ethnonursing research or ethno-nursing research
- purposive sample
- observational method
- content analysis or thematic analysis
- constant comparative method
- mixed methods
- author citations, e.g. Glaser & Strauss; Denkin & Lincoln; Heidegger, Husserl, etc.
- perceptions or attitudes or user views or viewpoint or perspective
- ethnographic or micro-ethnographic or mini-ethnographic
- field studies hermeneutics
- theoretical sample
- discourse analysis
- focus groups
- ethnography or ethnological research
- psychology
- focus group or focus groups
- descriptions

- themes
- emotions or opinions or attitudes
- scenarios or contexts
- hermeneutic or hermeneutics
- emic or etic or heuristic or semiotics
- participant observation
- lived experience
- narrative analysis
- discourse analysis
- life experience or life experiences
- interpretive synthesis

Developing a Search Strategy for quantitative evidence

Databases that index quantitative data

The following is a list of major databases, together with search terms that may be helpful in identifying quantitative evidence such as randomised/randomized clinical trials.

Cochrane Library

The search interface for this collection permits the user to search all eight individually or altogether using a single strategy. CENTRAL – The Cochrane Central Register of Controlled Trials (Clinical Trials) – filters controlled clinical trials from the major health care databases (MEDLINE, EMBASE, CRD, etc.) and other sources (including unpublished reports). Most of the studies are RCTs and therefore an excellent starting point for evidence of effectiveness in the absence of a systematic review.

Search terms for CENTRAL:

- clinical trial [pt]
- randomized [tiab]*
- placebo [tiab]
- dt [sh]*
- randomly [tiab]
- trial [tiab]
- groups [tiab]
- animals [mh]
- humans [mh]

CINAHL (Ebsco)

There is no specific limiter for randomized controlled trials in CINAHL. The best search strategy is to search for your topic by using the CINAHL Headings Clinical Trial and Clinical Trial Registry (see their scope notes). Clinical Trial, which is used for experimental trial/trials, explodes to the following list of subheadings:

- Double-blind studies
- Intervention trials
- Preventive trials
- Single-blind studies
- Therapeutic trials

MEDLINE (through Ovid platform)

The major MeSH heading used here is randomized controlled trials for which the scope note reads: "Clinical trials that involve at least one test treatment and one control treatment, concurrent enrolment and follow-up of the test- and control-treated groups, and in which the treatments to be administered are selected by a random process, such as the use of a random-numbers table". This heading covers the following topics: clinical trials, randomized; controlled clinical trials, randomized; randomized clinical trials; trials, randomized clinical. DO NOT use Controlled Clinical Trials, of which Randomized Controlled Trials is a subset. NOTE: MEDLINE picks up English and US spelling without any limits put on them or put into combined sets.

PsycINFO (Ovid)

As with CINAHL, there is no specific heading for Randomized Controlled Trials in the PsycINFO thesaurus. The closest subject heading is Clinical Trials, used since 2004; the scope note reads: "Systematic, planned studies to evaluate the safety and efficacy of drugs, devices, or diagnostic or therapeutic practices. Used only when the methodology is the focus of discussion". PsycINFO picks up English and US spelling) without any limits put on them or put into combined sets.

TRIP database

Search – as phrase (within single quotation marks)

- 'randomized controlled trial'
- rct
- rct*
- 'clinical trial' – consider this term as well because it appears several times in document title with randomized controlled trial or RCT

EMBASE (Ovid)

As with CINAHL and PsycINFO, there is no specific heading for Randomized Controlled Trials in EMBASE. The best heading to use is Clinical Study (14,540 citations), which can be narrowed by selecting 'More Fields' (example title as 'ti:'), and/or 'Limits' and/or 'More Limits' as required, very similar to MEDLINE and PsycINFO via Ovid. Clinical Study is used for clinical data and medical trials.

Associated subheadings that may contain RCT data are the following:

- Case report
- Case study
- Hospital based case control study
- Case control study
- Intervention study
- Major clinical study

Boolean searching

Use any combination of terms with Boolean OR, for example “predict.tw OR guide.tw” as Boolean AND strategy invariably compromises sensitivity. Alternatively, selected combinations of the above terms with researcher’s considered text words (e.g. ‘diabetes’) may achieve high sensitivity or specificity in retrieving studies, or journal subsets using the Boolean AND and thus reducing the volume of literature searched.

Text word searching No indexing terms contribute to optimized search strategies so typing in text words that are relevant to RCTs and clinical trials is best. Precision may be improved by applying the application of AND/AND NOT Boolean operators of addition of clinical content terms or journal subsets using the Boolean AND.

Search terms

- exp randomized controlled trial/
- (random\$ or placebo\$).ti,ab,sh.
- ((singl\$ or double\$ or triple\$ or treble\$) and (blind\$ or mask\$)).tw,sh
- controlled clinical trial\$.tw,sh
- (human\$ not animal\$).sh,hw.

Clinical Evidence (Ovid)

Clinical Evidence is a database that uses Cochrane Library, MEDLINE, EMBASE and others to look for good systematic reviews and then primary studies. For most questions on interventions, this means finding randomized controlled trials using the ‘search’ prompt.

Expanded Academic Index

RCTs can be found here whether using Subject Guide, Basic, Advanced Search or Publication strategies:

Bandolier

Oxford-based Bandolier finds information about evidence of effectiveness from PubMed, Cochrane Library and other web-based sources each month concerning: systematic reviews, meta-analyses, randomized trials, and high quality observational studies. Large epidemiological studies may be included if they shed important light on a topic. Use the ‘Advanced Search’ capability to find RCTs.

Current Controlled Trials (CCT)

CCT provides access to databases that house RCT data for the following regularly updated organizations:

- ISRCTN Register – trials registered with a unique identifier
- Action Medical Research
- King' College, London
- Laxdale Ltd
- Leukaemia Research Fund
- Medical Research Council, UK
- NHS Trusts Clinical Trials Register
- NHS and R&D HTA Program
- NHS R&D 'Time-Limited' National Programs
- NHS R&D Regional Programs
- National Institutes of Health (NIH) – RCTs on NIH ClinicalTrials.gov website
- Wellcome Trust

UK Clinical Trials Gateway

The easy-to-follow search tips for searching the metaRegister of Controlled Trials (mRCT) are located at this URL: http://www.controlled-trials.com/mrct/search_tips#quicksearch

PsiTri

This is a free clinical trial-based database with links to the Cochrane Collaboration, on treatments and interventions for a wide range of mental health-related conditions. The trial data, which is extracted from the references reporting on a specific trial, includes information regarding: health condition, interventions/treatment, participants, research methods, blinding, outcomes, i.e. how the effect of the interventions was measured, etc.

SIGN (Scottish Intercollegiate Guidelines Network)

The RCT search filter used by SIGN to retrieve randomized controlled trials has been adapted from the first two sections of the strategy designed by the Cochrane Collaboration, identifying RCTs for systematic review.

MEDLINE

- Randomized controlled trials/
- Randomized controlled trial.pt.
- Random allocation/
- Double blind method/
- Single blind method/
- Clinical trial.pt.
- Exp clinical trials/
- Or/1-7
- (clinic\$ adj trial\$1).tw.

- ((singl\$ or doubl\$ or treb\$ or tripl\$) adj (blind\$3 or mask\$3)).tw.
- Placebos/
- Placebo\$.tw.
- Randomly allocated.tw.
- (allocated adj2 random).tw.
- Or/9-14
- 8 or 15
- Case report.tw.
- Letter.pt.
- Historical article.pt.
- Review of reported cases.pt.
- Review, multicase.pt.
- Or/17-21
- 16 not 22

EMBASE

- Clinical trial/
- Randomized controlled trial/
- Randomization/
- Single blind procedure/
- Double blind procedure/
- Crossover procedure/
- Placebo/
- Randomi?ed controlled trial\$.tw.
- Rct.tw.
- Random allocation.tw.
- Randomly allocated.tw.
- Allocated randomly.tw.
- (allocated adj2 random).tw.
- Single blind\$.tw.
- Double blind\$.tw.
- ((treble or triple) adj (blind\$).tw.
- Placebo\$.tw.
- Prospective study/
- Or/1-18
- Case study/

- Case report.tw.
- Abstract report/ or letter/
- Or/20-22
- 19 not 23

CINAHL

- Exp clinical trials/
- Clinical trial.pt.
- (clinic\$ adj trial\$1).tw.
- ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj (blind\$3 or mask\$3)).tw.
- Randomi?ed control\$ trial\$.tw.
- Random assignment/
- Random\$ allocat\$.tw.
- Placebo\$.tw.
- Placebos/
- Quantitative studies/
- Allocat\$ random\$.tw.
- Or/1-11

PEDro, an initiative of the Centre for Evidence-Based Physiotherapy (CEBP)

PEDro is the Physiotherapy Evidence Database. It has been developed to give rapid access to bibliographic details and abstracts of randomized controlled trials, systematic reviews and evidence-based clinical practice guidelines in physiotherapy. Most trials on the database have been rated for quality to help you quickly discriminate between trials which are likely to be valid and interpretable and those which are not. The database is updated once a month (except January), the oldest record dates back to 1929.

<http://www.otseeker.com/>

OTseeker is a database that contains abstracts of systematic reviews and randomized controlled trials relevant to occupational therapy. Trials have been critically appraised and rated to assist you to evaluate their validity and interpretability. These ratings will help you to judge the quality and usefulness of trials for informing clinical interventions. In one database, OTseeker provides you with fast and easy access to trials from a wide range of sources. We are unable to display the abstract of a trial or systematic review until the journal that it is published in, or the publisher of the journal, grants us copyright permission to do so. As OTseeker was only launched in 2003, there are many journals and publishers that we are yet to contact to request copyright permission. Therefore, the number of trials and systematic reviews for which we are able to display the abstracts will increase over time as we establish agreements with more journals and publishers.

