

EDITION

2011

Reviewers' Manual

JBIR Library of Systematic Reviews

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THE JOANNA BRIGGS
INSTITUTE



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of ADELAIDE

Joanna Briggs Institute
Reviewers' Manual
2011 Edition

Joanna Briggs Institute Reviewers' Manual: 2011 edition

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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 fifteenth year of operation and has grown into an international not-for-profit research and development organisation within the Faculty of Health Sciences at the University of Adelaide.

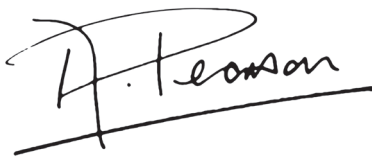
We collaborate internationally with over 70 entities across the world who subscribe to our definition of what constitutes evidence and our methodologies and methods in relation to evidence synthesis. The Institute and its collaborating entities promote and support the synthesis, transfer and utilisation 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 randomised 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 end of the signature.

Professor Alan Pearson AM

Executive Director

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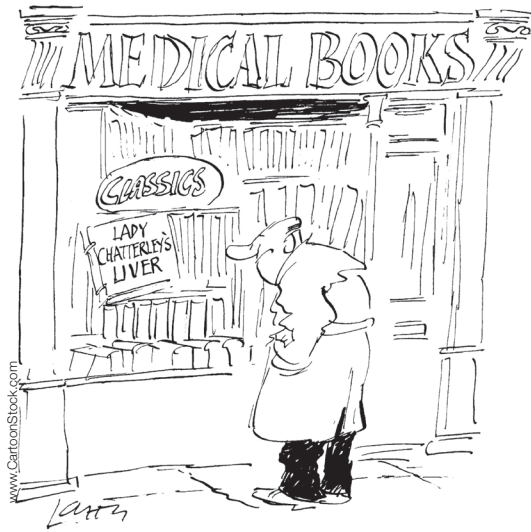
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Introduction:

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 SUMARI User Guide.

Planning a JBI systematic review

The JBI Synthesis Science Unit (SSU) 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 2 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.

JBI also accepts for co-publication:

- Cochrane Collaboration reviews; and
- Campbell Collaboration 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 two reviewers who have been trained in the JBI approach to systematic reviews; a primary and secondary reviewer. Consideration of expertise in the topic and the systematic review process should be considered 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 to identify topics that are currently in development and avoids accidental duplication of topics. Once registered, a title is valid for 6 months from the date of entry in the database. Should a protocol not be completed within that timeframe 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://www.joannabriggs.edu.au/Access%20Evidence/Systematic%20Review%20Registered%20Titles>

These and other points of consideration are detailed in the subsequent sections of this handbook.

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
- through SSU directly as a Remote reviewer.

All Reviewers should have completed the JBI CSR training program or equivalent systematic review training programs (Cochrane or Campbell) within the last 3 years, and been an active contributor to the development of systematic reviews for JBI including reviews co-registered with the Cochrane Collaboration. 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 members of that entity on the JBI website. Students undertaking systematic reviews through a collaborating entity should also be listed as core staff in the same way. There is no similar requirement for remote reviewers, who should submit protocols directly to SSU.

For reviews that are co-registered with either the Cochrane Collaboration or the Campbell Collaboration, review authors must register their title with respective review groups, prior to submission with JBI. The submission to either Cochrane or Campbell must include the JBI centre name and affiliation with JBI to be valid.

Currently, review authors are required to notify JBI of their intent to co-register a systematic review, however all the peer reviewing is undertaken through either Cochrane Review Groups (CRGs) or the Campbell Collaboration, as appropriate. Once the protocol has been approved, reviewers are required to send a copy of their protocol to their nominated SSU contact. This also applies to the subsequent systematic review report.

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

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 System for the Unified Management, Assessment and Review of Information (SUMARI) is the Joanna Briggs Institutes 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; and
- Effectiveness.

and to conduct economic evaluations of activities and interventions.

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); and
- JBI Analysis of Cost, Technology and Utilisation Assessment and Review Instrument (ACTUARI).

Before reviewers are able to use any of the SUMARI modules or CReMS, they need to register through the JBI website and obtain a username and password. This process is free of charge. 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 a .pdf document which should be submitted via email to the SSU.

Comprehensive systematic reviews

A systematic review is considered to be a comprehensive systematic review when it includes 2 or more types of evidence, such as both qualitative and quantitative, in order to address a particular review objective. Reviewers do this by utilising multiple modules of the SUMARI software.

Umbrella Reviews

In areas where several systematic reviews have been published, it may be appropriate to conduct an umbrella review. An umbrella review summarises the findings from several reviews and can provide a useful summary of a large body of research in a single document. ¹

Umbrella reviews have several alternate names in the literature:

- Overview of Reviews;
- Review of Reviews;
- Summary of Systematic Reviews; and
- Synthesis of Reviews.

Summarising systematic reviews is one method of producing a high-quality synthesised overview of a specific area and provides evidence to address such broad questions such as:

- What is known on the topic?
- What are the current recommendations for practice?
- What remains unknown on the topic?
- What are the recommendations for future research?

Also, with regard to a particular intervention, ²

- What interventions work on average?
- Who does it work/not work for?
- Do certain versions of the intervention or treatment work better or best?
- Are certain versions of the intervention ineffective?

There may however be technical difficulties associated with conducting an umbrella review, such as:

- Lack of high quality systematic reviews to include; and
- Interpretation may be difficult as the review is far removed from original primary studies and original data may be misinterpreted
- Lack of appropriate critical appraisal instruments

The JBI approach

JBI will consider umbrella reviews for publication and critical appraisal and data extraction instruments for use with systematic reviews can be located on the Joanna Briggs Collaboration (JBC) Intranet webpage (formerly the Directors Page) and are shown in **Appendices II** and **III**. Currently, however, SUMARI software does not support the conduct of umbrella reviews and reviewers interested in conducting an umbrella review should contact the SSU for guidance.

Scoping Reviews

Scoping reviews can be useful as a preliminary assessment in determining 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.¹

The JBI approach

JBI will consider scoping reviews for publication, however currently SUMARI software does not support the conduct of scoping reviews and reviewers interested in conducting this type of review should contact the SSU for guidance.

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. The primary reviewer then leads the review and is the key contact between the JBI SSU and others involved in the review. 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 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 recognised 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 SSU;
- 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 and DARE databases will assist to establish whether or not a recent review report exists on the 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 3 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?

The JBI SSU assists and guides authors in the development and completion of their systematic reviews.

All Centres and ESG's 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 **P**opulation, the **I**ntervention being investigated and its **C**omparator and ends with a specific **O**utcome(s) of interest to the review. A specific mnemonic (**PICO**) for qualitative reviews has also been developed which identifies the key aspects **P**opulation, the phenomena of **I**nterest, and the **C**ontext. A more generic mnemonic that can be used across quantitative and qualitative reviews is the **SPICE** mnemonic, where the **S**etting, **P**erspective, **I**ntervention, **C**omparison and (method of) **E**valuation are described.

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 generalisability 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 synthesised. 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.

As with other international organisations, JBI advocates for, and expects standardisation 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 SUMARI computer software.

As mentioned previously, SUMARI includes the CReMS software, designed to assist reviewers 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 with the SSU

Once a topic has been identified and the title registered, the protocol should be submitted for peer review to the SSU. 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 by e-mail to the nominated SSU contact person, as determined by geographical region. Please contact JBI for further details.

JBI computer software will guide the reviewer through each stage of the systematic review protocol (and subsequent report). To be accepted, all fields within the protocol must be complete, with the relevant appraisal and data extraction instruments appended. Protocols meeting these criteria are then uploaded to the JBI database of protocols by the SSU:

<http://www.joannabriggs.edu.au/Access%20Evidence/Systematic%20Review%20Protocols>

Co-registration of protocols and systematic reviews with the Cochrane Collaboration

JBI quantitative reviews consider many types of evidence and are not confined to the inclusion of randomised controlled trial (RCT) data. It may be appropriate for an author to limit the scope of their review to RCT data, in which case they are encouraged to co-register their review with The Cochrane Collaboration.

Review authors should notify the SSU of their intent to co-register a systematic review and the review will be allocated a SSU project number (code) as usual, however all peer review is undertaken through the Cochrane Collaboration by the relevant Cochrane Review Group.

Firstly, review authors must register their title with an appropriate Cochrane Review Group prior to submission to JBI. Secondly, once the protocol has been approved by the Cochrane Collaboration, a copy of the approved protocol together with evidence of its approval (such as email or letter of confirmation) must be sent to the SSU.

Finally, once the systematic review has been completed and published by the Cochrane Collaboration, a copy together with evidence of its approval (such as email or letter of confirmation) must be sent to the SSU.

At each stage of the review authors must clearly identify the name of the JBI Centre/Group including the words: “a Collaborating/Affiliate Centre/Group of the Joanna Briggs Institute”

Reviews conducted through Cochrane entities must follow Cochrane processes and procedures. These are documented in the Cochrane Handbook for Systematic Reviews of Interventions, which can be accessed from the following web link:

<http://www.cochrane.org/training/cochrane-handbook>

Once the review is completed, it is published in the online Cochrane Library. The review authors are encouraged to submit a shortened article derived from the original review in the International Journal of Evidence-Based Health Care or another journal identified by the reviewers, citing the source review for the full report.

Hierarchy of Study Designs

For each type of evidence on the JBI FAME scale, (Feasibility, Appropriateness, Meaningfulness and Effectiveness), there are assigned JBI levels of evidence. The web link for the JBI levels of evidence can be found at:

<http://www.joannabriggs.edu.au/About%20Us/About%20Us/JBI%20Approach/Levels%20of%20Evidence%20%20FAME>

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.³ Several international organisations 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

In quantitative research, study designs that include fewer controls (and therefore impose less control over unknown factors or potential sources of bias) are considered to be lower quality of evidence – hence a hierarchy of evidence is created on the basis of the amount of associated bias and, therefore, certainty of an effect. Many JBI reviews will consider a range of designs for inclusion and a protocol should be a statement about the primary study designs of interest and the range of studies that will be considered appropriate to the review objective and questions. For quantitative research, study designs include:

- Experimental e.g. randomised controlled trials (RCTs);
- Quasi experimental e.g. non-randomised controlled trials;
- Observational (Correlational) – e.g. cohort, case control studies;
- Observational (Descriptive) – e.g. case series and case study; and
- Expert opinion.

Hierarchy of Quantitative Evidence – JBI Levels of Evidence

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.

The JBI levels of evidence are discussed in a later section in more detail and can be found in *Appendix VI* and at the web address:

<http://www.joannabriggs.edu.au/About%20Us/About%20Us/JBI%20Approach/Levels%20of%20Evidence%20%20FAME> briefly they are as follows:

- Level 1** (strongest evidence) Meta-analysis (with homogeneity) of experimental studies (e.g. RCT with concealed randomisation) OR One or more large experimental studies with narrow confidence intervals;
- Level 2** One or more smaller RCTs with wider confidence intervals OR Quasi-experimental studies (without randomisation);
- Level 3** a. Cohort studies (with control group);
 b. Case-controlled;
 c. Observational studies (without control group);
- Level 4** Expert opinion, or physiology bench research, or consensus.

In this case quantitative evidence is ranked in terms of research findings most likely to provide valid information on the effectiveness of a treatment/care option. Such hierarchies usually have the systematic review with meta-analysis at the top, followed closely by RCTs. There are several other hierarchies of evidence for assessing studies that provide evidence on diagnosis, prevention and economic evaluations; ⁴ their focus remains quantitative. The major disadvantage in this is that while some health topics may concentrate on treatment/management effectiveness, their themes may possibly not be addressed by RCTs. For example, Kotaska suggests that vaginal breech birth is too complex and multifaceted to be appropriately considered within trials alone.⁵ It has been reported how one RCT on breech birth has changed practice.⁵ The reasons for this are likely to be complicated and involve underlying professional beliefs as well as the evidence. The emphasis, however, on trials as the apogee of the hierarchy of evidence may be viewed as only encouraging an acceptance of this as the 'gold standard' in all circumstances, rather than reflecting on whether a specific subject or topic is best considered from a different perspective, using different research approaches. It must be acknowledged that quantitative studies alone cannot explore or address all the complexities of the more social aspects of human life.⁶ For example, in midwifery this would include qualitative themes such as experience of birth, parenthood, or topics regarding social support, transition to parenthood, uptake of antenatal screening, education, or views on lifestyle such as smoking, etc.⁷ These are more appropriately explored through qualitative research approaches that seek to explore and understand the dynamics of human nature, what makes them believe, think and act as they do.⁸⁻¹⁰

Note: There is no widely accepted hierarchy of evidence for qualitative studies. Current methodological opinion related to qualitative review does not require any distinction between critical or interpretive studies, therefore choices 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 of a phenomenon of interest.