Developing a Search Strategy for Economic evidence

In searching for Economic evidence, the following suggestions for search terms and databases may be helpful.

Search terms related to the following aspects of types of participants (population):

specific disease/conditions, stage of the disease, severity of the disease, co-morbidities, age, gender, ethnicity, previous treatments received, setting (for example, hospital, community, outpatient).

Search terms related to at least the following aspects of types of interventions:

interventions, mode of delivery, types of personnel who deliver it, co-interventions. Also, the same for search terms related to types of comparators.

Search terms related to different types of outcomes:

mortality outcomes, morbidity outcomes, health related quality of life outcomes, economic outcomes. There are different types of outcomes reported in economic evaluation studies: symptom-free days, cholesterol levels, years of life saved, vomiting frequency, number of asthma attacks avoided, Quality-adjusted life years (QALYs), Disability-Adjusted Life Year (DALY), Healthy-Year Equivalent (HYE), Net-Benefits (NB), Net Present Value (NPV), Benefit/Cost Ratio, incremental cost-effectiveness ratio, incremental cost-utility ratio.

Search terms related to types of studies:

cost-minimisation analysis, CMA, cost-effectiveness analysis, CEA, cost-utility analysis, CUA, cost-benefit analysis, CBA, decision tree, state-transition model, dynamic model, Markov model, cohort longitudinal model, population cross-sectional model, deterministic model, stochastic model, probabilistic model, prospective study, retrospective study.

Search terms need to be adapted to the different resources in which the strategy will be run to reflect the differences in database indexing, search commands and search syntax.⁶⁰

If the search is undertaken in a general database (for example, Medline) the subject search terms (for participants, interventions, comparator, outcomes) should be combined with search terms related to the economic evaluation studies. If the search is undertaken in a specialist economic database additional economic search terms may not be required.

Databases for economic evaluations include:⁶⁰

- NHS Economic Evaluation Database (NHS EED)
- Health Economic Evaluation Database (HEED)
- Cost-effectiveness Analysis (CEA) Registry
- Health Technology Assessment (HTA) database
- Paediatric Economic Database Evaluation (PEDE)
- European Network of Health Economic Evaluation Databases (EURONHEED)
- COonnaissance et Decision en Economie de la Sante (CODECS)

Health Business Elite

This database provides comprehensive journal content detailing all aspects of health care administration and other non-clinical aspects of health care institution management. Topics covered include hospital management, hospital administration, marketing, human resources, computer technology, facilities management and insurance. Health Business™ Elite contains full text content from more than 480 journals such as H&HN: Hospitals & Health Networks, Harvard Business Review (available back to 1922), Health Facilities Management, Health Management Technology, Healthcare Financial Management, Marketing Health Services, Materials Management in Health Care, Modern Healthcare, and many more.

Health Business Elite is supplied by Ebsco.

Subject Coverage

Subject coverage includes:

- Hospital Management
- Hospital Administration
- Marketing
- Human Resources
- Computer Technology
- Facilities Management
- Insurance

EconLit (Ebscohost)

EconLit, the American Economic Association's electronic database, is the world's foremost source of references to economic literature. EconLit adheres to the high quality standards long recognized by subscribers to the *Journal of Economic Literature* (JEL) and is a reliable source of citations and abstracts to economic research dating back to 1969. It provides links to full text articles in all fields of economics, including capital markets, country studies, econometrics, economic forecasting, environmental economics, government regulations, labor economics, monetary theory, urban economics and much more. *EconLit* uses the JEL classification system and controlled vocabulary of keywords to index six types of records: journal articles, books, collective volume articles, dissertations, working papers, and full text book reviews from the *Journal of Economic Literature*. Examples of publications indexed in EconLit include: *Accounting Review*, *Advances in Macroeconomics*, *African Finance Journal*, *American Economist*, *British Journal of Industrial Relations*, *Business Economics*, *Canadian Journal of Development Studies*, *Harvard Business Review*, *Journal of Applied Business Research*, *Marketing Science*, *Policy*, *Small Business Economics*, *Technology Analysis and Strategic Management*, etc. EconLit records include abstracts of books, journal articles, and working papers published by the Cambridge University Press. These sources bring the total records available in the database to more than 1,010,900.

Descriptor Classification Codes

The Descriptor Classification Code (CC) is a four-digit alpha numeric or numeric code representing Descriptor Headings (or Subjects) within EconLit. Descriptor codes for post-1990 records (see link below) are four digit alpha numeric codes (M110). Pre-1991 Descriptor codes are numeric (1310).

B400 - Economic Methodology: General

B410 - Economic Methodology

B490 - Economic Methodology: Other

Searchable fields

The default fields for unqualified keyword searches consist of the following: Title, Author, Book Author, Reviewer, Editor, Author Affiliation, Publisher Information, Geographic Descriptors, Festschrift, Named Person, Source Information, Subject Descriptors, Descriptor Classification Codes, Keywords, Availability Note and the Abstract Summary.

*Note: The EBSCOhost Near Operator (N) used in proximity searching interferes with unqualified keyword searching on a Descriptor Classification Code beginning with an "N". In this instance, use the CC (Descriptor Classification Code) search tag to avoid inconclusive search results. Example Search: CC N110

The following list will help you locate detailed information referenced in this database as a field.

| Tag | Description | Example |
|-----|--|-----------------------|
| AB | Abstract[Word Indexed] Searches the abstract summaries for keywords | AB Great Depression |
| AF | Author Affiliation[Word Indexed] Searches institution of affiliation or address of Author or Reviewer | AF Swarthmore College |
| AR | Author[Phrase Indexed] Searches the exact Author(s) or Reviewer(s) name in last name, followed by first name and possible middle initial or name | AR Alberts, Robert J. |
| AU | Author[Word Indexed] Searches the Author(s) or Reviewer(s) last name, followed by first name and possible middle initial or name | AU Boeri |
| BA | Book Author[Word Indexed] Searches the book author(s) last name followed by first name and possible middle initial | BA Jones, Stephen |
| CC | Descriptor Classification Code [Phrase Indexed] Searches for the exact Descriptor Classification Code. | CC G310 |
| DE | Descriptors[Word Indexed] Searches exact descriptor terms | DE advertising |
| DT | Publication DateSearches the date published in CCYYMM format | DT 199402 |
| FS | Festschrift[Word Indexed] Festschrift Honoree last name followed by first name and possible middle initial | FS Moore, Geoffrey |

| Tag | Description | Example |
|-----|---|-----------------------------|
| FT | Full Text[Phrase Indexed] Limits to titles which have a review (full text) available. The valid entries for this field are: Y = Yes N = No | FT Y |
| JN | Journal Name[Phrase Indexed] Searches the exact journal name which is displayed as part of the source field | JN Journal of Finance |
| KW | Keywords[Phrase Indexed] Searches exact terms in the Keywords field | KW Developing Countries |
| LA | Language[Word Indexed] Searches the language the article was written in. | LA Spanish |
| PT | Publication Type[Phrase Indexed] Searches the exact publication type. Values consist of the following: <ul style="list-style-type: none"> • Book • Book Review • Collective Volume Article • Dissertation • Journal Article • Working Paper | PT Journal Article |
| SO | Source[Word Indexed] Searches words in the source in which the article was published | SO Accounting Review |
| SU | Descriptors[Word Indexed] Searches for subject terms/ codes in the Descriptor, Descriptor Classification Code and Keywords fields | SU history or SU E310 |
| TI | Title [Word Indexed] Searches keywords in the document title | TI Law and Finance |
| TX | All Text [Word Indexed] Performs a keyword search of all the database's searchable fields. | TX Medicine |
| UD | Update Code [Numerically Indexed] Searches the update code in CCYYMM format | UD 200005 |

Searching for text and opinion evidence

A research librarian should be able to assist with development of a search strategy for textual evidence. Examples of search strategies for finding expert opinion based literature are as follows:

BioMedCentral

Opinion and text-based evidence as part of research articles can be found using the 'Advanced' searching strategy (with filter option as needed) only over any time period and the keyword results are as follows:

'expert' [title] and 'opinion' [title]
'expert opinion' [title – exact phrase]
'editorial' [title] and 'opinion' [title]
'opinion' [title] and 'evidence' [title, abstract and text]
'editorial opinion' [title – exact phrase]
'medical' [title] and 'experts' [title]
clinical' [title] and 'knowledge' [title]
opinion-based' [title, abstract and text]
'opinions' [title]
'expert opinion' [title, abstract and text]
'testimony' [title, abstract and text]
'comment' [title]
'opinion-based' [title, abstract and text] and 'evidence' [title, abstract and text]

Also use Boolean search strategy for any combination of the above terms.

National Guideline Clearinghouse (NGC)

The home page (<http://www.guideline.gov/>) is the starting point for searching for opinion/expert/text-based evidence on this US-based site. NGC uses several search strategies, including Boolean, phrase searching, concept mapping, keyword or text word, parentheses (go to <http://www.guideline.gov/help/howtosearch.aspx>).

Cochrane Library

There are several ways to use Cochrane Library to find opinion or expert-related evidence.

(a) MeSH Searching

Cochrane Library has the same MeSH identifiers as MEDLINE and the CRD databases, so use them to find expert opinion-type evidence in Cochrane.

(b) Exact phrase searching – use double quotation marks around terms in 'Search' box [option to use is Title, Abstract or Keywords].

"opinion-based"
"expert testimony"
"medical expert"
"personal opinion"
"clinical opinion"

“medical opinion”

“editorial comment”

“commentary”

(c) Advanced searching – Boolean Central boxes permit you to specify individual search terms or phrases; right-hand boxes are for selecting field (author, keywords, all text); left-hand boxes for Boolean operators. Results of Boolean searching with Title, Abstract and Text option:

expert AND opinion

opinion AND based AND evidence

opinion-based AND evidence

expert-based AND evidence

expert AND opinion AND evidence

expert AND testimony

editorial AND comment AND evidence

editorial AND opinion AND evidence

editorial AND commentary AND evidence

(d) Searching by Restriction Use the Restrict Search by Product section to limit the search to a specific Cochrane Library database or databases.