Chapter One:

Qualitative Evidence and Evidence-Based Practice

Qualitative evidence or qualitative data allows researchers to analyse human experience and cultural and social phenomena. ¹¹ Qualitative evidence has its origins in research methods from the humanities and social sciences and seeks to analyse the complexity of human phenomena in naturalistic settings and from a holistic perspective. ¹² The term 'qualitative' refers to various research methodologies including ethnography, phenomenology, action research, discourse analysis and grounded theory. Research methods include interview, observation and interpretation of written material. Researchers who use qualitative methodologies seek a deeper truth, 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". ¹³

In the healthcare or medical context, qualitative research:

"...seeks to understand and interpret personal experiences, behaviours, 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". ¹⁴

Qualitative evidence is especially useful and applicable in areas where there is little pre-existing knowledge, where it is difficult or inappropriate to generate a hypothesis and where issues are complex and require more detailed exploration. ¹⁵ 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". ¹⁶

Qualitative Evidence and Healthcare

Qualitative methods and data are increasing in usage in evidence-based healthcare research. Instead of quantifying or statistically portraying the data or findings, qualitative research focuses on individuals and gives voice to the patient/client or provider in the healthcare decision-making process. As an example, the question: 'What proportion of smokers have tried to give up?' leads to statistical answers while the question 'Why do people continue to smoke?', leads the researcher into exploring the ideas and concerns people who smoke tobacco may have about their smoking habits. ¹⁶

Qualitative research is undertaken because it:

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

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

Acknowledgement of the contribution that qualitative research findings make in improving the quality and relevance of healthcare conditions is increasing. As an example, the Guidance for Undertaking Reviews in Health Care published by the Centre for Reviews and Dissemination at the University of York in 2009 ¹⁷ 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.

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. ¹⁸⁻²⁰ 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. ¹⁹

Philosophical perspectives, research methodologies and methods

A philosophical perspective encompasses our assumptions of the theory, the practice and the research methodologies which 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 aims at understanding. 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 and it is important when undertaking a JBI qualitative systematic review to ensure that there is congruity between the philosophical position adopted in a research study, the study methodology and the study methods. 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. 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.
Critical enquiry <i>Seeks to change.</i>	Action research Involves researchers participating with the researched to effect change. Feminist research Seeks to create social change to benefit women. Discourse Analysis assumes that language socially and historically constructs how we think about and experience ourselves, and our relationships with others.	Participative group work Reflective Journals. (Quantitative methods can be used in addition to qualitative methods). Qualitative in-depth interviews. Focus Groups. (Quantitative methods can be used in addition to qualitative methods). Study of communications, written text and policies.

Qualitative textual analysis

There is no hierarchy of evidence among methodologies for qualitative studies. A JBI aggregative systematic review does not require any distinction between critical or interpretive studies; therefore the choice regarding types of qualitative studies is the decision of the reviewers. The units of analysis in qualitative papers are the findings, presented as themes, metaphors or concepts as identified by the researchers (not the reviewer). The traditions of the methodology associated with a particular paper are considered to be embedded within the findings, rather than distinct to the findings. Accordingly, JBI reviews include a range of methodological studies in order to capture the whole of a phenomenon of interest rather than merely a one dimensional aspect.

The synthesis of qualitative data

The synthesis or “pooling” of the findings of qualitative research remains a contested field. It is contested by some quantitative researchers who suggest that, because of the “subjective” and individual nature of human experience, the findings of qualitative research are unlikely to be generalisable.

The synthesis of qualitative data is also contested amongst qualitative researchers themselves, based on ideological, philosophical and methodological differences between the different qualitative research approaches.^{21, 22}

While some qualitative researchers argue that the synthesis of qualitative studies is impossible and meaningless, it is acknowledged by others as crucial if the findings are to have impact in the real world of policy and practice in health care.²² Despite the support for the notion of qualitative synthesis, there is no emerging consensus on appropriate guidance for the systematic review of qualitative evidence for health and social care.²³ The two dominant, opposing views that characterise the ongoing debate surrounding the meta-synthesis of qualitative evidence focus on integration or aggregation versus interpretation

The JBI Approach to Meta-Synthesis

The JBI model of meta-synthesis uses an integrative or meta-aggregative approach to the synthesis of qualitative evidence (regardless of study design) which is designed to model the Cochrane Collaboration process to review and analyse randomised clinical trials and yet remain sensitive to the nature of qualitative approaches to research.²⁴ The JBI Qualitative Assessment and Review Instrument (QARI) computer software was developed specifically for the meta-aggregation of qualitative research studies.

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 move beyond an outcome of implicit suggestions in order to produce declaratory or directive statements to guide practitioners and policy makers.²³

As such, the JBI approach contrasts with the meta-ethnography approach to qualitative evidence synthesis which has a focus on interpretation rather than aggregation. Meta-ethnography was conceived by Noblit and Hare ²⁵ as a method of synthesis whereby interpretations could be constructed from two or more qualitative studies. It draws on the findings and interpretations of qualitative research using a purposive sampling method and the analysis is a process of interactive construction of emic interpretations with the goal of producing new theoretical understandings. ²⁶

JBI recognises the usefulness of alternate interpretive approaches such as meta-ethnography, as well as narrative synthesis and thematic synthesis. As an example, 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 non-research evidence (e.g. qualitative, quantitative, economic), and Thematic Synthesis is of use in drawing conclusions based on common elements across otherwise heterogeneous studies. JBI considers, however, that these approaches do not seek to provide guidance for action and aim only to 'anticipate' what might be involved in analogous situations and to understand how things connect and interact.

Meta-aggregation is the preferred JBI approach for developing recommendations for action. The JBI-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.



"YOU'LL BE PLEASED TO KNOW YOU'RE MAKING GOOD PROGRESS- YOU'VE JUST BECOME A STATISTIC."

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 incorporates the Population, the Phenomena of Interest and the Context. There is no specific requirement for an outcome to be included in qualitative results so the Outcome Section may be left out of the protocol.

The title of the protocol should be as descriptive as is reasonable and reflect core elements of the review. 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 as the following example illustrates:

The meaning of smoking to young women in the community, and their experiences of smoking cessation as a primary health care intervention: a systematic review of the qualitative evidence.

This example provides readers with a clear indication of the population (young women), the phenomena of interest (the meaning of smoking and experience of smoking cessation), and the context (communities and primary care) as well as the fact that it is a systematic review of qualitative evidence.

Background

The Joanna Briggs Institute places significant emphasis on a comprehensive, clear and meaningful background section to 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. Definitions can assist to provide clarity. Where complex or multifaceted phenomena are being described, it may be important to detail the whole of the phenomenon for an international readership.

The background should avoid making value-laden statements unless they are specific to papers that illustrate the topic and/or need for a systematic review of the body of literature related to the topic. For example: "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. 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 "Smith indicates young women were found to take up cigarette smoking as an expression of independence or a sign of self confidence". Such statements in the background need to be balanced by other points of view, emphasising the need to synthesise potentially diverse bodies of literature.

The background should conclude with a statement indicating the reviewer has examined the Cochrane Library, JBI Library of Systematic Reviews, CINAHL and other relevant databases and not found any current or planned reviews on the same topic.

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?

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. For example:

The objective of this review is to establish the meaning of smoking and the experience of smoking cessation to young women in community settings.

The specific questions to be addressed are:

- What meaning do young women who smoke tobacco place upon smoking tobacco? and
- What are their experiences of programmed and/or self guided approaches to smoking cessation?

Inclusion criteria

Population/Types of participants

In the above example, the PICo mnemonic describes the population (young women). 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. The term population is used in the PICo but it is not intended to imply aspects of population pertinent to quantitative reviews such as sampling methods, sample sizes or homogeneity. Rather, population characteristics that may be based on exposure to a disease, or intervention, or interaction with health professionals as they relate to the qualitative experiences or meanings individuals associate with are examples of the types of population characteristics that may need to be considered by the review.

Phenomena of Interest

Also in the above example, the phenomenon of interest is young women's experiences in relation to uptake and/or cessation of tobacco smoking. The level of detail ascribed to the phenomena at this point in protocol development may vary with the nature or complexity of the topic. It may be clarified, expanded or revised as the protocol develops.

Context

In a qualitative review, context will vary depending on the objective of the review, and the specific questions constructed to meet the objective. Context may include but is not limited to consideration of cultural factors such as geographic location, specific racial or gender based interests, detail about the setting such as acute care, primary health care, or the community as they relate to the experiences or meanings individuals or groups reported in studies.

Outcomes

As there is no clear international consensus on the construct of qualitative questions for systematic review, no specific requirement for an outcome statement exists in qualitative reviews. An outcome of interest may be stated (this may relate to, or describe the phenomena of interest), or this section may reasonably be left out of the protocol.

Types of studies

This section should flow naturally from the criteria that have been established up to this point, and particularly from the objective and questions the review seeks to address. There should be a match between the review objectives and the study designs of the studies sought for the review, especially in terms of the methodology and the research methods used. There should be a statement about the primary study type and the range of studies that will be used if the primary study type is not found.

The CReMS software offers optional standardised text consisting of statements regarding the types of studies considered for inclusion in a JBI qualitative review. The choice of set text will depend on the methodological approach taken by the 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.

In the absence of research studies, other text such as opinion papers and reports will be considered. If you wish to include opinion papers and reports select Textual Evidence and the NOTARI analytical Module and then select to insert set text now.

Option 2: This review will consider interpretive studies that draw on the experiences of #?# with #?# including, but not limited to, designs such as phenomenology, grounded theory, ethnography, action research and feminist research.

In the absence of research studies, other text such as opinion papers and reports will be considered. If you wish to include opinion papers and reports select Textual Evidence and the NOTARI analytical Module and then select to insert set text now.

Option 3: This review will consider critical studies that explore #?# including, but not limited to, designs such as action research and feminist research.

In the absence of research studies, other text such as opinion papers and reports will be considered. If you wish to include opinion papers and reports select Textual Evidence and the NOTARI analytical Module and then select to insert set text now.

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 might be conducted to aggregate evidence related to social interactions that occur within health care, or seek to establish insights into social, emotional or experiential phenomena and generate new theories. Critical reviews might be conducted to explore and theorise about issues of power in relationships while a critical and interpretive review might be conducted to bring both elements together.

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 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 research methods/methodologies will be considered for inclusion in the review (e.g. phenomenology, ethnography). Quantitative systematic reviews will often include a hierarchy of studies that will be considered, however this is not the case for qualitative reviews. A qualitative review may consider text and opinion in the absence of qualitative research.

If a review is to consider text and opinion in the absence of qualitative research studies, this should be detailed in the protocol and the appropriate NOTARI¹ tools appended.

Within systematic reviews the search strategy is described as a three-phase process, beginning with the identification of initial key words followed by analysis of the text words contained in the title and abstract, and of the index terms used in a bibliographic database 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.

1 See Section 5 for more information on the JBI NOTARI software.

The process describing searching has been standardised in CReMS as follows:

The search strategy aims to find both published and unpublished studies. A three-step search strategy will be utilised 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 standardised text is optional and 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 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 centre. 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 excluded and should thus be used with caution, the decision preferably to 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 principal 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 commercially 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.

The Joanna Briggs Institute is an international collaboration with an extensive network of centres, ESGs and other entities worldwide. 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 the SSU regarding access to the University of Adelaide Barr Smith Library title through an ever-increasing range of electronic resources are available.

In addition to databases of published research, there are several online sources of grey 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.

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 cognisant 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.²⁷ 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 IV*. Most checklists use a series of criteria that can be scored as being met, not met or unclear or not applicable. The decision as to whether or not to include a study can be made based on meeting a pre-determined proportion of all criteria, or on certain criteria being met. It is also possible to weight the different criteria differently. In JBI reviews the assessment criteria are built in to the analytical module QARI. These decisions about the scoring system and any cut-off for inclusion should be made in advance, and be agreed upon by all participating reviewers before critical appraisal commences.

Reviewers need to discuss whether a cut-off point will be established for each review, and if so, whether it will be based on either key items in the appraisal scale or a tally of responses. Applying a cut-off point on the basis of weighting or overall scores is a decision that needs to be detailed in the protocol and should be based on sound reasoning. Applying a cut-off point based on a number of items in the appraisal checklist that were answered Yes compared with No does not guarantee that those papers with the maximum credibility will be included and review authors should consider carefully before taking this approach,

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 standardised 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 standardised 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 IV* 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.

There is an ongoing international debate around the role of critical appraisal of qualitative research for the purposes of systematically reviewing a body of literature.²⁸ The debate extends from whether appraisal has any role at all in qualitative reviews, through whether criteria should be explicit or implicit statements of guidance and how the ratings should be used. Given similar questions continue to arise with quantitative research, it is likely this will continue to be discussed and debated in the long-term for qualitative reviews. The JBI approach rests on both the need for standardisation of process to facilitate quality monitoring and the view that evidence to inform health care practice should be subject to critique of its quality. Furthermore this critique should inform decisions reviewers make regarding which studies to include or exclude and the criteria on which those decisions are made should be transparent.