PubMed

The search strategy for citations will involve two kinds: text word and MeSH:

(a) Examples of keyword/phrase searching

‘Expert opinion’ is a very broad search term and it will bring up a large number of results, so this needs to be refined. Use the ‘Limits’ screen to filter according to your needs, for example: title/abstract; humans, English language, full-text; date range 2001-2011 (‘published in the last 10 years’).

(b) MeSH searching

The relevant subject headings are:

(i) Expert Testimony – use for: expert opinion; expert opinions; opinion, expert

(ii) Comment [Publication Type] - use for commentary, editorial comment, viewpoint

(iii) Editorial [Publication Type] – scope note: ‘the opinions, beliefs, and policy of the editor or publisher of a journal...on matters of medical or scientific significance to the medical community or society at large’.

In PubMed, subject headings can be searched in conjunction with subheadings. For example, Expert Testimony has the following: ‘economics’, ‘ethics’, ‘history’, ‘legislation and jurisprudence’, ‘methods’, ‘standards’, ‘statistics and numerical data’, ‘trends’, ‘utilisation’.

Documenting a search strategy

One of the major strengths of a systematic review is the systematic approach to identifying relevant studies. An important factor in this process is documenting the search and the findings of the search.

Commonly, electronic databases are used to search for papers, many such databases have indexing systems or Thesauruses, which allow users to construct complex search strategies and save them as text files. These text files can then be imported into bibliographic software such as Endnote for management. 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 and consider the comprehensiveness and exhaustiveness of the search strategy for each included database. Any restrictions to the search such as timeframe, number of databases searched and languages should be reported in this section of the report and any limitations or implications of these restrictions should be discussed in the discussion section of the review.

Each electronic database is likely to use a different system for indexing key words within their search engines. Hence the search strategy will be tailored to each particular database. These variations are important and need to be captured and included in the systematic review report. Additionally, if a comprehensive systematic review is being conducted through CReMS, the search strategies for each database for each approach are recorded and reported via CReMS and are added as appendices.

Regardless of the specific review approach adopted (e.g. qualitative or quantitative), the search strategy needs to be comprehensively reported. Commonly, electronic databases are used to search for papers, and many such databases have indexing systems or Thesauruses which allow users to construct complex search strategies and save them as text files. 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 and consider the comprehensiveness and exhaustiveness of the search strategy for each included database.

Managing references

Bibliographic programs such as Endnote can be extremely helpful in keeping track of database searches and are compatible with the CReMS software. Further guidance can be sought from the SUMARI user guide. A research librarian or information scientist is also an extremely useful resource when conducting the search.

When conducting a JBI systematic review using CReMS, references can be imported into CReMS from bibliographic software such as Endnote, either one at a time, or in groups. To import references in groups, the references need to be exported from the reference manager software (such as Endnote) as a text file. Endnote contains a series of fields for a range of publication types. The current version of CReMS requires that the 'journal' category of publication be chosen, and that every field be complete. Before exporting a text file from Endnote, ensure that the 'author/date' format has been selected.

Once exported, the results can be imported into CReMS; any references not successfully imported will be listed in a dialogue box. These can then be added manually to CReMS. In CReMS, studies can be allocated to the different analytical modules; each study can be allocated to multiple modules. Papers that are not included studies but are used to develop the background or to support the discussion can be imported or added to CReMS and allocated the setting 'reference'.

References

- 1 Guyatt G, Sackett D, Sinclair J et al. Users' Guides to the Medical Literature IX. A Method for Grading Health Care Recommendations. *JAMA*. 1995;274(22):1800-4.
- 2 The Joanna Briggs Institute. The Joanna Briggs Institute Reviewers' Manual 2008 Edition. Adelaide: The Joanna Briggs Institute 2008.
- 3 Kotaska A. Inappropriate use of randomized trials to evaluate complex phenomena: case study of vaginal birth delivery. *BMC Medical Research Methodology*. 2004;329(7473):1039-42.
- 4 Muir Gray J. Evidence based policy making. *British Medical Journal*. 2004;329(7374):988.
- 5 Proctor S, Renfrew M. Linking research and practice in midwifery. Edinburgh: Bailliere Tindall 2000.
- 6 Pearson A. The JBI Approach to Evidence-Based Practice. 2008 [cited 2010 Nov 30]; Available from: www.joannabriggs.edu.au/pdf/about/Approach.pdf
- 7 Pearson A, ed. Evidence based practice in nursing and healthcare: Assimilating research, experience and expertise. Oxford: Blackwell 2007.
- 8 Pope C. Qualitative research in health care. London: BMJ publishing group 1999.
- 9 Jordan Z, Donnelly P, Pittman P. A short history of a big idea. Melbourne: The Joanna Briggs Institute 2006.
- 10 Ailinger R. Contributions of qualitative evidence to evidence based practice in nursing. *Revista Latino-americana de Enfermagem*. 2003;11(3):275-9.
- 11 Denzin N, Lincoln Y, eds. Handbook of qualitative research. Third ed. California: Thousand Oaks; SAGE publications 2005.
- 12 Wong S, Wilczynski N, Haynes R. Developing optimal search strategies for detecting clinically relevant qualitative studies in Medline. *Stud Health Technol Inform*. 2004;107(1):311-6.
- 13 Black N. Why we need qualitative research. *Journal of Epidemiological Community Health*. 1994;48:425-6.
- 14 Greenhalgh T, Taylor R. Papers that go beyond numbers (qualitative research). *BMJ*. 1997;315(7110):740-3.
- 15 Evans D. Database searches for qualitative research. *J Med Libr Assoc*. 2002;13(3):290-3.
- 16 Centre for Reviews and Dissemination. Centre for Reviews and Dissemination, Guidelines for undertaking reviews in health care. In: Dissemination, ed.: University of York 2009.
- 17 Barbour R. The case for combining qualitative and quantitative approaches in health services research. *J Health Serv Res Policy*. 1999;4(1):39-43.
- 18 Forman J, Creswell J, Damschroder L, Kowalski C, Krein S. Qualitative research methods: key features and insights gained from use in infection prevention research. *Am J Infect Control*. 2008;36(10):764-71.

- 19 Moffatt S, White M, Mackintosh J, Howel D. Using quantitative and qualitative data in health services research - what happens when mixed method findings conflict? *BMC Health Serv Res.* 2006;6:28.
- 20 Chin P, Jacobs M. *Theory in Nursing: A Systematic Approach.* St Louis: Mosbey 1987.
- 21 Sandelowski M, Barosso J. *Handbook for Synthesizing Qualitative Research.* New York: Springer Publishing Company 2007.
- 22 Thorne S, Jensen L, Kearney M, Noblit G, Sandelowski M. Qualitative metasynthesis: reflections on methodological orientation and ideological agenda. *Qual Health Res.* 2004;14(10):1342-65.
- 23 Sandelowski M, Docherty S, Emden C. Focus on qualitative Methods Qualitative Metasynthesis: Issues and Techniques. *Research in Nursing and Health.* 1997;20:365-71.
- 24 Pearson A. Balancing the evidence: incorporating the synthesis of qualitative data into systematic reviews. *JBIR Report.* 2004;2(2):45-65.
- 25 Hannes K, Lockwood C. Pragmatism as the philosophical foundation for the Joanna Briggs meta-aggregative approach to qualitative evidence synthesis. *J Adv Nurs.* 2011;67(7):1632-42.
- 26 Barza M, Trikalinos TA, Lau J. Statistical Considerations in Meta-analysis. *Infectious Disease Clinics of North America.* 2009;23(2):195-210.
- 27 Borenstein M, Hedges L, Higgins J, Rothstein H. *Introduction to Meta-analysis.* Chichester: John Wiley & Sons 2009.
- 28 Greenhalgh T. How to read a paper. Statistics for the non-statistician. II: "Significant" relations and their pitfalls. *BMJ.* 1997;315(7105):422-5.
- 29 Greenhalgh T. How to read a paper. Statistics for the non-statistician. I: Different types of data need different statistical tests. *BMJ.* 1997;315(7104):364-6.
- 30 Bastian H. Personal views: Learning from evidence based mistakes. *British Medical Journal.* 2004;329(7473):1053.
- 31 Moher D. The inclusion of reports of randomized trials published in languages other than English in systematic reviews *Health Technology Assessment.* 2003;7(41):1-90.
- 32 Pearson A, Field J, Jordan Z. *Evidence based practice in nursing and health care; Assimilating research, experience and expertise.* Oxford: Blackwell Publishing 2007.
- 33 Trohler U. *The 18th century British Origins of a critical approach.* Edinburgh: Royal College of Physicians 2000.

- 34 Miller S, Fredericks M. The Nature of "Evidence" in Qualitative Research Methods. *International Journal of Qualitative Evidence*. 2003;2(1):39-51.
- 35 Pearson A, Wiechula R, Court A, Lockwood C. A re-consideration of what constitutes "evidence" in the healthcare professions. *Nursing Science Quarterly*. 2007;20(1):85-8.
- 36 Shadish W, Cook T, Campbell T. *Experimental and quasi-experimental designs for generalized causal inference*. Boston Houghton Mifflin Company 2001.
- 37 Altman D, Bland J. Treatment allocation in controlled trials: why randomise? *British Medical Journal*. 1999;318:1209.
- 38 Schulz K, Grimes D. Blinding in randomized trials: hiding who got what. *Lancet*. 2002;359:696-700.
- 39 Higgins J, Green S. *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.0.2 2009 [cited 2010 October 2010]; Available from: www.cochrane-handbook.org.
- 40 Ioannidis JP. Integration of evidence from multiple meta-analyses: a primer on umbrella reviews, treatment networks and multiple treatments meta-analyses. *CMAJ*. 2009;181(8):488-93.
- 41 Petitti D. *Meta-analysis, Decision Analysis, and Cost-Effectiveness Analysis: Methods for Quantitative Synthesis in Medicine*. Second Edition ed. New York: Oxford University Press 2000.
- 42 Deeks J, Higgins J, Altman D. *Analyzing and presenting results: section 8*. 426 ed. Chichester: John Wiley and Sons Ltd 2006.
- 43 Higgins J, Thompson S, Deeks J, Altman D. Statistical heterogeneity in systematic reviews of clinical trials: a critical appraisal of guidelines and practice. *Journal of Health Services Research and Policy*. 2002;7(1):51-61.
- 44 Hardy R, Thompson S. Detecting and describing heterogeneity in meta-analysis. *Statistics in Medicine*. 1998;17(8):841-56.
- 45 Deeks J, Higgins J, Altman D. *Statistical methods for examining heterogeneity and combining results from several studies in meta-analysis*. London: BMJ Publishing Group 2001.
- 46 Liberati A, Altman D, Tetzlaff J et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *PLoS Medicine*. 2009;6(7):e1000100.
- 47 Moher D, Liberati A, Tetzlaff J, Altman D. Preferred reporting items for systematic reviews and meta-analyses: The PRISMA statement. *PLoS Medicine*. 2009;6(7):e1000097.
- 48 Annemans L. *Health economics for non-economists. An introduction to the concepts, methods and pitfalls of health economic evaluations*. . Gent: Academia Press 2008.
- 49 Elliott R, Payne K. *Essentials of Economic Evaluation in Healthcare*. London: Pharmaceutical Press 2005.
- 50 Gold M, Siegel J, Russell L, Weinstein M. *Cost-Effectiveness in Health and Medicine*. New York: Oxford University Press 1996.
- 51 Hoch J, Dewa C. An introduction to economic evaluation: What's in a Name?. *Can J Psychiatry*. 2005;50(3).
- 52 Drummond MF. Allocating resources. *Int J Technol Assess Health Care*. 1990;6(1):77-92.

- 53 de Verteuil R, Tan W. Self-monitoring of blood glucose in type 2 diabetes mellitus: systematic review of economic evidence. *JB I Library of Systematic Reviews*. 2010;8(8):302-42.
- 54 Lister-Sharp D, McDonagh M, Khan K, Kleijnen J. A rapid and systematic review of the effectiveness and cost-effectiveness of the taxanes used in the treatment of advanced breast and ovarian cancer. *Health Technol Assess* 2000;4(17).
- 55 Sackett D, Rosenberg J, Gray J, Haynes R. Evidence based medicine: what is is and what it isn't. *British Medical Journal* 1996;312:71-2.
- 56 Tonelli M. In Defense of Expert Opinion *Academic Medicine* 1999;74 (11):1187-92.
- 57 Woolf S. Evidence Based Medicine and Practice Guidelines: An Overview. *Cancer Control* 2000;7(7):362-7.
- 58 University of New Mexico. Gray literature and how to find it. 2007 [cited; Available from: <http://hsc.unm.edu/library/subject/graylit.shtml>]
- 59 Shaw R, Booth A, Sutton A et al. Finding qualitative research: an evaluation of search strategies. *BMC Medical Research Methodology*. 2004;4(5):1-5.
- 60 Glanville J, Paisley S. Chapter 7: Searching for evidence for cost-effectiveness decisions. In: Shemlit I, Mugford M, Vale L, Marsh K, Donaldson Ce, eds. *Evidence-based decisions and economics: health care, social welfare, education and criminal justice*. Oxford: Wiley-Blackwell 2010.

Glossary

Action Research: a method of collaborative research which seeks to create self-critical communities as a basis for change

Association: a term to describe a relationship between two factors. Often used where there is no clear causal effect of one variable upon the other

Benefit-cost ratio: a ratio commonly used to describe the conclusion of a Cost–Benefit study. It is the ratio of the present value of benefits to the present value of costs.

Category/categories: terms used to describe a group of findings that can be grouped together on the basis of similarity of meaning. This is the first step in aggregating study findings in the JBI meta-aggregation approach of meta-synthesis.

Causation: a term to describe a relationship between two factors where changes in one factor leads to measurable changes in the other

Comprehensive systematic review: a JBI comprehensive systematic review is a systematic review that incorporates more than one type of evidence, e.g. both qualitative and quantitative evidence

Continuous: data that can be measured on a scale that can take any value within a given range such as height, weight or blood pressure

Control: in general, refers to a group which is not receiving the new intervention, receiving the placebo or receiving standard healthcare and is being used to compare the effectiveness of a treatment

Convenience sampling: a method for recruiting participants to a study. A convenience sample refers to a group who are being studied because they are conveniently accessible in some way. A convenience sample, for example, might be all the people at a certain hospital, or attending a particular support group. A convenience sample could make be unrepresentative, as they are not a random sample of the whole population

Correlation: the strength and direction of a relationship between variables

Cost-benefit analysis (CBA): an analytic tool for estimating the net social benefit of a program or intervention as the incremental benefit of the program less the incremental costs, with all benefits and costs measured in monetary units (e.g. dollars)

Cost-effectiveness analysis (CEA): an analytic tool in which costs and effects of a program and at least one alternative are calculated and presented in a ratio of incremental costs to incremental effect

Cost-effectiveness ratio: the incremental cost of obtaining a unit of health effect (such as dollars per year, or life expectancy) from a given health intervention, when compared with an alternative

Cost-minimisation analysis (CMA): an analytic tool used to compare the net costs of programs that achieve the same outcome

Costs: in economic evaluation studies refer to the value of resources that have a cost as a result of being used in the provision of an intervention

Cost-utility analysis (CUA): an economic evaluation study in which costs are measured in monetary units and consequences are typically measured as quality-adjusted life-years (QALYs)

Critical appraisal: the process of comparing potentially relevant studies to pre-defined criteria designed in order to assess methodological quality. Usually checklists are used with items designed to address specific forms of bias dependent on study design. Action research, feminist research and discourse analysis are methodologies associated with this paradigm.

Critical research paradigm: a qualitative research paradigm that aims to not only describe and understand but also asks what is happening and explores change and emancipation.

Dichotomous: data that can be divided into discrete categories such as, male/female or yes/no

Direct costs: represent the value of goods, services and other resources that are consumed in the provision of an intervention or in dealing with the side effects or other current and future consequences linked to it

Direct medical costs: represent the value of health care resources (e.g. tests, drugs, supplies, health care personnel and medical facilities) consumed in the provision of an intervention or in dealing with the side effects or other current and future consequences linked to it

Direct nonmedical costs: represent the value of nonmedical goods, services and other resources, such as child care and transportation, consumed in the provision of an intervention or in dealing with the side effects or other current and future consequences linked to it

Discount rate: the rate of interest used to calculate a present value or to discount future values

Discounting: a procedure for reducing costs or benefits occurring at different dates to a common measure by use of an appropriate discount rate

Discourse analysis: a research method that uses application of critical thought to social situations in order to expose hidden politics of socially dominant or marginalized discourses

Dominance: in economic evaluation, exists when one option, technology or intervention is more effective and has costs no higher than another or when it is at least as effective and has lower costs

Economic evaluation: a study that compares the costs and benefits of two or more alternative interventions or programs or services

Effect size: a value that reflects the strength of a relationship between two variables. Examples include differences in means (mean difference) correlation coefficients, relative risk and odds ratio

Effectiveness: the effect of a particular treatment or intervention, drug or procedure on defined outcomes when used in actual practice

Efficacy: concerns the effect of a particular treatment or intervention or procedure on outcomes under ideal conditions. It is the maximum benefit or utility under ideal conditions

Efficiency: is defined either as minimizing the opportunity cost of attaining a given output or as maximizing the output for a given opportunity cost

Ethnography: a term to describe the study of culture which recognizes everyday life (e.g. of a ward, or community) as a subject worthy of study to learn the meaning that people in a culture attach to activities, events, and rituals

Feminist research: a research method that describes women's experience in the world to explore change and emancipation

Findings: 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

Fixed cost: a cost of production that does not vary with the level of output. Fixed costs are those incurred whether patients are treated or not

Focus group interviews: a data collection method involving interactive discussion of a small group led by a trained moderator

Forest plot: a diagrammatic representation of the effect sizes of individual studies in meta-analysis

Full economic evaluation: considers both the costs and consequences for two or more interventions being compared within the analysis

Grounded theory: a qualitative research methodology developed by Glaser and Strauss to unite theory construction and data analysis.

Grey or gray literature: a term used to describe publications such as theses, papers and reports produced by agencies (such as government, academic, non-profit organizations, business and industry) that are not published by commercial publishers

Health care sector costs: include medical resources consumed by health care entities

Health economic evaluation: a comparative analysis of both the costs and the health effects of two or more alternative health interventions

Health economics: the discipline which deals with the application of economic principles and theories to health and the health sector

Heterogeneity: a measure of how different or incompatible studies are within a systematic review. Can have several dimensions such as clinical (e.g. the studies are clinically different), methodological (i.e. different study designs) or statistical (e.g. the studies have different effect sizes)

Homogeneity: a measure of how similar studies are within a systematic review. Can have several dimensions such as clinical (e.g. the studies are clinically similar or comparable) or statistical (e.g. the studies are statistically similar or comparable)

Illustration: an example of textual data from a primary qualitative research study that supports a finding in the meta-synthesis process. It can be in the form of a direct quote, observations or statements.