Data extraction

Data extraction refers to the process of sourcing and recording relevant results from the original (or primary) research studies that will be included in the systematic review. It is important that both reviewers use a standard extraction tool that they have practised using and then consistently apply. Doing so will facilitate accurate and reliable data entry into the QARI software for analysis. The QARI data extraction tool is in *Appendix V*. 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 standardised 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 instrument should be read through by both reviewers and each criterion discussed in the context of each particular review. Without discussion, reviewers are likely to take a slightly different interpretation of the questions, creating more work later in the review. Unlike the JBI data extraction process for quantitative experimental and economic reviews (which is conducted independently by two reviewers) the data extraction process of qualitative reviews using QARI may involve both or either of the reviewers. The general consensus is that one reviewer may extract the data but that it is useful for the second reviewer to read and discuss the extraction. The aim is not to minimise risk of error (unlike the quantitative and economic reviews) but rather to gain a shared understanding to facilitate effective progression through synthesis and write-up of the review.

As a systematic review seeks to summarise a body of international research literature, the data extraction needs to include information to inform readers, not just of the key findings, but also of the methodological framework, research methods used and other important contextual factors. 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.

Strategies to minimise the risk of error when extracting data from studies include:

- utilising a standardised data extraction form;
- pilot test extraction prior to commencement of review;
- train and assess data extractors; and
- have two people extract data from each study.

Unlike experimental studies, where reviewers can, if necessary, contact authors of publications and seek assistance in providing raw data, in qualitative studies this is not generally required as the reviewer only works with the findings reported by the author in each study.

Once the detail about the nature of the publication, its setting, methodologies, methods and other relevant data have been extracted, the focus turns to identifying particular findings. Considered first order or level one analysis, specific findings (and illustrations from the text that demonstrate their origins) are identified and entered in the analytical module QARI.

The units of extraction in this process are specific findings and illustrations from the text that demonstrate the origins of those findings. Note that in QARI a finding is defined as:

A conclusion reached by the researcher(s) and often presented as themes or metaphors.

To identify findings, reviewers read the paper carefully and continue to re-read it closely at least a second time and identify the findings and enter them into QARI. Each finding is extracted and textual data that illustrates or supports the finding is also extracted. In this approach, the reviewer is searching the paper to locate data in the form of direct quotes or observations or statements that lead to the finding being reported in each primary study. This is a form of confirmation of authenticity that demonstrates the level of association between each identified finding in terms of how clearly and/or directly it can be attributed to participants or observations in the primary research.

The level of congruency between findings and supporting data from the primary studies is graded to communicate the degree to which the interpretation of the researcher is credible. There are three levels of credibility in the analytical module QARI as described below:

Unequivocal - relates to evidence beyond reasonable doubt which may include findings that are matter of fact, directly reported/observed and not open to challenge;

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

Unsupported - when neither 1 nor 2 apply and when most notably findings are not supported by the data.

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 grading of findings (unequivocal, credible or unsupported) is conducted concurrently with the identification and extraction of findings into the analytical module QARI.

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. Within the protocol, the methods by which studies will be combined should be described in as much detail as is reasonably possible.

The optional set text in CReMS provides a framework that reviewers can extend or edit, and clarifies the synthesis involved in meta-aggregation through the analytical module QARI:

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 (Level 1 findings) rated according to their quality, and categorising these findings on the basis of similarity in meaning (Level 2 findings). These categories are then subjected to a meta-synthesis in order to produce a single comprehensive set of synthesised findings (Level 3 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.

One of the challenges in synthesising textual data is agreeing on and communicating techniques to compare the findings of each study between reviewers. The QARI approach to the meta-aggregation of qualitative research findings involves categorising and re-categorising the findings of two or more studies to develop synthesised findings. Although not considered a formal requirement of the protocol, reviewers are encouraged to discuss and pilot 2 or more studies through the process if they have not previously conducted a qualitative synthesis. This will enable the primary and secondary reviewers (plus any associate reviewers) to be clear on how they will assign findings to categories, and how the categories will be aggregated in to synthesised findings.

Differing research methods such as phenomenology, ethnography or grounded theory, can be mixed in a single synthesis of qualitative studies because the synthesis is of findings and not data. This is a critical assumption of the QARI process. QARI meta-aggregation does not involve a reconsideration and synthesis of primary data - it is restricted to the combination of findings that is, processed data). Contrary to Noblit and Hare's original views regarding meta-ethnography, JBI consider it unnecessary to restrict meta-synthesis to studies undertaken using the same methodology.²⁵

The process of meta-aggregation is illustrated in Figure 1.

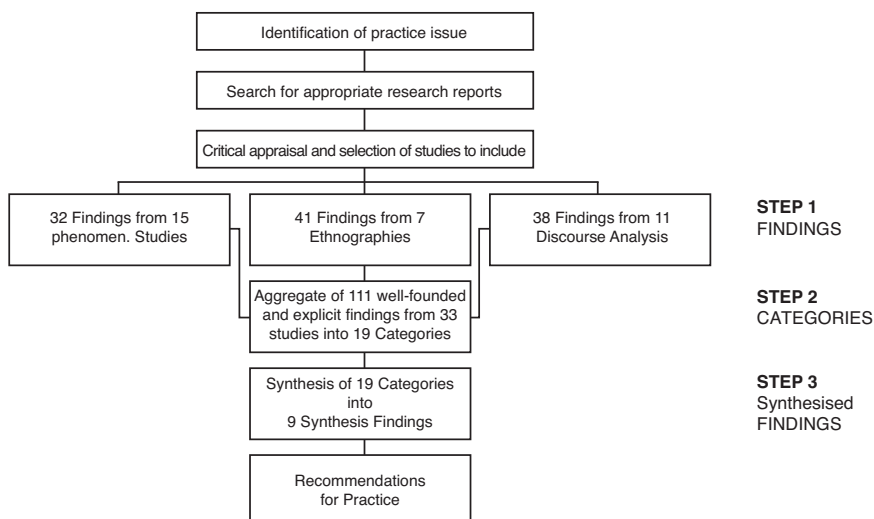


Figure 1. Illustration of the meta-aggregation process

Narrative Summary

Although the focus of this section has been on describing and explaining the approach to meta-aggregation, the protocol should also describe a process for developing a narrative summary to anticipate the possibility that aggregative synthesis is not possible. Narrative summary should draw upon the data extraction, with an emphasis on the textual summation of study characteristics as well as data relevant to the specified phenomena of interest.

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 the JBI's policy on commercial funding of review activity.

Acknowledgements

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

References

Protocols are required to use 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.)

More information about the Vancouver 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.)

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

Once a protocol has been approved, it is published on the JBI website. Protocols can be found at: <http://www.joannabriggs.edu.au/Access%20Evidence/Systematic%20Review%20Protocols>

Chapter Three:

The Systematic Review and Synthesis of Qualitative Data

Please refer to the JBI website for specific presentation requirements for systematic review reports <http://www.joannabriggs.edu.au>

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

JBI systematic reviews should use Australian spelling and authors should therefore follow the latest edition of the Macquarie Dictionary. 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 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:

This should be the same as detailed in the protocol.

Review authors:

The names, contact details and the JBI affiliation of each reviewer.

Executive Summary:

This section is 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 are included in the executive summary:

Background:

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

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.

Phenomena of interest

This section presents all of the phenomena examined, as detailed in the protocol.

Types of studies

As per the protocol section, the types of studies that were considered for the review are described. There should be a statement about the target study type and whether or not this type was 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 details search activity (e.g. databases searched, initial search terms and any restrictions) for the review, as predetermined in the protocol.

Data Collection

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

Data Synthesis

This section includes a brief description of how the data was synthesised, included whether there is a meta-synthesis and/or a narrative summary.

Conclusions

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

Implications for practice

This section should consist of 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 describes 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 includes the following sections:**Background**

As discussed in the protocol section, The Joanna Briggs Institute 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.

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 qualitative review aspects include: Population, phenomenon of Interest and Context as per the PICo mnemonic.

Types of studies

This section should flow from the background. There should be a statement about the target study type (e.g. interpretive or critical) and the range of studies that were used.

Types of participants

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

Types of Phenomena of Interest

There should be a statement or list of the phenomena of interest examined. This section should be concise as the Background section provides the opportunity to describe the main aspects of the interventions.

Search strategy

Documenting a search strategy

This section should include an overview of the search strategy used to identify articles considered by the review. The search strategy needs to be comprehensively reported. Commonly, electronic databases are used to search for papers, many such databases have indexing systems or thesauri, 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 to 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 the nuances of 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 SUMARI, the search strategies for each database for each approach are recorded and reported via CReMS. Commonly, these are added as appendices.

Using QARI, there is a series of standardised fields related to critical appraisal, which focus on the methods of the review and assessment of methodological quality.

Critical appraisal

This section of the review includes the results of critical appraisal with the QARI instrument. As discussed in the section on protocol development, it is JBI policy that qualitative studies should be critically appraised using the QARI critical appraisal instrument. 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 response of “unclear”. This discussion should take place before independently conducting the appraisal. The QARI critical appraisal tool should be attached to the review.

The methodological quality of included papers is discussed in the results section of the review.

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

This section of the review includes details of the types of data extracted for inclusion in the review. Data extraction begins with recording of the methodology (such as phenomenology, ethnography or action research), identifying the setting and describing the characteristics of the participants. When data extraction of the study background detail 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 qualitative reviews, synthesis is conducted in the QARI analytical module, and the final report is generated in CReMS.

Extracting data from Critical and Interpretive studies

Data extraction serves the same purpose across study designs – to summarise 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 standardised 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 standardised 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 was it; 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 analyse the data; a list, (though not exhaustive) of examples is provided below:

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

Authors Conclusions

This the conclusion reached by the study author.

Reviewers Conclusions

This is the conclusion reached by the Reviewer.

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?

Data extraction in the analytical module QARI is also step one in data synthesis. It may be useful to read this section on extraction, then the corresponding section on data synthesis to gain an overview of how the two processes are inter related.

Qualitative research findings cannot be synthesised using quantitative techniques and although it is possible to mirror the systematic process used in of quantitative reviews, reviewers need to exercise their judgement when extracting the findings of qualitative studies, particularly as the nature of a “finding” for practice is poorly understood.

Reports of qualitative studies frequently present study findings in the form of themes, metaphors or categories. In QARI the units of extraction are specific findings (reported by the author(s) of the paper, often presented as themes, categories or metaphors) and illustrations from the text that demonstrate the origins of the findings.

In QARI a finding is therefore defined as a conclusion reached by the researcher(s) that is often presented as a theme or metaphor.

Once a reviewer has collected all the individual Findings, with illustrations, the Findings can be collated to form user-defined categories. To do this, the reviewer needs to read all of the findings and identify similarities that can then be used to create categories of one or more findings.

As the process relates to textual findings rather than numeric data, the need for methodological homogeneity – so important in the meta-analysis of the results of quantitative studies – is not a consideration. The meta-aggregation of findings of qualitative studies can legitimately aggregate findings from studies that have used radically different, competing and antagonistic methodological claims and assumptions, within a qualitative paradigm. Meta-aggregation in QARI does not distinguish between methodologies or theoretical standpoints and adopts a pluralist position that values viewing phenomena from different perspectives. Qualitative meta-aggregation evaluates and aggregates qualitative research findings on the basis of them being the result of rigorous research processes.

Data synthesis

This section of the report should include how the findings were synthesised. Where meta-aggregation is possible, qualitative research findings should be pooled using QARI. This 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 categorising 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 synthesised 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 optional set text in CReMS describes the process by which these options are implemented in the protocol development section as follows:

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 (Level 1 findings) rated according to their quality, and categorising these findings on the basis of similarity in meaning (Level 2 findings). These categories are then subjected to a meta-synthesis in order to produce a single comprehensive set of synthesised findings (Level 3 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.

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

- their own rules for setting up categories;
- how to assign findings to categories; and
- how to aggregate categories into synthesised findings.

The JBI-QARI approach to synthesising the findings of qualitative studies requires reviewers to consider the validity of each study report as a source of guidance for practice; identify and extract the findings from papers included in the review; and to aggregate these findings as synthesised findings. To reiterate:

Findings are conclusions reached and reported by the author of the paper, often in the form of themes, categories or metaphors.

Findings as explicitly stated in the paper are extracted and textual data that illustrates or supports the findings are also extracted and inserted with a page reference. Many qualitative reports only develop themes and do not report findings explicitly. In such cases, the reviewer/s may need to develop a finding statement from the text.

Each finding should be assigned a level of credibility, based on the congruency of the finding with supporting data from the study from which the finding was taken. Qualitative evidence has three levels of credibility:

Unequivocal - relates to evidence beyond reasonable doubt which may include findings that are matter of fact, directly reported/observed and not open to challenge

Credible - relates to those findings that are, albeit interpretations, plausible in light of the data and theoretical framework. They can be logically inferred from the data. Because the findings are interpretive they can be challenged.

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

When all findings and illustrative data have been identified, the reviewer needs to read all of the findings and identify similarities that can then be used to create categories of more than one finding.

Categorisation is the first step in aggregating study findings and moves from a focus on individual studies to consideration of all findings for all studies 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 synthesised findings. QARI sorts the data into a meta-synthesis table or "QARI-View", when allocation of categories to synthesised 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 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?

Results

Description of studies

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. A flowchart should be used to illustrate this, such as that shown in Figure 2.²⁹

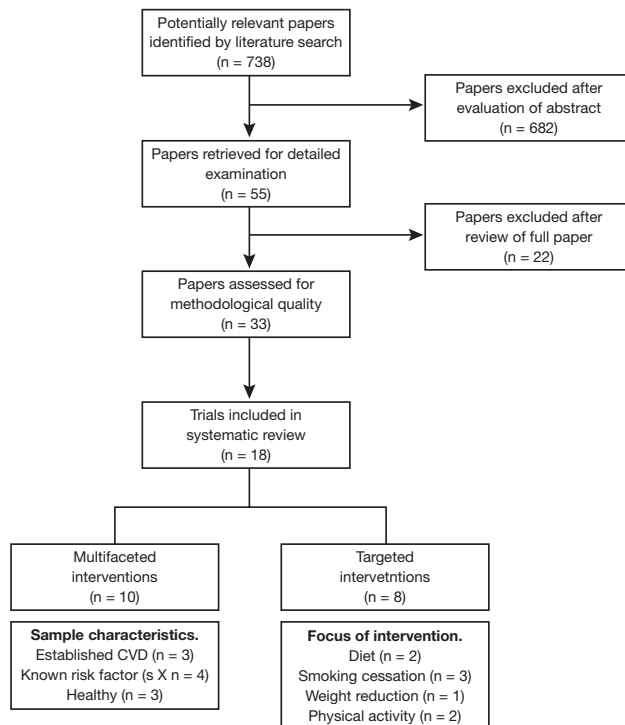


Figure 2. illustration of how numbers of studies and their management can be reported.²⁹

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

Methodological Quality

The discussion of the overall methodological quality of included studies should be included in this section.

Review findings

There is no standardised international approach to structuring how the findings of qualitative reviews are reported. The audience for the review should be considered when structuring and writing up the findings. QARI-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 QARI-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 (QARI-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 guidance for consideration rather than a prescription.

This section must be organised in a meaningful way based on the objectives of the review and the criteria for considering studies. The reviewer should comment on the appropriateness of the QARI-view graph.

Discussion

This section should provide a detailed discussion of issues arising from the conduct of the review, as well as a discussion of the findings of the review and of the significance of the review findings in relation to practice and research. 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; and
- 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

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 the reviewer's opinion. Recommendations must be clear, concise and unambiguous.

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 small sample sizes or methodological weaknesses. Implications for research should avoid generalised statements calling for further research, but should be linked to specific issues (such as longer follow up periods).

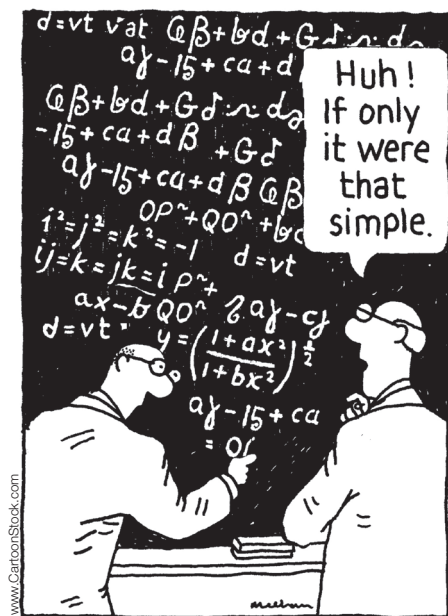
Developing recommendations

The Joanna Briggs Institute develops and publishes recommendations for practice with each systematic review, wherever possible. Across the different types of evidence and approaches to systematic reviews, a common approach is the construct of recommendations for practice, which can be summed up as the requirement for recommendations to be phrased as declaratory statements. Recommendations are drawn from the results of reviews and given a level of evidence (see below) based on the nature of the research used to inform the development of the recommendation. Recommendations are a reflection of the literature and do not include any nuances of preference or interpretation that reviewers or review panels may otherwise infer.

Assigning levels of evidence

The Joanna Briggs Institute and its entities, assign a level of evidence to all recommendations drawn in JBI Systematic Reviews. The reviewers (in conjunction with their review panel) should draft and revise recommendations for practice and research, and include a level of evidence congruent with the research design that led to the recommendation. The JBI Levels of Evidence are in *Appendix VI*.

The level of evidence relates to individual papers included in the systematic review. The levels of evidence for clinical and economic effectiveness reflect current international standards and expectations. However, as JBI takes a broader conceptual view of evidence, as reflected in the capacity to conduct reviews on the feasibility, appropriateness or meaningfulness of health care or health care experiences, the JBI levels of evidence incorporate particular criteria related to the appraisal of included studies, with the overall of assessing the trustworthiness of the evidence.



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.³⁰⁻³³ The strength of quantitative evidence lies in its validity and reliability – the same measurements should yield the same results or answers time after time.³³⁻³⁶

The methods associated with quantitative research in healthcare have developed out of the study of natural and social sciences.³⁷ 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.³⁷ 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; the substantiation or confirmation that is needed in order to believe that something is true.³⁸ The type of evidence needed depends on the nature of the activity, its purpose, and in JBI reviews has been classified accordingly as evidence of feasibility, appropriateness, meaningfulness and effectiveness.³⁹ 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.⁴

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 relationship 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 VII* and the differences between the study designs are discussed below. *Appendix VIII* 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

Randomised experimental designs

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. Randomised 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 randomisation 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”.⁴⁰

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.^{41, 42} and this is why it appears as an item on critical appraisal checklists.

RCTs provide robust evidence on whether or not a casual 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 randomisation or control group, or blinding), and end with those most at risk of bias (e.g. descriptive studies with no randomisation, control group or blinding). The study designs of interest will depend on the nature of the question.

In addition to 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-randomised or quasi experimental studies.

Non-randomised 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 which case, the strength of evidence is thought to be less robust and the study is more prone to bias.⁴⁰ 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-randomised 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 all the factors 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 summarise 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 Correlational or Descriptive.

Correlational studies

A correlational study aims to summarise 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 Correlational study designs are Cohort and Case-control.

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 for example. 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 summarised by calculating relative risk and retrospective cohort studies should be summarised 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. Case reports and case series are types of descriptive studies.

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".

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. 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 focussed review questions.

Review Questions

Among adults in the acute postoperative phase (5 days) following skin grafting, what dressings used in the management of the STSG donor site are most effective:

- in reducing time to healing;
- in reducing rates of infection; and
- in reducing 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?

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 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 (for example: “the use of acupuncture is effective in increasing smoking cessation rates in hospitalised 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 hospitalised patients”. Such statements in the background need to be balanced by other points of view, emphasising 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).

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, is 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, gender). In the earlier example, the PICO mnemonic describes the population (adults) within a specific setting (acute care) within a specific time frame (5 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 generalised 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.

Types of 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”^{2, 43} and they are useful to summarise 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. Any reviewers interested in undertaking an umbrella review through JBI, are urged to contact the SSU.

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. If a systematic review plans to consider primary research studies and secondary research (such as other systematic reviews), the differences in research methodologies should be taken into account. As with different study designs, it is inappropriate to combine findings of systematic reviews directly with those of primary studies, due to the differences in research methods and underlying statistical assumptions used by those research methods, therefore data from systematic reviews and primary studies should be analysed separately within the review.

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 studies 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. have some form of randomisation or control, or blinding), and end with those most at risk of bias (e.g. descriptive studies with no randomisation, 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 levels of evidence that describe effectiveness should be used alongside any recommendations and these levels are based upon the included study designs that provided evidence for those recommendations. This is discussed further in subsequent sections. 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 standardised 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 randomised controlled trials, non-randomised 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.

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

Search strategy

The aim of a systematic review is to identify all relevant international research on a given topic. This is achieved by utilising 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 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 standardised in CReMS:

The search strategy aims to find both published and unpublished studies. A three-step search strategy will be utilised 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 standardised 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 numbers 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 *Appendix XV*.

The Joanna Briggs Institute 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.

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

***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 VII*). 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).

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 standardised 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 standardised 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 randomised 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-randomised studies, since the effect sizes in these are almost invariably affected by confounders.³¹

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.

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 standardised 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 IX*). Other error-minimising 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 standardisation 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 standardised 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 generalisability 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:

$$SD = \frac{\sqrt{\sum (X - \bar{X})^2}}{N - 1}$$

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.

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 versus 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.⁴⁴

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.⁴

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.²

Studies to be included in JBI systematic reviews with meta-analysis should be similar to each other so that generalisation 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.^{4, 31}

The main areas where data from included studies should be comparable can be categorised as: clinical, methodological and statistical. The followings questions should be considered when deciding whether or not to combine data in a meta-analysis:^{30, 31, 45}

- 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?
- Statistical – were outcomes measured in the same way, at the same time points, using comparable scales?

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 al³¹ and Barza et al³⁰ also provide good 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 it may not be useful to combine the data in meta-analysis, and presenting the results in a narrative summary may be more appropriate,³¹ however presentation of the results as a table or as a graphic (such as forest plot) may still be useful in conveying the result to the reader.

Statistical pooling of study data provides a summary estimate, using transparent rules specified in advance.³¹ 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; and
- whether fixed or random effects models will be utilised 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 synthesised 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 Review Manager (for reviews conducted through a Cochrane Review Group). 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 synthesised 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.

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 Vancouver referencing. 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. An example is shown below.

In text:

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 and that there is no heterogeneity between the studies¹.

In reference section:

1. Borenstein M, Hedges LV, Higgins JPT and Rothstein HR (2009) *Introduction to meta-analysis*, Wiley chapter 10-12, p61-75.

More information about the Vancouver 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 paper, numbered in Roman numerals and referred to in the text. At a minimum, this section should include the JBI critical appraisal and data extraction tools (this occurs automatically when using CReMS).

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

Once a protocol has been approved, it is published on the JBI website. Protocols can be found at: <http://www.joannabriggs.edu.au/Access%20Evidence/Systematic%20Review%20Protocols>

Chapter Six:

The Systematic Review and Synthesis of Quantitative Data

Please refer to the JBI website for specific presentation requirements for systematic review reports <http://www.joannabriggs.edu.au>

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 Australian spelling and authors should therefore follow the latest edition of the Macquarie Dictionary. 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 synthesised – 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.

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 qualitative 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 response of “unclear”. This discussion should take place before independently conducting the appraisal. The critical appraisal tool should be attached to the review.

***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 generalisability 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 standardised data extraction instrument.

Data synthesis

This section should describe how the extracted data was synthesised. If the data was heterogeneous and is presented as a narrative summary, potentially 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 with a risk ratio. Borenstein et al 2009 ³¹ describe the effect size as being the “currency of the systematic review” as the aim of a meta-analysis is to summarise the effect size of each included study to obtain a summary effect. The summary effect is shown as a diamond on a forest plot. 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 3 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?

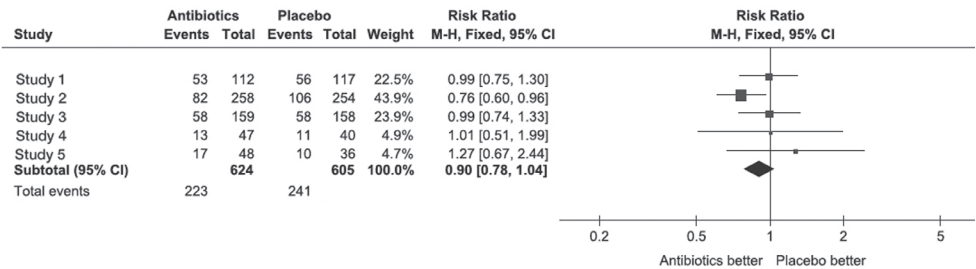


Figure 3. Example of Forest plot

A formal statistical test of the similarity of studies is provided by the test of homogeneity.⁴⁶ 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.⁴⁷ 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)⁴⁸ 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^{45, 48} (absolute measures of effect include the risk difference and the number needed to treat – these are not currently included as analytical options in CReMS/MASARI and thus will not be discussed further). There is little difference between the RR and OR in terms of consistency between studies.⁴⁸
- 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.⁴⁵
- 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 of two statistical assumptions – 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).

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 analyse the heterogeneity away and should not be considered as a substitute for a thorough investigation into the reasons for the heterogeneity.⁴⁷ 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.^{45, 48}

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 are 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).⁴⁸

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.⁴⁸

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 standardised 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.⁴⁵ 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 4, with the following stages of identifying and retrieving studies for inclusion:

- Numbers of studies identified;
- Numbers of studies retrieved for detailed examination;
- Numbers of studies excluded on the basis of title and abstract;
- Numbers of full text articles retrieved;
- Numbers of studies excluded on the basis of full text;
- Numbers of appraised studies;
- Numbers of studies excluded studies following critical appraisal and an overview of reasons for exclusion; and
- 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.