Indirect costs: refer in economics to the productivity gains or losses related to illness or death
Interpretive paradigm: a research paradigm that seeks to understand implicit meanings. Ethnography and Phenomenology are research methodologies associated with this paradigm

Intervention: in general, a form of health care provided to individual patients or groups/communities; it may also be used when describing a particular form of treatment being tested (see treatment)

Interviews: a data collection method that may involve semi or unstructured conversation with an explicit purpose

JBIG: Joanna Briggs Institute

JBIG Affiliation: association with a JBIG collaborating entity such as a collaborating centre or an evidence synthesis group

JBIG ACTUARI: Joanna Briggs Institute Analysis of Cost Technology and Utilisation Assessment and Review Instrument

JBIG CReMS: Joanna Briggs Institute Comprehensive Review Management Software, used for conduct and management of a JBIG systematic review. There are four component analytical modules:

JBIG MASTARI: Joanna Briggs Institute Meta Analysis Statistics Assessment and Review Instrument. The analytical module designed for JBIG systematic reviews of effectiveness evidence

JBIG NOTARI: Joanna Briggs Institute Narrative Opinion and Text Assessment and Review Instrument. The analytical module designed for JBIG systematic reviews of text and opinion evidence

JBIG QARI: Joanna Briggs Institute Qualitative Assessment and Review Instrument. The analytical module designed for JBIG systematic reviews of qualitative evidence

JBIG SUMARI: Joanna Briggs Institute System for the Unified Management, Assessment and Review of Information, JBIG computer software package

Levels of Credibility: used in meta-synthesis to determine the validity of findings in QARI qualitative research and NOTARI text and opinion analytical modules

- Unequivocal – evidence which is beyond reasonable doubt
- Credible – evidence that while subject to interpretation, is plausible
- Unsupported – such evidence may be noted in review but is not included in a JBIG meta-synthesis of findings and categories in synthesized findings

Mean: the standard measure of central tendency for normally distributed continuous data; the average

Meta-aggregation: a term used to describe the JBIG model for the synthesis of qualitative evidence. It seeks to move beyond an outcome of implicit suggestions in order to produce declaratory or directive statements in order to guide practitioners and policy makers

Meta analysis (meta-analysis): a statistical combination of data from similar studies, used to give an overview of the included studies

Meta ethnography: a method of synthesis of qualitative data which aims to produce new theoretical understandings.

Methods: a general term to describe the processes of data collection and data analysis, such as interviews, observation, or other measurement of outcomes

Methodology: a general term to describe the theory and assumptions behind how research should be conducted, e.g. clinical trials, ethnography. It is important in determining which methods should be used to collect data and how the results should be interpreted

Narrative analysis: a term used to describe the extraction of immediately apparent key concepts or meanings of a study. Used in qualitative research

Narrative (life history): a term to describe research that uses stories of events and happenings as qualitative data

Narrative summary: a textual combination of data, often used when heterogeneity of included studies is high (i.e. studies are dissimilar in terms of patients, methods or data). Not to be confused with narrative review.

Non-participant observation: a method of data collection where the observer collects data by observation alone and does not participate in the activity

Observation: a data collection method that involves the systematic recording of the behavioral patterns of people, objects and occurrences without questioning or communication with them

OR: the odds ratio, or cross products ratio, is the ratio of the odds of an event occurring in one group to it occurring in another group; it is the primary measure of association in case-control studies

Paradigm: a generally accepted world view or philosophy. Informs the methodology and methods used to conduct research

Overview of reviews: a term applied to systematic reviews that draw together evidence from a series of other systematic reviews. This type of review can be useful in providing an overview of research within a particular area. Also known as umbrella reviews

Partial economic evaluation: interventions or services through consideration of costs or consequences alone (but not both)

Participant observation: a research method that involves the observer participating in the activity and simultaneously observing what is occurring

Patient and family costs: include the patient's or family's share of direct medical as well as direct nonmedical costs.

Perspective: the economic term that describes whose costs are relevant in the evaluation based on the purpose of the economic evaluation study.

Phenomenology: a research methodology that aims to discover and understand the meaning of individual human life experiences by studying individual phenomena/foci of interest.

Positivist paradigm: a paradigm that attempts to view the world objectively. This paradigm informs quantitative research and is concerned with the numerical measurement of phenomena

Post nominal: letters placed after the name of a person to indicate that they hold a position, educational degree, accreditation, office or honour.

Primary study: a research publication which forms the basis of the data set of a systematic review

Productivity costs: the costs associated with lost or impaired ability to work or to engage in leisure activities due to morbidity and lost economic productivity due to death

Protocol: a pre-determined plan for the conduct of a systematic review. It provides details of how the review will be conducted and reported

QALY: quality-adjusted life-year is a generic measure of health-related quality of life that takes into account both the quantity and the quality of life generated by interventions/treatments.

QARI-view: a meta aggregation table created by QARI which includes the categories and findings from which the synthesized findings originated.

Qualitative research: a broad term used to describe the various research methodologies including ethnography, phenomenology, narrative analysis and grounded theory

Qualitative textual analysis: a data analysis method used in qualitative research to extract data from texts or interview transcripts

Random allocation: a method that uses the play of chance to assign participants to comparison groups in a study (e.g. by using a random numbers table or a computer-generated random sequence). Random allocation implies that each individual or unit being entered into a trial has the same chance of receiving each of the possible interventions. It also implies that the probability that an individual will receive a particular intervention is independent of the probability that any other individual will receive the same intervention.

Random sampling: a method for recruiting people to a study that is representative of the population of interest. This means that everyone in the population has an equal chance of being approached to participate in the survey. The process is meant to ensure that a sample is as representative of the population as possible. It has less bias than a convenience sample, that is, a group that the researchers have more convenient access to

Randomization: the process of randomly allocating participants into one of the arms of a controlled trial. There are two components to randomization: the generation of a random sequence and its implementation, ideally in a way so that those entering participants into a study are not aware of the sequence.

Recurrent costs: the value of recurrent resources

Review authors: the authors of a systematic review; for a JBI systematic review there are at least two review authors, at least one of whom has undertaken CSR training with JBI or the Cochrane Collaboration

Reflective journaling: a research method used in qualitative research that involves a summary (written or oral) of an experience which involves analyzing or critiquing the experience

RR: the relative risk, or risk ratio, is the ratio of the risk of an event occurring in one group to the risk of it occurring in another group; it is the primary measure of association in cohort studies

Scoping review: a type of review that aims to determine the size and scope of a body of literature on a topic, with the aim of identifying what research exists and where the gaps are. No formal critical appraisal but search aims are comprehensive

SD: standard deviation, a measure of the variance of data points around a measure of central tendency

SE: standard error or standard error of the mean, a measure of the variance of data points around a measure of central tendency

Semi-variable costs or semi-fixed costs: costs that have both a fixed and a variable cost component

Sensitivity: a measure of a diagnostic or screening test's ability to correctly detect people with a particular disease (diseased). It is the proportion of diseased patients that are correctly identified by obtaining a positive test result. Not to be confounded with sensitivity of a search strategy

Sensitivity analyses: mathematical calculations that isolate factors involved in a decision analysis or economic analysis to indicate the degree of influence each factor has on the outcome of the entire analysis

SMD: standardized mean difference, a method used to compare the mean difference between studies. The mean difference in each study is divided by the SD of that study, to create an index which can be compared across studies

Specificity: a measure of a diagnostic or screening test's ability to correctly detect people without a particular disease (non-diseased). It is the proportion of non-diseased patients that are correctly identified by obtaining a negative test result. Not to be confounded with specificity of a search strategy

Study authors: the authors of a primary study

Summary effect: a statistical combination of effect sizes

Synthesis: a term to describe the combining or 'pooling' of the findings of qualitative research studies

Synthesized finding: an over-arching 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

Treatment: in general, a form of health care provided to patients or groups/communities; however, throughout this manual it is often used to designate a specific form of health care, the effectiveness of which is being tested compared to a placebo or a standard, or control health care. In this capacity, treatment and intervention may be used interchangeably

Umbrella review: a term applied to systematic reviews that draw together evidence from a series of other systematic reviews. This type of review can be useful in providing an overview of research within a particular area. Also known as overview of reviews

Variable cost: a cost of production that varies directly with the level of output. Variable costs are incurred from the patient's treatment. Variable costs include drugs, blood products, and medical investigations

Visual ethnographic methods: explicit observation of a social, cultural, work environment in order to collect data on tacit cultural rules

Weighted mean: the importance of mean of a study to a meta-analysis can be adjusted, often used when certain values are more important than others: they supply more information.