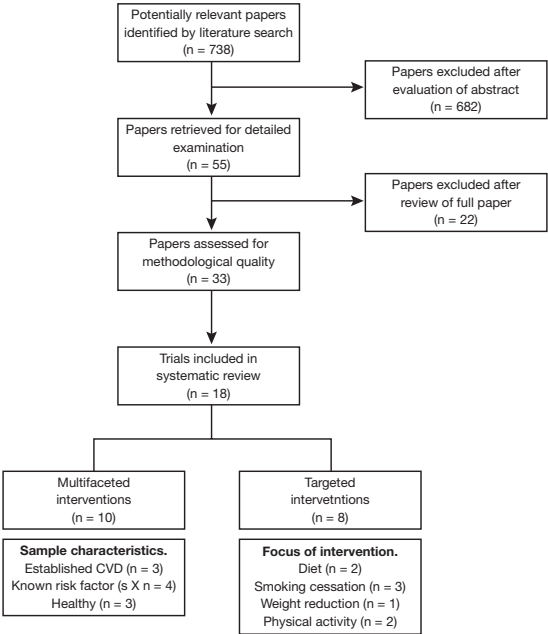


Figure 4. An example of a flowchart

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 use of tables, graphs and in text reference to specific appendices is encouraged.

Assessment of methodological quality

This section should summarise 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 6 using the MASTARI checklist (the criteria should be detailed in the protocol). Of the remaining 20 included studies, 15 were randomised controlled trials and 5 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 organised in a meaningful way based on the objectives of the review and the criteria for considering studies. There is no standardised 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, 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 Review Manager (for reviews conducted through a Cochrane Review Group) or through MASTARI. All results must be double entered in order to avoid data entry errors. Odds ratio (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 MASTARI 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 standardised mean difference (SMD);
- Cohen's standardised mean difference (SMD); or
- Weighted mean difference (WMD).

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

- DerSimonian and standardised 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 summarising 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.

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

Discussion

The aim of this section is to summarise 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. ^{49, 50}

Points to consider in this section include:

- Where any problems identified undertaking the search (perhaps there is little primary research on this topic or perhaps it is poorly indexed by the databases that were searched or perhaps the search was insufficient)?
- What limitations were found in the included primary research (e.g. were there inconsistencies or errors in reporting)?
- How do the review findings fit with what is currently known on the topic (from issues highlighted in the Background section)?
- Are the findings generalisable 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; and
- 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 level of evidence of effectiveness (*Appendix VI*). Assigning levels of evidence is discussed further in separate section.

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 generalised statements calling for further research, but should be linked to specific issues. Recommendations must be clear, concise and unambiguous and be assigned a JBI level of evidence of effectiveness (*Appendix VI*). Assigning levels of evidence is discussed further in separate section.

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 Vancouver style, as previously discussed in the Protocol section.

Appendices

The appendices should include:

- critical appraisal form(s);
- data extraction form(s);
- table of included studies; and
- table of excluded studies with justification for exclusion.

These appendices are automatically generated in CReMS.

■ *Are all appendices correctly numbered and attached to the report?*

Assigning levels of evidence

The Joanna Briggs Institute entities currently assign a level of evidence to all recommendations drawn in JBI Systematic Reviews. The reviewers (in conjunction with their review panel) should draft and revise recommendations for practice, and include a level of evidence congruent with the research design that led to the recommendation. The JBI Levels of Evidence for Effectiveness are summarised below:

Level 1 Meta analysis (with homogeneity) of experimental studies (e.g. RCT's with concealed randomisation) OR one or more large experimental studies with narrow confidence intervals.
Level 2 One or more smaller RCT's with wider confidence intervals OR quasi experimental studies (without randomisation)
Level 3 a) Cohort studies with a control group b) Case-controlled study c) Observational studies (without a control group)
Level 4 Expert opinion OR physiology bench research OR consensus

The level of evidence relates to individual papers included in the systematic review. Recommendations made in systematic review reports each need level of evidence using the scale illustrated above and reflect current international standards and expectations. However, as JBI takes a broader conceptual view of evidence, as reflected in the capacity to conduct reviews on the feasibility or meaningfulness of health care or experiences, the JBI levels of evidence incorporate particular criteria related to the appraisal of included studies from paradigms other than the quantitative paradigm.

Developing recommendations

The Joanna Briggs Institute develops and publishes recommendations for practice with each systematic review. Across the different types of evidence and approaches to systematic reviews, a common approach to the construct of recommendations for practice has been developed, which can be summed up as the requirement for recommendations to be phrased as declaratory statements. Recommendations are drawn from the results of reviews and given a level of evidence based on the nature of the research used to inform the development of the recommendation. Recommendations are a reflection of the literature and do not include any nuances of preference or interpretation that reviewers or review panels may otherwise infer.

Has the correct JBI level of evidence been assigned to each recommendation made in the systematic review?



"Our funding ran out again. Whip up another batch of crystal meth."

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, dollar value. A health economic evaluation looks to compare both the health effects and the costs of two or more alternative health interventions⁵¹. To do this often the study designs encountered are similar to those for 'quantitative' evidence already described (Section 3) with added inclusion of cost measurement. Studies that incorporate sometimes complex modelling of data are also frequently encountered whilst addressing economic evidence.

In any society, the 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 resource use 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 development⁵².

The generalisability 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)^{53 54}. 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 effects⁵⁵. 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 length⁵⁴.

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 2 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 2. 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 (eg. 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 (eg. dollars)	Benefits measured in natural units (eg. 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 (eg. incremental cost-effectiveness ratio ICER)
Cost-Utility Analysis (CUA)	Costs measured in monetary units (eg. dollars)	Benefits expressed in summary measures as combined quantity and quality measures (eg. 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 (eg. dollars)	Benefits measured in monetary units (eg. dollars);	It is difficult to measure the value of all health outcomes in monetary units (eg. 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 upon 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 valorisation of every unit from who's perspective it is.⁵¹ Another important consideration is cost and how it is categorised.

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 categorised as “direct medical”, “direct non-medical”, and “indirect costs”. Direct medical costs are those incurred by the health service, 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 and 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 simply refer to those costs that vary dependent on the number of cases treated, such as drugs administered. Fixed costs on the other hand, don't 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 at some future time. 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

JBIs economic evaluation reviews are conducted through the ACTUARI module of the SUMARI software. Before reviewers are able to use CReMS or any of the SUMARI modules, they need to register through the JBI website and obtain a username and password. This process is free of charge.

The ACTUARI module is designed to manage, appraise, extract and analyse 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 3 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. This is done by sending a draft of the review protocol to the SSU for peer review.

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.

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:⁵⁶

"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:⁵⁶

"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:⁵⁶

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 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.

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, emphasising 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.

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, is 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: ⁵⁶

"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: ⁵⁶:

"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."

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, 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: ⁵⁶

"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."

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 (QALY's)

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, Cost-Effectiveness 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 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 standardised in JBI CReMS as follows:

The search strategy aims to find both published and unpublished studies. A three-step search strategy will be utilised 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 standardised 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 used 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 numbers 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 standardised 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 X*) as an appendix. The checklist is a series of criteria that can be scored as being met, not met or unclear.

The standardised 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 standardised 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 XI* 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.

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 standardised approach and tool to data extraction from ACTUARI software. The standardised data extraction can be found in *Appendix XII*.

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

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 standardised text gives an overview of synthesis as follows:

“Economic findings will, where possible be synthesised 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 synthesised 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 reviewer’s 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 utilised 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 visualisation and interpretation by readers clearer and easier.

■ ***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 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.

More information about the Vancouver 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 paper, numbered in Roman numerals and referred to in the text. At a minimum, this section should include the JBI critical appraisal and data extraction tools (this occurs automatically when using CReMS).

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

Once a protocol has been approved, it is published on the JBI website.

Protocols can be found at:

<http://www.joannabriggs.edu.au/Access%20Evidence/Systematic%20Review%20Protocols>

Chapter Nine:

The Systematic Review and Synthesis of Economic Data

Please refer also to the JBI website for specific presentation requirements for systematic review reports <http://www.joannabriggs.edu.au>.

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.

JBI systematic reviews should use Australian spelling and authors should therefore follow the latest edition of the Macquarie Dictionary. 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 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 synthesised, 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, The Joanna Briggs Institute 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.

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.

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 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 X*. 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/methods⁵¹ including models, retrospective studies and prospective studies. There are guidelines focusing specifically on decision-making models and Markov analyses for health economic evaluations.

Has the ACTUARI 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? How were any differences resolved?

ACTUARI critical appraisal checklist items are discussed further in *Appendix XI*

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 standardised ACTUARI data extraction form can be found in *Appendix XII*. 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 healthcare (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 standardised criteria for diagnosis, setting (for example, hospital, community, outpatient), who should make the diagnosis of the specific disease, other important characteristics of participants (such as for example different response to the treatment). Summarise 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

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

Reviewer's Comments

Summarise 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: randomised 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 1 year, survival at 5 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 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 5 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 5. 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 synthesised 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 synthesised 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 summarised using a hierarchical decision matrix.

Examples of narrative summary of economic evidence (from Lister-Sharp et al. ⁵⁷):

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
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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 reviewer's 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 visualisation 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 6, 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 6. 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 3 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 organised in a meaningful way based on the objectives of the review and the criteria for considering studies.

There is no standardised 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. Figure 7 below.

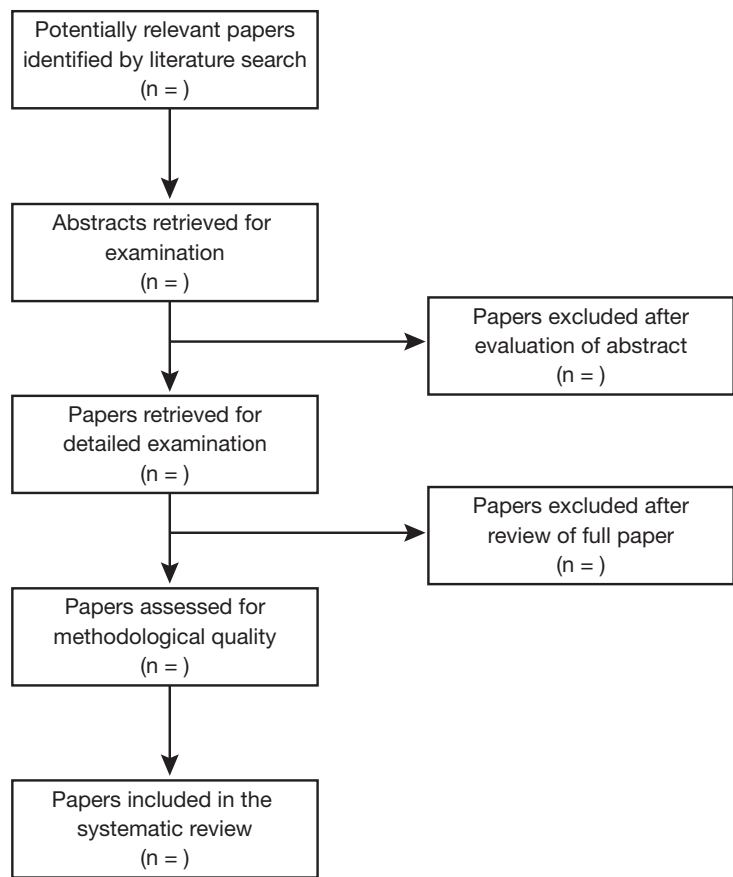


Figure 7. A typical flowchart to detail study identification

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 summarise 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.

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Points to consider in this section include:

- Where any problems identified undertaking the search (perhaps there is little primary research on this topic or perhaps it is poorly indexed by the databases that were searched or perhaps the search was insufficient)?
- What limitations were found in the included primary research (e.g. were there inconsistencies or errors in reporting)?
- How do the review findings fit with what is currently known on the topic (from issues highlighted in the Background section)?
- Are the findings generalisable 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; and
- 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 level of evidence of feasibility (*Appendix V*).

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 generalised statements calling for further research, but should be linked to specific issues. Recommendations must be clear, concise and unambiguous and be assigned a JBI level of evidence of feasibility (*Appendix V*).

Developing recommendations for practice

The Joanna Briggs Institute develops and publishes recommendations for practice with each systematic review.

Across the different types of evidence and approaches to systematic reviews, a common approach to the construct of recommendations for practice has been developed, which can be summed up as the requirement for recommendations to be phrased as declamatory statements. Recommendations are drawn from the results of reviews and given a grade of recommendation based on a specific level of evidence justified by the nature of the research used to inform the development of the recommendation.

Recommendations are a reflection of the literature and do not include any nuances of preference or interpretation that reviewers or review panels may otherwise infer.

Assigning levels of evidence

The Joanna Briggs Institute and its collaborating centres and Evidence Synthesis Groups currently assign a level of evidence to all recommendations drawn in JBI Systematic Reviews. The reviewers (in conjunction with their review panel) should draft and revise recommendations for practice, and include a level of evidence congruent with the research design that led to the recommendation.

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 Vancouver style, as previously discussed in the Protocol section.

Appendices

The appendices should include:

- critical appraisal form(s);
- data extraction form(s);
- table of included studies; and
- table of excluded studies with justification for exclusion.

These appendices are automatically generated in CReMS.