WMD: weighted mean difference, a form of meta-analysis suited to continuous data measured on the same scale

Appendices

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Appendix I - JBI systematic review title registration form

Systematic Review Title:

Centre:

Primary Reviewer

Name:

Email address:

Secondary Reviewer

Name:

Email address:

PICO


Population:

Intervention/Phenomena of Interest:

Comparator/Context:

Outcome(s):

Appendix II - QARI critical appraisal tools



QARI - Qualitative Assessment and Review Instrument

[Reviews](#)
[Study](#)
[Categories](#)
[Synthesis](#)
[Logout](#)
[About](#)

Select
Detail
Assessment
Extraction
Findings

Assessment for : Author - Journal (2011)
Type: Primary
User: catalin1

| Criteria | Yes | No | Unclear | Not Applicable | Comment |
|--|-----------------------|-----------------------|-----------------------|-----------------------|----------------------|
| 1) There is congruity between the stated philosophical perspective and the research methodology. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 2) There is congruity between the research methodology and the research question or objectives. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 3) There is congruity between the research methodology and the methods used to collect data. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 4) There is congruity between the research methodology and the representation and analysis of data. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 5) There is congruity between the research methodology and the interpretation of results. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 6) There is a statement locating the researcher culturally or theoretically. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 7) The influence of the researcher on the research, and vice-versa, is addressed. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 8) Participants, and their voices, are adequately represented. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 9) The research is ethical according to current criteria or, for recent studies, there is evidence of ethical approval by an appropriate body. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 10) Conclusions drawn in the research report do appear to flow from the analysis, or interpretation, of the data. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |

Include:

Reason:

Appendix III - Discussion of QARI appraisal tools

The 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 rigour 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 IV - QARI data extraction tools




ReviewsStudyCategoriesSynthesisLogoutAbout

Extraction Details: Author - Journal (2011)
* denotes field which will appear in report appendix
Methodology:
Method: *
Phenomena of Interest: *
Setting:
Geographical:
Cultural:
Participants: *
Data Analysis:
Authors Conclusion: *
Reviewers Comments: *
Complete

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Appendix V (a) - MASTARI critical appraisal tools
Randomized Control / Pseudo-randomized Trial



ReviewsStudyLogoutAbout


Assessment for : Author - Journal (2011)
Type: Primary
User: catalini
Design: Randomised Control Trial / Pseudo-randomised Trial

| Criteria | Yes | No | Unclear | Not Applicable | Comment |
|--|-----------------------|-----------------------|-----------------------|-----------------------|----------------------|
| 1) Was the assignment to treatment groups truly random? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 2) Were participants blinded to treatment allocation? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 3) Was allocation to treatment groups concealed from the allocator? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 4) Were the outcomes of people who withdrew described and included in the analysis ? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 5) Were those assessing outcomes blind to the treatment allocation? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 6) Were the control and treatment groups comparable at entry? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 7) Were groups treated identically other than for the named interventions? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 8) Were outcomes measured in the same way for all groups? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 9) Were outcomes measured in a reliable way? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 10) Was appropriate statistical analysis used? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |

Include: Undefined
Reason:

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Appendix V (b) - MASTARI critical appraisal tools Comparable Cohort / Case Control Studies



MAStARI - Meta Analysis of Statistics Assessment and Review Instrument

Reviews Study Logout About

Assessment for: Author - Journal (2011)

Type: Primary
User: catalin1
Design: Comparable Cohort / Case Control Studies

Select
Detail
Assessment
Extraction
Results
Meta-Analysis


| Criteria | Yes | No | Unclear | Not Applicable | Comment |
|---|-----------------------|-----------------------|-----------------------|-----------------------|----------------------|
| 1) Is sample representative of patients in the population as a whole? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 2) Are the patients at a similar point in the course of their condition/illness? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 3) Has bias been minimised in relation to selection of cases and of controls? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 4) Are confounding factors identified and strategies to deal with them stated? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 5) Are outcomes assessed using objective criteria? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 6) Was follow up carried out over a sufficient time period? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 7) Were the outcomes of people who withdrew described and included in the analysis? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 8) Were outcomes measured in a reliable way? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 9) Was appropriate statistical analysis used? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |

Include: Undefined ▾
Reason:

Update Undo Cancel

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Appendix V (c) - MASTARI critical appraisal tools Descriptive / Case Series Studies



MAStARI - Meta Analysis of Statistics Assessment and Review Instrument

Reviews Study Logout About

Assessment for: Author - Journal (2011)

Type: Primary
User: catalin1
Design: Descriptive / Case Series Studies

Select
Detail
Assessment
Extraction
Results
Meta-Analysis

| Criteria | Yes | No | Unclear | Not Applicable | Comment |
|---|-----------------------|-----------------------|-----------------------|-----------------------|----------------------|
| 1) Was study based on a random or pseudo-random sample? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 2) Were the criteria for inclusion in the sample clearly defined? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 3) Were confounding factors identified and strategies to deal with them stated? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 4) Were outcomes assessed using objective criteria? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 5) If comparisons are being made, was there sufficient descriptions of the groups? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 6) Was follow up carried out over a sufficient time period? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 7) Were the outcomes of people who withdrew described and included in the analysis? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 8) Were outcomes measured in a reliable way? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 9) Was appropriate statistical analysis used? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |

Include: Undefined ▾
Reason:

Update Undo Cancel

Appendix VI - Discussion of MASTARI critical appraisal checklist items

As discussed in the section on protocol development, it is JBI policy that all study types must be critically appraised using the critical appraisal instruments for specific study designs incorporated in to the analytical modules of the SUMARI software. The primary and secondary reviewer should discuss each item of appraisal for each study design included in their review.

In particular, discussions should focus on what is considered acceptable to the needs of the review in terms of the specific study characteristics such as randomization or blinding in RCTs. 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 take place before independently conducting the appraisal.

Critical Appraisal of Quantitative Evidence

Within quantitative reviews, there is a range of study designs that may be incorporated. A common approach is to state a preferred hierarchy of types of studies, often beginning with randomized controlled trials/quasi-randomized controlled trials, then other controlled designs (cohort and case controlled) followed by descriptive and case series studies. This section of the handbook illustrates how each of these designs is critically appraised using the criteria in the JBI analytical module MASTARI. The individual checklists can be located in Appendix V.

Randomized and quasi-randomized controlled trials

There are 10 questions to guide the appraisal of randomized and quasi-randomized controlled trials.

1. Is the assignment to treatment groups truly random?

There are three broad types of randomization within trials, randomization, quasi (or pseudo) and stratified randomization. True randomization occurs when every patient has a truly equal chance of being in any group included in the trial. This may involve using computer generated allocation methods to ensure allocation is truly random. True randomization will minimise selection bias, thus identification of the method of randomization provides reviewers with a good indication of study quality. In the presence of true randomization, the sample is said to be representative of the population of interest, with homogeneity of characteristics at baseline. Hence any variation between groups in the trial would be expected to reflect similar differences in the relevant population.

In quasi randomization, allocation is not truly random, being based on a sequential method of allocation such as birth date, medical record number, or order of entry in to the study (alternate allocation). These methods may not conceal allocation effectively; hence there is an increased risk of selection bias associated with their usage.

The third type of randomization commonly utilized in randomized trials is stratification. Stratification may be used where a confounding factor (a characteristic that is considered likely to influence the study results, i.e. medications or co-morbidities) needs to be evenly distributed across groups.

Whichever approach to randomization is used, it should be described with sufficient detail to enable reviewers to determine whether the method used is sufficient to minimise selection bias. Authors of primary studies have competing interests in describing their methods, the need to be descriptive at times conflicts with the need to fit within word limits. However, brevity in the methods often leaves reviewers unable to determine the actual method of randomization. Generalist phrases such as 'random', 'random allocation' or 'randomization' are not sufficient detail for a reviewer to conclude randomization was 'truly random', it is then up to the reviewer to determine how to rank such papers. This should be raised in initial discussion between the primary and secondary reviewers before they commence their independent critical appraisal.

2. Are participants blinded to treatment allocation?

Blinding of participants is considered optimal as patients who know which arm of a study they have been allocated to may inadvertently influence the study by developing anxiety or conversely, being overly optimistic, attempting to 'please' the researchers. This means under- or over-reporting outcomes such as pain or analgesic usage; lack of blinding may also increase loss to follow-up depending on the nature of the intervention being investigated.

3. Is allocation to treatment groups concealed from the allocator?

Allocation is the process by which individuals (or groups if stratified allocation was used) are entered in to one of the study arms following randomization. The Cochrane Systematic Review handbook states: When assessing a potential participant's eligibility for a trial, those who are recruiting participants... should remain unaware of the next assignment in the sequence until after the decision about eligibility has been made. Then, after assignment has been revealed, they should not be able to alter the assignment or the decision about eligibility. The ideal is for the process to be impervious to any influence by the individuals making the allocation.³⁹

Allocator concealment of group allocation is intended to reduce the risk of selection bias. Selection bias is a risk where the allocator may influence the specific treatment arm an individual is allocated to, thus optimally, trials will report the allocator was unaware of which group all study participants were randomized to, and had no subsequent influence on any changes in allocation.

4. Are the outcomes of people who withdrew described and included in the analysis?

Commonly, intention to treat analysis is utilized where losses to follow-up are included in the analysis. Intention to treat (ITT) analysis may reduce bias due to changes in the characteristics between control and treatment groups that can occur if people either drop out, or if there is a significant level of mortality in one particular group. The Cochrane Systematic Review handbook identifies two related criteria for ITT analysis, although it is equally clear that how these criteria are applied remains an issue of debate:

- Trial participants should be analyzed in the groups to which they were randomized regardless of which (or how much) treatment they actually received, and regardless of other protocol irregularities, such as ineligibility
- All participants should be included regardless of whether their outcomes were actually collected.³⁹

5. Are those assessing the outcomes blind to the treatment allocation?

In randomized controlled trials, allocation by a third party not otherwise directly involved in the implementation of the study is preferred. Where these resources are not available, electronic assignment systems may be described in trials. Inadequate blinding of allocation is associated with more favorable outcomes for the primary intervention of interest in RCTs.³⁹

Reviewers should seek to establish whether those assessing outcomes were truly blinded to allocation. Some sources suggest blinded assessment reduces the risk of detection bias. Note that studies reporting multiple outcomes may be at risk of detection bias for some outcomes within a study, but not others. Therefore, attempts should be made to establish if outcomes assessors were blinded to all outcomes of interest to the review.

6. Are the control and treatment groups comparable at entry?

Homogeneity or comparability at entry is related to the method of allocation. If allocation is truly random, groups are more likely to be comparable as characteristics are considered to be randomly distributed across both groups. However, randomization does not guarantee comparability. Primary studies should report on the baseline characteristics of all groups, with an emphasis on any differences between groups that reach statistical probability.

7. Are groups treated identically other than for the named intervention?

Studies need to be read carefully to determine if there were any differences in how the groups are treated – other than the intervention of interest. If there is a difference in how the groups are treated that arises from flaws in the trial design, or conduct, this is known as a systematic difference and is a form of bias which will skew study results from the accuracy the primary authors would otherwise have intended. Randomization, blinding and allocation concealment are intended to reduce the effects of unintentional differences in treatment between groups.