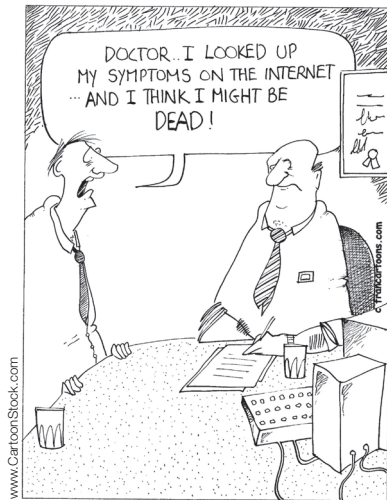
■ ***Are all appendices correctly numbered and attached to the report?***

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 reviewer's commercial links and affiliations. The contribution of colleagues or Institutions should also be acknowledged.



**Text and Opinion
Based Evidence**

Chapter Ten:

Text and Opinion Based Evidence and Evidence Based Practice: Protocol and Title 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'.⁴

Opinion-based evidence refers to expert opinions, comments, assumptions or assertions that appear in various journals, magazines, monographs and reports.^{4, 58-60} 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".⁶⁰

The synthesis of text and opinion

The synthesis of expert opinion findings within the systematic review process is not well recognised in mainstream⁴ evidence based practice and it is acknowledged that efforts to appraise the 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, one additional mnemonic may be useful to the nature of opinion-based systematic reviews. The mnemonic SPICE includes the more generalised term evaluation rather than outcome, and may be more useful in textual evidence by avoiding association with the quantitative implications of outcomes being associated with causal evidence, particularly randomised controlled trials. SPICE incorporates the Setting, Perspective, Intervention, Comparison and Evaluation. However, 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 mnemonic elements 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.

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 utilised 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 method. 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 standardised 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 standardised for this type of literature, while the methods are the same as for appraisal of any type of literature. Standardised 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 XIII*.

■ 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 XIV*. 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 summarised 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 summarising 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?

- **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 standardised 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 only develop themes and 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 standardised 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 synthesised. 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 synthesised 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 synthesised 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 categorising 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 synthesised 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 synthesised findings by bringing together key conclusions drawn from all of the included papers. Conclusions are principal opinion statements embedded in the paper by the reviewer(s) 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 generated into NOTARI.

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.

Categorising 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 synthesised findings.

A synthesis is defined as a group of categorised conclusions that allows for the generation of recommendations for practice. This process is illustrated in Figure 8.

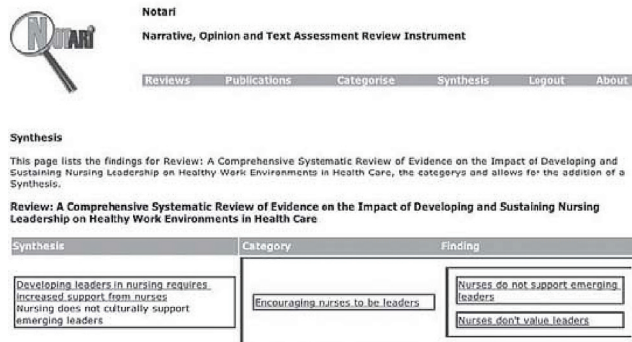


Figure 8. Meta-view graph of a JBI-NOTARI aggregation.

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 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 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.

More information about the Vancouver 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.

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

Once a protocol has been approved, it is published on the JBI website. Protocols can be found at: <http://www.joannabriggs.edu.au/Access%20Evidence/Systematic%20Review%20Protocols>

Chapter Eleven:

The Systematic Review and Synthesis of Text and Opinion Data

Please refer to the JBI website for specific presentation requirements for systematic review reports <http://www.joannabriggs.edu.au>.

All JBI systematic reviews are based on approved peer reviewed systematic reviews protocols. 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 Australian spelling and authors should therefore follow the latest edition of the Macquarie Dictionary. 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 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, 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 types of 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 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 synthesised, 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, The Joanna Briggs Institute 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.

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. For a review of text and opinion the SPICE mnemonic (Setting, Perspective, Intervention, Comparison and Evaluation) may be helpful. .

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 is 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 *Appendix XIV*.

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". 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 standardised 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.⁴

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 behaviour 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.

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 standardised 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 summarising 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 analyse 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 summarise 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.

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. The meta-aggregation of findings of qualitative studies can legitimately aggregate findings from studies that have used radically different, competing and antagonistic methodological claims and assumptions, within a qualitative paradigm. Meta-aggregation in NOTARI does not distinguish between methodologies or theoretical standpoints and adopts a pluralist position that values viewing phenomena from different perspectives.

Data Synthesis

This section of the report should include how the findings were synthesised. Where meta-aggregation is possible, textual findings should be pooled using NOTARI however, if necessary, the reviewer may use interpretive techniques to summarise the findings of individual papers .

The processes for categorisation and formulating synthesised 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 categorising 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 synthesised 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 categorising 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 synthesised 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; and
- how to aggregate categories into synthesised findings.

Conclusions are principal findings reached by the reviewer(s) after examining the results of data analysis, for example themes, metaphors, consisting of a statement that relates to two or more phenomena, variables or circumstances that may inform practice. A reviewer can add conclusions to a study after an extraction is completed on that paper

The JBI approach to synthesising 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 synthesised findings. To reiterate:

Findings are conclusions reached and reported by the author of the paper, often in the form of themes, categories or metaphors.

The most complex problem in synthesising 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 categorising and re-categorising the conclusions of two or more studies to develop synthesised 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, and
- how to aggregate categories into synthesised findings.

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

Many text and opinion-based reports only develop themes and 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.

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:

Unequivocal - relates to evidence beyond reasonable doubt which may include findings that are matter of fact, directly reported/observed and not open to challenge

Credible - relates to those findings that are, albeit interpretations, plausible in light of the data and theoretical framework. They can be logically inferred from the data. Because the findings are interpretive they can be challenged.

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 synthesised findings. NOTARI sorts the data into a meta-synthesis table or “NOTARI-View”, when allocation of categories to synthesised 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 numbers of studies that were included and excluded from the review. A flowchart such as that shown in Figure 9.

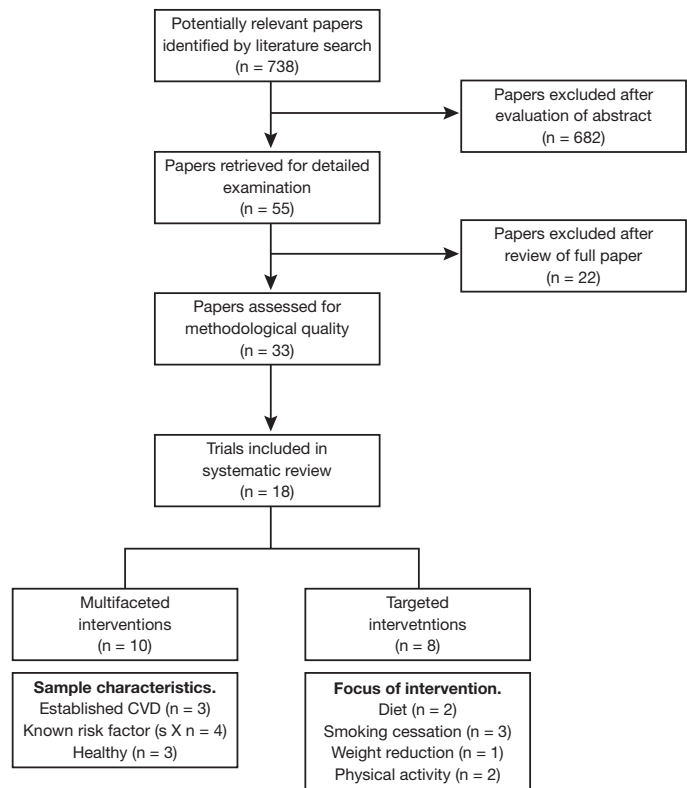


Figure 9. A flowchart of search results

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: Numbers of studies identified, Numbers of retrieved Papers, Numbers of appraised Papers, Numbers of excluded Papers and overview of reasons for exclusion, Numbers 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 use of tables, graphs and in text reference to specific appendices is encouraged.

Review Findings

There is no standardised international approach to structuring how the findings 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 in to 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 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.

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 generalised statements calling for further research, but should be linked to specific issues (such as longer follow up periods).

Developing recommendations

The Joanna Briggs Institute develops and publishes recommendations for practice with each systematic review, wherever possible. Across the different types of evidence and approaches to systematic reviews, a common approach is the construct of recommendations for practice, which can be summed up as the requirement for recommendations to be phrased as declaratory statements.

Assigning levels of evidence

The Joanna Briggs Institute and its entities, assign a level of evidence to all recommendations drawn in JBI Systematic Reviews. The reviewers (in conjunction with their review panel) should draft and revise recommendations for practice and research, and include a level of evidence congruent with the research design that led to the recommendation. The JBI Levels of Evidence can be found in *Appendix VI*.

The level of evidence relates to individual papers included in the systematic review. The levels of evidence reflect current international standards and expectations. However, as JBI takes a broader conceptual view of evidence, as reflected in the capacity to conduct reviews on the feasibility, appropriateness or meaningfulness of health care or health care experiences, the JBI levels of evidence incorporate particular criteria related to the appraisal of included studies, with the overall of assessing the trustworthiness of the evidence.

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 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.

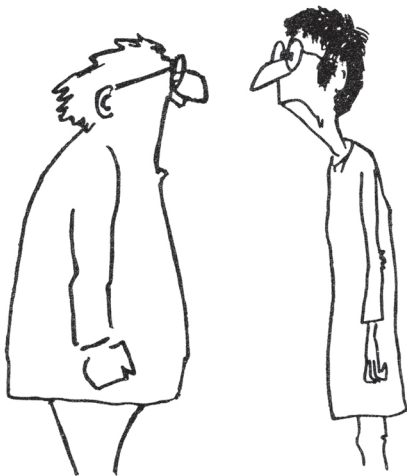
More information about the Vancouver style is detailed in the International Committee of Medical Journal Editors' revised 'Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication', and can be found at <http://www.ICMJE.org/>

Appendices

The appendices should include:

- critical appraisal form(s);
- data extraction form(s);
- table of included studies; and
- table of excluded studies with justification for exclusion.

These appendices are automatically generated in CReMS.



"Being a brilliant, inspiring teacher is NOT adequate, Hackwell. You MUST publish if you're to be part of THIS team!"

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 an internal quality improvement process through the submission (and subsequent approval) of a protocol and a review to the Synthesis Science Unit (SSU). The review is then uploaded to the JBI Library of Systematic Reviews. The JBI Library of Systematic Reviews publishes systematic reviews undertaken by the Joanna Briggs Institute and its international collaborating centres and groups. However there is facility within the Library for publication of systematic reviews undertaken by authors unrelated to the Joanna Briggs Institute.

Centres undertaking systematic reviews as their core focus are required to submit their systematic review reports to the JBI Library of Systematic Reviews in order for it to be considered as output for their Centre. This output is used to determine the Centre's status and funding eligibility on an annual basis.

The JBI library of systematic reviews

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 now houses all JBI SSRs in PDF that have been published since inception. The Library is available to members/JBI COnNECT+ subscribers via the JBI website (<http://www.joannabriggs.edu.au/>) and each SRR is assigned a volume and issue number. In 2010 the JBI Library of Systematic Reviews was given an International Standard Serial Number (ISSN).

The uploading of a review report to the JBI Library of Systematic Reviews occurs only when a review report has been received by the SSU (in PDF format generated from SUMARI), peer-reviewed with any recommended changes made by the review authors, and the updated report returned to the SSU. The primary author is notified by the SSU when the report has been approved and an Exclusive Licence Form (ELF) is sent. Only when the ELF has been returned to the Receiving Editor of the Library, will the review be formatted and uploaded into the Library. The Receiving Editor may need to contact the primary author if they have any issues related to formatting. To avoid delay the following is recommended:

- Submitting the entire report in portrait layout (as opposed to landscape)
- Not locking or anchoring tables or figures
- Not placing the excluded studies into a table

The primary author will be notified once the review has been uploaded into the Library.

Please note: Only systematic reviews that have had their protocols approved by the SSU prior to review submission are eligible to be published in the JBI Library of Systematic Reviews. Those who have not submitted a protocol to the SSU will be invited to submit their review to the International Journal of Evidence-Based Healthcare (see below).

The International Journal of Evidence-Based Healthcare

The International Journal of Evidence-Based Healthcare (IJEBHC), a Wiley-Blackwell publication is a fully refereed journal that publishes original scholarly work relating to the synthesis, transfer and utilisation of evidence to inform multidisciplinary health care practice.

Reviewers may choose to submit their full SRR to the IJEBHC instead of the JBI Library of Systematic Reviews however this will not be counted as core output for the Collaborating Centre or Group. Alternatively reviewers who have already published their full SRR in the JBI Library of Systematic Reviews are encouraged to submit a paper derived from their SRR (and citing their original review in the JBI Library) in the IJEBHC or other journal (thus enabling authors to generate two refereed publications).

The current suggestion for the IJEBHC is to submit the systematic review executive summary/abstract along with an additional 3-500 word section on 'Translation to Practice' addressing potential strategies and priorities for translating the findings into practice.

The IJEBHC uses an online system called Scholar One to manage submissions (URL: <http://mc.manuscriptcentral.com:80/ijebh>). Reviewers need a username and password (these have either already been provided, or may be set up by using the 'Create Account' option in the top right corner of the website). Manuscripts must be de-identified BEFORE uploading as the peer review system relies upon a blinded approach.

Authors (and peer reviewers) can access instructions on use of the system from: <http://mcv3help.manuscriptcentral.com/tutorials/index.htm>

Authors are required to meet the stated requirements for the journal, and complete a copyright assignment form and conflict of interest form.

Information concerning these is available from the journal's home page:

<http://www.wiley.com/bw/journal.asp?ref=1744-1595&site=1>

Editor-in-Chief

Emeritus Professor Derek Frewin AO

Faculty of Health Sciences, The University of Adelaide and the Cardiac Clinic, Royal Adelaide Hospital, Adelaide, South Australia, Australia

International Editorial Board

Details of the Editorial Board can be found at:

<http://onlinelibrary.wiley.com/journal/10.1111/%28ISSN%291744-1609/homepage/EditorialBoard.html>

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 9th – 11th 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 healthcare 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 an annual "Best Practice Information Sheet" booklet.

Specifically, the SSU supports quality improvement and increased output of systematic reviews by accepting responsibility for all internal peer reviews of systematic review protocols. It provides constructive feedback to reviewers, and assists reviewers in improving protocols, search strategies and reporting. Furthermore, the SSU encourages reviewers to complete systematic reviews in a timely fashion by monitoring the progress of registered systematic reviews and maintaining contact with reviewers.

On receipt of new protocols submitted to the Institute for approval (prior to uploading to the database of systematic review protocols), members of the SSU will rigorously review the protocol and give supportive, constructive feedback to authors and establish a supportive peer review process to enable authors to develop a high quality protocol. Unit staff will also offer additional assistance – 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. Following submission this feedback is provided to authors within a two-week timeframe.

Once a protocol is approved and uploaded to the database of protocols, Unit staff will work with reviewers to facilitate completion of the review and will monitor progress towards completion on a three monthly basis. When a completed report is submitted to the unit, SSU research fellows rigorously review the report and give supportive, constructive feedback to authors and establish a supportive process to enable authors to finalise and subsequently publish the report. Following submission of the report, feedback is provided to authors within a four-week time frame.

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.

Develop Best Practice Information Sheets

Unit staff will write all Best Practice information sheets in liaison with Collaborating Centres (to identify and address potential cross-cultural issues - and to ensure that recommendations for practice stated in BPIS are transferable across cultures).

Reviewer training and accreditation

JBIR reviews can only be conducted by accredited JBIR reviewers – who must complete systematic review training through a registered Cochrane entity or an approved JBIR trainer. The conduct of the formal JBIR Comprehensive Systematic Review Training Program (CSRTP) is the responsibility of the Joanna Briggs Institute and its Centres.

The CSRTP consists of the following 5 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 studies in a Cochrane Review of Effects (2 days)

Module 3: The appraisal, extraction and pooling of quantitative data from experimental, non-experimental, diagnostic and prognostic studies (2 days)

Module 4: The appraisal, extraction and pooling of qualitative data from qualitative studies, narrative and text from opinion papers (2 days)

Module 5: 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, 3 and 4 are the most commonly taught). Core staff of a Centre are eligible to receiving 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:

- Maintain a high level of professionalism
- Maintain their knowledge and skills in teaching and in the content of JBI programs
- Promote JBI, the Cochrane Collaboration 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, summarised 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, registering the protocol with the SSU, and the JBI peer review process are able to have their reviews included in the JBI Library of Systematic Reviews (ISSN 1838-2142), and the review is considered centre output by association. The review remains the intellectual property of the student.

As mentioned previously, Collaborating centres are encouraged to submit a paper derived from their review, and citing their original review in the JBI Library of Systematic Reviews, to the Institute's journal (The International Journal of Evidence-Based Healthcare) or another journal.

Evidence Synthesis Groups

Evidence Synthesis Groups (ESG's) 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 CSRTP 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 Evidence Synthesis Groups 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, which is also written by the Synthesis Science Unit. Further information on these documents is provided below.

Best Practice Information Sheets

Best Practice Information Sheets follow a set format and are designed by JBI in Adelaide and printed by Wiley-Blackwell Publishing. Best Practice information sheets are written by the SSU and may be based on systematic reviews published through the Collaboration or from external systematic reviews.

In the case of external systematic reviews, permission is sought from the originators of the existing review to use it to develop a Best Practice information sheet. If this is granted, the SSU, (in consultation with the authors of the review), draft the sheet. If a topic is nominated for a Best Practice information Sheet, and has not been the subject of a systematic review, the Joanna Briggs Institute or Collaborating Centre may undertake to conduct one.

Best Practice information sheets are considered current for a maximum of 3 years. Updates of Best Practice may be published electronically and/or in hard copy via Wiley-Blackwell.

Each Best Practice information sheet developed by the SSU is sent out to the authors of the review and then to Collaborating Centres from different regions for their feedback to identify and address potential cross-cultural issues - and to ensure that recommendations for practice stated in BPIS are transferable across cultures. The BPI drafts are then forwarded to the Publications and Promotions team for final development and publication as either electronic or hard copy.

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 along side the Best Practice information sheet 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 SSU.

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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

is 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 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) is an analytic tool for estimating the net social benefit of a programme or intervention as the incremental benefit of the program less the incremental costs, with all benefits and costs measured in monetary units (eg., dollars)

Cost-effectiveness analysis

(CEA) is 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

is 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) is 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) is 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 all 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

is the rate of interest used to calculate a present value or to discount future values

Discounting

is 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 marginalised 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

is a study that compares the costs and benefits of two or more alternative interventions or programmes 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

refers to 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 minimising the opportunity cost of attaining a given output or as maximising the output for a given opportunity cost

Ethnography

is a term to describe the study of culture which recognises 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 term used in qualitative research to describe conclusions reached by a researcher after examining the results of the data analysis in their primary research, often presented in the form of themes or metaphors

Fixed cost

is 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 organisations, 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

is defined as a comparative analysis of both the costs and the health effects of two or more alternative health interventions

Health economics

is the discipline which deals with the application of economic principles and theories to health and the health sector

Heterogeneity

is 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 healthcare provided to individual patients or groups/communities; it may also be used when describing a particular form of treatment being tested (see treatment)

Interview

a data collection method that may involve semi or unstructured conversation with an explicit purpose

JBİ

the Joanna Briggs Institute

JBİ Affiliation

association with a JBİ collaborating entity such as a collaborating centre or an evidence synthesis group

JBİ ACTUARI

Joanna Briggs Analysis of Cost Technology and Utilisation Assessment and Review Instrument

JBİ CReMS

Joanna Briggs Institute Comprehensive Review Management Software, used for conduct and management of a JBİ systematic review. There are four component analytical modules: JBİ MASTARI, JBİ NOTARI, JBİ QARI and JBİ ACTUARI

JBİ MASTARI

Joanna Briggs Institute Meta Analysis Statistics Assessment and Review Instrument. The analytical module designed for JBİ systematic reviews of effectiveness evidence

JBİ Notari

Joanna Briggs Institute Narrative Opinion and Text Assessment and Review Instrument. The analytical module designed for JBİ systematic reviews of text and opinion evidence

JBİ QARI

Joanna Briggs Institute Qualitative Assessment and Review Instrument. The analytical module designed for JBİ systematic reviews of qualitative evidence

JBİ SUMARI

Joanna Briggs Institute System for the Unified Management, Assessment and Review of Information, JBİ 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

evidence which is beyond reasonable doubt

Credible evidence

evidence that while subject to interpretation, is plausible

Unsupported evidence

such evidence may be noted in review but is not included in a JBİ 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 JBİ 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 confounded 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 the behavioural 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

is 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

simply describes 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

is 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

are 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

are 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 synthesised 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.

Randomisation

The process of randomly allocating participants into one of the arms of a controlled trial. There are two components to randomisation: 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

are 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 Cochrane

Reflective Journaling

a research method used in qualitative research that involves a summary (written or oral) of an experience which involves analysing 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 to be 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

are costs that have both a fixed and a variable cost component.

Sensitivity

is 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

refer to 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

standardised 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

Synthesised finding

a group of categories combined together on the basis of similarity of meaning

Treatment

In general, a form of healthcare provided to patients or groups/comunities; however, throughout this manual it is often used to designate a specific form of healthcare, the effectiveness of which is being tested compared to a placebo or a standard, or control healthcare. In this capacity, treatment and intervention may be used interchangeably.

Umbrella review

is 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

is 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

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Appendix I – Title registration form

Title:	
Centre name:	
Reviewer name:	
Reviewer email:	
Population:	
Intervention:	
Context:	
Outcome:	

Appendix II – Critical appraisal tool for Systematic reviews

JBI Critical Appraisal Checklist for Systematic Reviews			
Reviewer _____		Date _____	
Author _____	Year _____	Record Number _____	
	Yes	No	Unclear
1. Is the review question clearly and explicitly stated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Was the search strategy appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Were the sources of studies adequate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Were the inclusion criteria appropriate for the review question?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Were the criteria for appraising studies appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Was critical appraisal conducted by two or more reviewers independently?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Were there methods used to minimise error in data extraction?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Were the methods used to combine studies appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Were the recommendations supported by the reported data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Were the specific directives for new research appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Overall appraisal: Include <input type="checkbox"/> Exclude <input type="checkbox"/> Seek further info. <input type="checkbox"/>			
Comments (Including reasons for exclusion)			

Appendix III – Data extraction tools for Systematic reviews

JBI Data Extraction Form for Systematic Review of Experimental/Observational Studies

Reviewer _____ Date _____

Author _____ Year _____

Journal _____ Record Number _____

Included studies

RCT ☐ Quasi-RCT ☐ Longitudinal ☐

Participants

Retrospective ☐ Observational ☐ Other _____

Setting _____

Population _____

Interventions

Intervention 1 _____

Intervention 2 _____

Intervention 3 _____

Clinical outcome measures

Outcome Description	Scale/measure

Meta-analysis results

Dichotomous data

Outcome	Intervention () number / total number	Intervention () number / total number	Statistic Combined measure (CI)

Continuous data


Outcome	Intervention () number / total number	Intervention () number / total number	Statistic Combined measure (CI)

Summary of Narrative Results

Authors Conclusions

Comments

Appendix IV – 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 style="width: 100%;" 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 style="width: 100%;" 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 style="width: 100%;" 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 style="width: 100%;" 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 style="width: 100%;" 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 style="width: 100%;" 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 style="width: 100%;" type="text"/>
8) Participants, and their voices, are adequately represented.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input style="width: 100%;" 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 style="width: 100%;" 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 style="width: 100%;" type="text"/>

Include Undefined

Reason

Update
Undo
Cancel

Appendix V – QARI data extraction tools



QARI - Qualitative Assessment and Review Instrument

ReviewsStudyCategoriesSynthesisLogoutAbout

Select

Detail

Assessment

Extraction

Findings

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

No


Update

Undo

Cancel

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Appendix V – QARI data extraction tools – Findings



QARI - Qualitative Assessment and Review Instrument

ReviewsStudyCategoriesSynthesisLo

Select
Detail
Assessment
Extraction
Findings

Findings for: Author - Journal (2011)

Finding

Illustration from Study
(Include Page Reference)

Evidence

Category

Include

(None)

Yes

Insert

Undo

Cancel

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Appendix VI – JBI Levels of evidence

The Joanna Briggs Institute, our Collaborating Centres and Evidence Translation Groups currently assign a level of evidence to all conclusions drawn in JBI Systematic Reviews.