8. Are outcomes measured in the same way for all groups?

In identifying how robust the outcomes for a study are, the definitions, scales and their values as well as methods of implementation of scales need to be the same for all groups. This question should include consideration of the assessors: were they the same people or trained in the same way, or were there differences such as different type of health professionals involved in measurement of group outcomes?

9. Are outcomes measured in a reliable way?

Are the instruments used to measure outcomes adequately described, and have they been previously validated, or piloted within the trial? These types of questions inform reviewers of this risk to detection bias. Give consideration to the quality of reporting of findings. If an RCT reports percentage of change but gave no baseline data, it is not possible to determine the relevance of the reported value between groups (or within a single group). If a P value is reported but no confidence interval given, the significance has been established, but the degree of certainty in the finding has not.

10. Is appropriate statistical analysis used?

As with any consideration of statistical analysis, consideration should be given to whether there is a more appropriate alternate statistical method that could have been used. Advice from a statistician may be needed to establish if the methods of analysis were appropriate.

Cohort (with control)/case-controlled studies

Cohort studies compare outcomes in groups that did and did not receive an intervention or have an exposure. However, the method of group allocation in Cohort or Case-controlled studies is not random. Case-control or cohort studies can be used to identify if the benefits observed in randomized trials translate into effectiveness across broader populations in clinical settings and provide information on adverse events and risks.³⁹

1. Is the sample representative of patients in the population as a whole?

This question relies upon knowledge of the broader characteristics of the population of interest. If the study is of women undergoing chemotherapy for breast cancer, knowledge of at least the characteristics, demographics, medical history is needed. The term population as a whole should not be taken to infer every individual from everywhere subject to a similar intervention or with similar disease or exposure characteristics. Instead, give consideration to specific population characteristics in the study, including age range, gender, morbidities, medications, and other potentially influential factors.

2. Are the patients at a similar point in the course of their condition/illness?

Check the paper carefully for descriptions of diagnosis and prognosis to determine if patients within and across groups have similar characteristics in relation to disease or exposure, for example tobacco use.

3. Has bias been minimized in relation to selection 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.

4. Are confounding factors identified and strategies to deal with them stated?

Confounding has occurred where the estimated intervention effect is biased by the presence of some difference between the comparison groups (apart from the intended intervention/s). Typical confounders include baseline characteristics, prognostic factors or concomitant interventions. 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 or 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.

5. Are outcomes assessed using objective criteria?

Refer back to item three of this appraisal scale and read the methods section of the paper again. If the outcomes are assessed based on existing definitions or diagnostic criteria, then the answer to this question is likely to be yes. If the outcomes are 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 are validated instruments as this has a significant impact on outcome assessment validity.

6. Is follow-up carried out over a sufficient time period?

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.

7. Are the outcomes of people who withdrew described and included in the analysis?

Any losses to follow-up, particularly from prospective studies, can introduce bias to observational research and over- or underestimation of treatment effects, as it does with trials. This bias may result if subjects lost from a study group have a different health response from those who remain in the study. Here the reviewer should look for accurate reporting of loss to follow-up and reasons for attrition. If loss to follow-up is similar across comparison groups, despite losses, estimated effects may be unbiased.

8. Are outcomes measured in a reliable way?

Having established the objectivity of the outcome measurement instrument (see item 5 of this scale), it is important to establish how the measurement is conducted. Are those involved in collecting data trained or educated in the use of the instrument/s? If there is more than one data collector, are they similar in terms of level of education, clinical or research experience, or level of responsibility in the piece of research being appraised?

9. Is appropriate statistical analysis used?

As with any consideration of statistical analysis, consideration should be given to whether there is a more appropriate alternate statistical method that could have been used. The methods section of cohort or case-control studies should be detailed enough for reviewers to identify the analytical technique 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 are included and how they relate to the outcome. If stratification is the analytical approach used, is 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.

Descriptive/case-series

1. Is the study based on a random or pseudo-random sample?

Recruitment is the calling or advertising strategy for gaining interest in the study, and is not the same as allocation, therefore; seemingly random methods of recruitment such as open advertising should not be considered a method of sampling. Moreover, a descriptive study commonly has a single arm; therefore allocation is not randomized between groups. Studies may report random allocation from a population, and the methods section should report how allocation was performed.

2. Are the criteria for inclusion in the sample clearly defined?

How is the sample recruited? Give consideration to whether responders have potential to differ in some significant way to non-responders. Is inclusion based on clearly defined characteristics or subjective values and opinions such as personal interest of the participants in the topic.

3. Are confounding factors identified and strategies to deal with them stated?

Any confounding factors should be identified, and the study report methods for measuring their potential impact on the study results. Confounding factors do not need to be 'controlled' or eliminated from a descriptive study, the results of these studies are useful regardless, but more so if an attempt is made to measure the scope of impact.

4. Are outcomes assessed using objective criteria?

If the outcomes are assessed based on existing definitions or diagnostic criteria, then the answer to this question is likely to be yes. If the outcomes are 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 are validated instruments as this has a significant impact on outcome assessment validity.

5. If comparisons are being made, is there sufficient description of groups?

This item should focus on any reported characteristics, note that the comparator group in a descriptive study may not be in the primary study, but may be extrapolated from other sources. Regardless of the source, some attempt should have been made to identify and measure the similarities between included groups.

6. Is follow-up carried out over a sufficient time period?

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.

7. Are the outcomes of people who withdraw described and included in the analysis?

Any losses to follow-up, particularly from prospective studies, can introduce bias to observational research and over- or underestimation of treatment effects, as it does with trials. This bias may result if subjects lost from a study group have a different health response from those who remain in the study. Here the reviewer should look for accurate reporting of loss to follow up and reasons for attrition. If loss to follow-up is similar across comparison groups, despite losses, estimated effects may be unbiased.

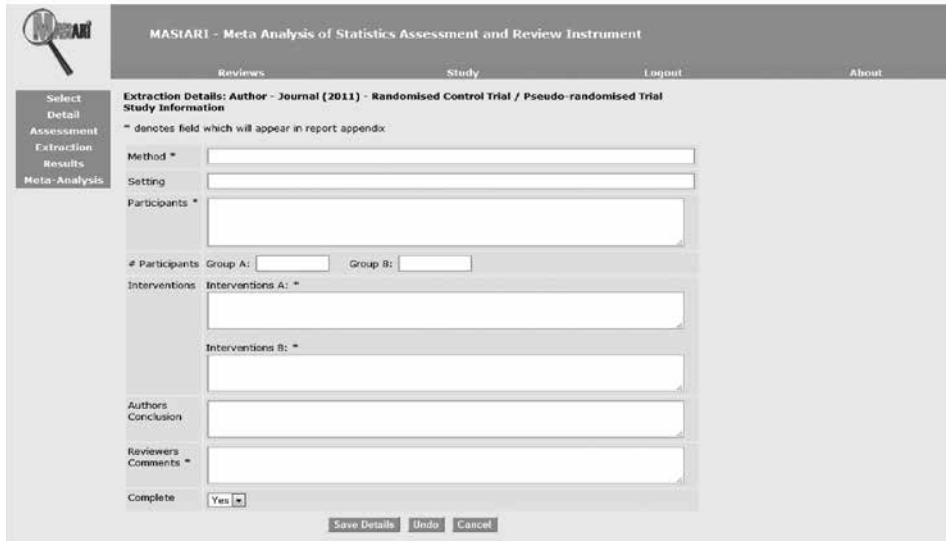
8. Are outcomes measured in a reliable way?

It is important to establish how the measurement is conducted. Are those involved in collecting data trained or educated in the use of the instrument/s? If there is more than one data collector, are they similar in terms of level of education, clinical or research experience, or level of responsibility in the piece of research being appraised? With descriptive studies, caution should be exercised where statistical significance is linked by authors with a causal effect, as this study design does not enable such statements to be validated.

9. Is appropriate statistical analysis used?

Broadly, two principles apply to determining if the statistical analysis was appropriate. Firstly, 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 for the study design and type of data collected. Secondly, did the authors report baseline data, or change values in addition to endpoint data? For example, reporting an endpoint as a percentage value, but no baseline values means reviewers are unable to determine the magnitude of change.

Appendix VII - MASTARI data extraction tools extraction details



MAStARI - Meta Analysis of Statistics Assessment and Review Instrument

Reviews Study Logout About

Extraction Details: Author - Journal (2011) - Randomised Control Trial / Pseudo-randomised Trial

Study Information

* denotes field which will appear in report appendix

Method *

Setting

Participants *

Participants Group A: Group B:

Interventions Interventions A: *

Interventions B: *

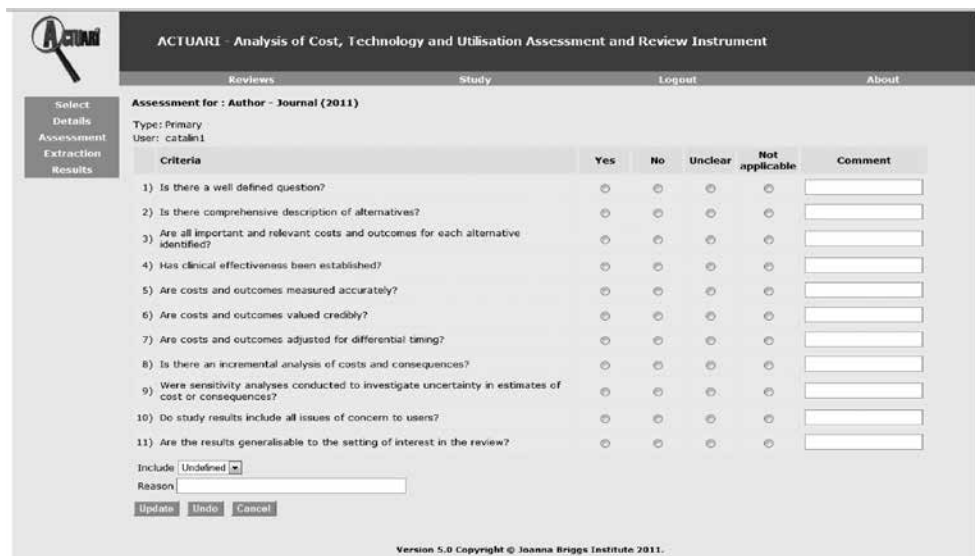
Authors Conclusion

Reviewers Comments *

Complete ☐ Yes ☐ No

Save Details Undo Cancel

Appendix VIII - ACTUARI critical appraisal tools



ACTUARI - Analysis of Cost, Technology and Utilisation Assessment and Review Instrument

Reviews Study Logout About

Assessment for: Author - Journal (2011)

Type: Primary
User: catalin1

| Criteria | Yes | No | Unclear | Not applicable | Comment |
|---|-----------------------|-----------------------|-----------------------|-----------------------|---------|
| 1) Is there a well defined question? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| 2) Is there comprehensive description of alternatives? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| 3) Are all important and relevant costs and outcomes for each alternative identified? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| 4) Has clinical effectiveness been established? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| 5) Are costs and outcomes measured accurately? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| 6) Are costs and outcomes valued credibly? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| 7) Are costs and outcomes adjusted for differential timing? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| 8) Is there an incremental analysis of costs and consequences? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| 9) Were sensitivity analyses conducted to investigate uncertainty in estimates of cost or consequences? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| 10) Do study results include all issues of concern to users? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |
| 11) Are the results generalisable to the setting of interest in the review? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |

Include

Reason

Update Undo Cancel

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Appendix IX - Discussion of ACTUARI critical appraisal checklist items

JBI critical appraisal checklist for economic evaluation studies

There are 11 questions in the JBI approach for critical appraisal of economic evaluation studies. JBI critical appraisal checklist for critical appraisal of economic studies is a general critical appraisal tool.

1. Is there a well-defined question?

Questions that will assist you in addressing this criterion:⁵²

- Did the study examine both costs and effects of the services or programs?
- Did the study involve a comparison of alternatives?
- Was a viewpoint for the analysis stated or was the study placed in a particular decision-making context?

2. Is there a comprehensive description of alternatives?

Questions that will assist you in addressing this criterion:⁵²

- Were any important alternatives omitted?
- Was (should) a do-nothing alternative (have been) considered?

3. Are all important and relevant costs and outcomes for each alternative identified?

Questions that will assist you in addressing this criterion:⁵²

- Was the range wide enough for the research question at hand?
- Did it cover all relevant viewpoints (e.g. those of the community or society, patients and third-party payers)?
- Were capital costs as well as operating costs included?

4. Has clinical effectiveness been established?

Questions that will assist you in addressing this criterion:⁵²

- Was there evidence that the program's effectiveness has been established? Was this done through a randomized, controlled clinical trial? If not, how strong was the evidence of effectiveness?

5. Are costs and outcomes measured accurately?

Questions that will assist you in addressing this criterion:⁵²

- Were costs and consequences measured accurately in appropriate physical units (e.g. hours of nursing time, number of physician visits, days lost from work, years of life gained) prior to valuation?
- Were any identified items omitted from measurement? If so, does this mean that they carried no weight in the subsequent analysis?
- Were there any special circumstances (e.g. joint use of resources) that made measurement difficult? Were these circumstances handled appropriately?

6. Are costs and outcomes valued credibly?

Questions that will assist you in addressing this criterion:⁵²

- Were the sources of all values (e.g. market values, patient or client preferences and views, policy makers' views and health care professionals' judgments) clearly identified?
- Were market values used for changes involving resources gained or used?
- When market values were absent (e.g. when volunteers were used) or did not reflect actual values (e.g. clinic space was donated at a reduced rate) were adjustments made to approximate market values?

7. Are costs and outcomes adjusted for differential timing?

Questions that will assist you in addressing this criterion:⁵²

- Were costs and consequences that occurred in the future discounted to their present values?
- Was any justification given for the discount rate used?

8. Is there an incremental analysis of costs and consequences?

Questions that will assist you in addressing this criterion:⁵²

- Were the additional (incremental) costs generated by the use of one alternative over another compared with the additional effects, benefits or utilities generated?

9. Are sensitivity analyses conducted to investigate uncertainty in estimates of cost or consequences?

Questions that will assist you in addressing this criterion:⁵²

- Was justification provided for the ranges of values (for key parameters) used in the sensitivity analysis?
- Were the study results sensitive to changes in the values (within the assumed range)?

10. Do study results include all issues of concern to users?

Questions that will assist you in addressing this criterion:⁵²

- Were the conclusions of the analysis based on some overall index or ratio of costs to consequences (e.g. cost-effectiveness ratio)? If so, was the index interpreted intelligently or in a mechanistic fashion?
- Were the results compared with those of other studies that had investigated the same questions?
- Did the study discuss the generalizability of the results to other settings and patient/client groups?
- Did the study allude to, or take account of, other important factors in the choice or decision under consideration (e.g. distribution of costs and consequences or relevant ethical issues)?
- Did the study discuss issues of implementation, such as the feasibility of adopting the preferred program, given existing financial or other constraints, and whether any freed resources could be used for other worthwhile programs?

11. Are the results generalizable to the setting of interest in the review?

Factors limiting the transferability of economic data are: demographic factors; epidemiology of the disease; availability of health care resources; variations in clinical practice; incentives to health care professionals; incentives to institutions; relative prices; relative costs; population values.

Appendix X - ACTUARI data extraction tools

ACTUARI - Analysis of Cost, Technology and Utilisation Assessment and Review Instrument

Reviews Study Logout About

Select
Details
Assessment
Extraction
Results

Extraction Details: Author - Journal (2011)

* denotes field which will appear in report appendix

Economic Evaluation Method: *

Interventions: *

Comparator:

Setting:

Geographical:

Participants: *

Source of effectiveness data:

Authors Conclusion: *

Reviewers Comments: *

Complete

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Appendix XI - NOTARI critical appraisal tools

NOTARI - Narrative, Opinion and Text Assessment and Review Instrument

Reviews Publication Categories Synthesis Logout About

Select
Detail
Assessment
Extraction
Conclusions

Assessment for : Author - Journal (2011)

Type: Primary
User: catalin1

| Criteria | Yes | No | Unclear | Not applicable | Comment |
|--|-----------------------|-----------------------|-----------------------|-----------------------|----------------------|
| 1) Is the source of the opinion clearly identified? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 2) Does the source of the opinion have standing in the field of expertise? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 3) Are the interests of patients/clients the central focus of the opinion? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 4) Is the opinion's basis in logic/experience clearly argued? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 5) Is the argument developed analytical? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 6) Is there reference to the extant literature/evidence and any incongruency with it logically defended? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |
| 7) Is the opinion supported by peers? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> |

Include

Reason

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Appendix XII - NOTARI critical appraisal discussion

The following text works through the critical appraisal checklist items.

1. Is the source of opinion clearly identified?

Is there a named author? Unnamed editorial pieces in journals or newspapers, or magazines give broader licence for comment, authorship should be identifiable.

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

The qualifications, current appointment and current affiliations with specific groups need to be stated in the publication and the reviewer needs to be satisfied that the author(s) has some standing within the field.

3. Are the interests of patients/clients the central focus of the opinion?

This question seeks to establish if the paper's focus is on achieving the best health outcomes or on advantaging a particular professional or other group? If the review topic is related to a clinical intervention, or aspect of health care delivery, a focus on health outcomes will be pertinent to the review. However, if for example the review is focused on addressing an issue of inter-professional behavior or power relations, a focus on the relevant groups is desired and applicable. Therefore this question should be answered in context with the purpose of the review. The aim of this question is to establish the author's purpose in writing the paper by considering the intended audience.

4. Is the opinion's basis in logic/experience clearly argued?

In order to establish the clarity or otherwise of the rationale or basis for the opinion, give consideration to the direction of the main lines of argument. Questions to pose of each textual paper include: What are the main points in the conclusions or recommendations? What arguments does the author use to support the main points? Is the argument logical? Have important terms been clearly defined? Do the arguments support the main points?

5. Is the argument that has been developed analytical? Is the opinion the result of an analytical process drawing on experience or the literature?

Does the argument present as an analytical construct of a line of debate or does it appear that ad hoc reasoning was employed?


6. Is there reference to the extant literature/evidence and any incongruence with it logically defended?

If there is reference to the extant literature, is it a non-biased, inclusive representation, or is it a non-critical description of content specifically supportive of the line of argument being put forward? These considerations will highlight the robustness of how cited literature was managed.

7. Is the opinion supported by peers?

This relates to peer opinion that has been published rather than peers in the sense of a colleague. To ascertain if the opinion expressed has wider support, consider also if the author demonstrated awareness of alternate or dominant opinions in the literature and provided an informed defence of their position as it relates to other or similar discourses.

Appendix XIII - NOTARI data extraction tools (Conclusions)



NOTARI - Narrative, Opinion and Text Assessment and Review Instrument

Reviews Publication Categories Synthesis Logout About

Select
Detail
Assessment
Extraction
Conclusions

Extraction Details: Author - Journal (2011)
* denotes field which will appear in report appendix

Type of Text:

Those Represented: *

Stated Allegiance/Position:

Setting:

Geographical:

Cultural:

Logic of Argument: *


Data Analysis:

Authors Conclusion: *

Reviewers Comments: *

Complete

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NOTARI - Narrative, Opinion and Text Assessment and Review Instrument

Reviews Publication Categories Synthesis Logout About

Select
Detail
Assessment
Extraction
Conclusions

Conclusions for: Author - Journal (2011)

Conclusion

Illustration from Publication
(Include Page Reference)

Evidence

Category

Include

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