The JBI Levels of Evidence are:

Levels of Evidence	Feasibility F (1-4)	Appropriateness A (1-4)	Meaningfulness M (1-4)	Effectiveness E (1-4)	Economic Evidence EE (1-4)
1	Metasynthesis of research with unequivocal synthesised findings	Metasynthesis of research with unequivocal synthesised findings	Metasynthesis of research with unequivocal synthesised findings	Meta-analysis (with homogeneity) of experimental studies (eg RCT with concealed randomisation) OR One or more large experimental studies with narrow confidence intervals	Metasynthesis (with homogeneity) of evaluations of important alternative interventions comparing all clinically relevant outcomes against appropriate cost measurement, and including a clinically sensible sensitivity analysis
2	Metasynthesis of research with credible synthesised findings	Metasynthesis of research with credible synthesised findings	Metasynthesis of research with credible synthesised findings	One or more smaller RCTs with wider confidence intervals OR Quasi-experimental studies (without randomisation)	Evaluations of important alternative interventions comparing all clinically relevant outcomes against appropriate cost measurement, and including a clinically sensible sensitivity analysis
3	a. Metasynthesis of text/opinion with credible synthesised findings b. One or more single research studies of high quality	a. Metasynthesis of text/opinion with credible synthesised findings b. One or more single research studies of high quality	a. Metasynthesis of text/opinion with credible synthesised findings b. One or more single research studies of high quality	a. Cohort studies (with control group) b. Case-controlled c. Observational studies (without control group)	Evaluations of important alternative interventions comparing a limited number of appropriate cost measurement, without a clinically sensible sensitivity analysis
4	Expert opinion	Expert opinion	Expert opinion	Expert opinion, or physiology bench research, or consensus	Expert opinion, or based on economic theory

Appendix VII – MASTARI critical appraisal tools Randomised Control / Pseudo-randomised Trial



MAStARI - Meta Analysis of Statistics Assessment and Review Instrument

ReviewsStudyLogoutAbout

Select
Detail
Assessment
Extraction
Results
Meta-Analysis

Assessment for : Author - Journal (2011)

Type: Primary
User: catalin1
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
Reason

UpdateUndoCancel

Appendix VII – MASTARI critical appraisal tools
Comparable Cohort / Case Control Studies



MAStARI - Meta Analysis of Statistics Assessment and Review Instrument

ReviewsStudyLogoutAbout

Select

Detail

Assessment

Extraction

Results

Meta-Analysis

Assessment for : Author - Journal (2011)

Type: Primary

User: catalin1

Design: Comparable Cohort / Case Control Studies

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

Appendix VII – MASTARI critical appraisal tools Descriptive / Case Series Studies



MAStARI - Meta Analysis of Statistics Assessment and Review Instrument

[Reviews](#)
[Study](#)
[Logout](#)
[About](#)

Select

Detail

Assessment

Extraction

Results

Meta-Analysis

Assessment for : Author - Journal (2011)

Type: Primary

User: catalin1

Design: Descriptive / Case Series Studies

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 style="width: 100%;" 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 style="width: 100%;" 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 style="width: 100%;" type="text"/>
4) Were outcomes assessed using objective criteria?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input style="width: 100%;" 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 style="width: 100%;" 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 style="width: 100%;" 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 style="width: 100%;" type="text"/>
8) Were outcomes measured in a reliable way?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input style="width: 100%;" type="text"/>
9) Was appropriate statistical analysis used?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input style="width: 100%;" type="text"/>

Include Undefined

Reason

Update
Undo
Cancel

Appendix VIII – 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 randomisation 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 randomised controlled trials/quasi-randomised 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 VI*.

Randomised and quasi-randomised controlled trials

There are 10 questions to guide the appraisal of randomised and quasi-randomised controlled trials.

1. Was the assignment to treatment groups truly random?

There are three broad types of randomisation within trials, randomisation, quasi- (or pseudo) and stratified randomisation. True randomisation 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 randomisation will minimise selection bias, thus identification of the method of randomisation provides reviewers with a good indication of study quality. In the presence of true randomisation, 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-randomisation, 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 randomisation commonly utilised in randomised 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 randomisation was used, it should be described with sufficient detail to enable reviewers to determine whether the method used was 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 randomisation. Generalist phrases such as “random”, “random allocation” or “randomisation” are not sufficient detail for a reviewer to conclude randomisation 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. Were 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. Was 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 randomisation. 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 ²

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 randomised to, and had no subsequent influence on any changes in allocation.

4. Were the outcomes of people who withdrew described and included in the analysis?

Commonly intention to treat analysis is utilised 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 analysed in the groups to which they were randomised 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. ²

5. Were those assessing the outcomes blind to the treatment allocation?

In randomised 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.²

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. Were the control and treatment groups comparable at entry?

Homogeneity or comparability at entry is related to the method of allocation. If allocation was truly random, groups are more likely to be comparable as characteristics are considered to be randomly distributed across both groups. However, randomisation 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. Were 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 were treated – other than the intervention of interest. If there was a difference in how the groups were treated that arose 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 away from the accuracy the primary authors would otherwise have intended. Randomisation, blinding and allocation concealment are intended to reduce the effects of unintentional differences in treatment between groups.

8. Were 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 needs 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. Were outcomes measured in a reliable way?

Were the instruments used to measure outcomes adequately described, and had 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. Was appropriate statistical analysis used?

As with any consideration of statistical analysis, consideration should be given to whether there was a more appropriate alternate statistical method that could have been used. 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 randomised trials translate into effectiveness across broader populations in clinical settings and provide information on adverse events and risks.²

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 minimised 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 behavioural, 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 were assessed based on existing definitions or diagnostic criteria, then the answer to this question is likely to be yes. If the outcomes were assessed using observer reported, or self reported scales, the risk of over- or under-reporting is increased, and objectivity is compromised. Importantly, determine if the measurement tools used were validated instruments as this has a significant impact on outcome assessment validity.

6. Was 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. Were 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. Were outcomes measured in a reliable way?

Having established the objectivity of the outcome measurement instrument (see item 5 of this scale), it's important to establish how the measurement was conducted. Were those involved in collecting data trained or educated in the use of the instrument/s? If there was more than one data collector, were they similar in terms of level of education, clinical or research experience, or level of responsibility in the piece of research being appraised?

9. Was appropriate statistical analysis used?

As with any consideration of statistical analysis, consideration should be given to whether there was a more appropriate alternate statistical method that could have been used. The methods section of cohort 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 utilising regression analysis, it is useful to identify if the study identified which variables were included and how they related to the outcome. If stratification was the analytical approach used, were the strata of analysis defined by the specified variables? Additionally, it is also important to assess the appropriateness of the analytical strategy in terms of the assumptions associated with the approach as differing methods of analysis are based on differing assumptions about the data and how it will respond.

Descriptive/Case-series**1. Was 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 sampling. Studies may report random sampling from a population, and the methods section should report how sampling was performed.

2. Were the criteria for inclusion in the sample clearly defined?

How was the sample recruited? Give consideration to whether responders have potential to differ in some significant way to non-responders. Was inclusion based on clearly defined characteristics or subjective values and opinions such as personal interest of the participants in the topic.

3. Were 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. Were outcomes assessed using objective criteria?

If the outcomes were assessed based on existing definitions or diagnostic criteria, then the answer to this question is likely to be yes. If the outcomes were assessed using observer reported, or self reported scales, the risk of over or under reporting is increased, and objectivity is compromised. Importantly, determine if the measurement tools used were validated instruments as this has a significant impact on outcome assessment validity.

5. If comparisons were being made, was 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. Was 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. Were 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. Were outcomes measured in a reliable way?

It's important to establish how the measurement was conducted. Were those involved in collecting data trained or educated in the use of the instrument/s? If there was more than one data collector, were they similar in terms of level of education, clinical or research experience, or level of responsibility in the piece of research being appraised? 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. Was 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.



"It's nothing that a few stem cells and 75 years of research can't fix."

Appendix IX – MASTARI data extraction tools

Extraction details



MAStARI - Meta Analysis of Statistics Assessment and Review Instrument

ReviewsStudyLogoutAbout

Select
Detail
Assessment
Extraction
Results
Meta-Analysis

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

Appendix IX – MASTARI data extraction tools

Dichotomous Data



MAStARI - Meta Analysis of Statistics Assessment and Review Instrument

ReviewsStudyLogoutAbout

SelectDetailAssessmentExtractionResultsMeta-Analysis

Dichotomous Results for: Author - Journal (2011)


Intervention	Result	
	n	N
New Abbreviation	<input type="text"/>	<input type="text"/>
V		
New Abbreviation	<input type="text"/>	<input type="text"/>

< back

DBL Data Entry

Delete Results

Continuous Data



MAStARI - Meta Analysis of Statistics Assessment and Review Instrument

ReviewsStudyLogoutAbout

SelectDetailAssessmentExtractionResultsMeta-Analysis

Continuous Results for: Author - Journal (2011)


Intervention	Result		
	Mean	SD	N
New Abbreviation	<input type="text"/>	<input type="text"/>	<input type="text"/>
V			
New Abbreviation	<input type="text"/>	<input type="text"/>	<input type="text"/>

< back

DBL Data Entry

Delete Results

Appendix X – ACTUARI critical appraisal tools



ACTUARI - Analysis of Cost, Technology and Utilisation Assessment and Review Instrument

[Reviews](#)
[Study](#)
[Logout](#)
[About](#)

Select
Details
Assessment
Extraction
Results

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"/>	<input type="text"/>
2) Is there comprehensive description of alternatives?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
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"/>	<input type="text"/>
4) Has clinical effectiveness been established?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
5) Are costs and outcomes measured accurately?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
6) Are costs and outcomes valued credibly?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
7) Are costs and outcomes adjusted for differential timing?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
8) Is there an incremental analysis of costs and consequences?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
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"/>	<input type="text"/>
10) Do study results include all issues of concern to users?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
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"/>	<input type="text"/>

Include

Reason

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Appendix XI – 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 ⁵⁵:

- 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 ⁵⁵:

- 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 ⁵⁵:

- 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 ⁵⁵:

- Was there evidence that the program's effectiveness has been established? Was this done through a randomised, 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 ⁵⁵:

- 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 ⁵⁵:

- 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 ⁵⁵:

- 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 ⁵⁵:

- Were the additional (incremental) costs generated by the use of one alternative over another compared with the additional effects, benefits or utilities generated?

9. Were sensitivity analyses conducted to investigate uncertainty in estimates of cost or consequences?

Questions that will assist you in addressing this criterion ⁵⁵:

- 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 ⁵⁵:

- 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 generalisability 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 generalisable 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 XII – 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 XII – ACTUARI data extraction tools

Clinical effectiveness and economic results



ACTUARI - Analysis of Cost, Technology and Utilisation Assessment and Review Instrument

ReviewsStudyLogoutAbout

Select
Details
Assessment
Extraction
Results

New Outcome for: Author - Journal (2011) - [Edit Extraction Details](#)

Clinical Effectiveness results

Study designs:

Year range of primary studies:

Analysis used:

Clinical outcome results:

Economic Effectiveness results

Date/s of economic data:

Modelling used:

Measure of benefits used in economic evaluation:

Direct costs:

Indirect costs:

Currency:

Statistical analysis of costs:

Sensitivity analysis:

Estimated benefits used in EE:

Cost results:

Synthesis of costs and results:

Outcome category

Clinical effectiveness

+ 0 -

+ ☒ A ☐ B ☐ C

Cost 0 ☐ D ☐ E ☐ F

- ☐ G ☐ H ☐ I

Key

Effectiveness Cost


+ Better Lower

0 Equal Equal

- Poorer Higher

Update outcome

Appendix XIII – NOTARI critical appraisal tools



NOTARI - Narrative, Opinion and Text Assessment and Review Instrument

ReviewsPublicationCategoriesSynthesisLogoutAbout

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 XIV – NOTARI data extraction tools
(Conclusions)



NOTARI - Narrative, Opinion and Text Assessment and Review Instrument

ReviewsPublicationCategoriesSynthesisLogoutAbout

SelectDetailAssessmentExtractionConclusions

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

No

UpdateUndoCancel

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NOTARI - Narrative, Opinion and Text Assessment and Review Instrument

ReviewsPublicationCategoriesSynthesisLogoutAbout

SelectDetailAssessmentExtractionConclusions

Conclusions for: Author - Journal (2011)

Conclusion

Illustration from Publication
(Include Page Reference)

Evidence

(None)

Category

Include

Yes

InsertUndoCancel

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Appendix XV – Some notes on searching for evidence

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 U.S. National Library of Medicine’s 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 5,200 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:

- In-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.
- Citations that precede the date that a journal was selected for MEDLINE indexing (when supplied electronically by the publisher).
- Some OLDMEDLINE citations that have not yet been updated with current vocabulary and converted to MEDLINE status.
- Citations 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-1990’s.
- Citations to author manuscripts of articles published by NIH-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 U.S. National Library of Medicine's® (NLM) premier bibliographic database that contains approximately 18 million references to journal articles in life sciences with a concentration on biomedicine.

Ovid is the search system provided to the Health Sciences/UCH/TCH community by the Health Sciences Library. It includes MEDLINE, as well as 12 other databases. 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 approx. 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.

Selected Ovid Features (Cont.)	Selected PubMed Features (Cont.)
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 customize 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.
3 to 32 week time lag from journal publication to Ovid MEDLINE access.	1 to 8 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, healthcare, 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".⁶¹

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.*⁴

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 organisations 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 may 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 organised 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://phppartners.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 organised 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; and
- (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 & 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 randomised 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, organisations, 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 Organisations

Do a Yahoo or Google Search using keywords Acupuncture, Alternative Medicine, Alternative Medicine databases, Acupuncture Organisations, 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 organisations 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 organisations 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 specialise 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 in that it is:

- Not formally part of 'traditional publishing models'. Producers, to name a few, include research groups, non-profit organisations, universities and government departments.
- In many cases high-quality research still waiting to be published and/or indexed.
- Not widely disseminated but nonetheless important in that an infrastructure does exist to disseminate this material and make it visible.
- Some organisations 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. I like Intute's brilliant search options: 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 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 allowing you to 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'll 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.

Its very good for a global perspective, includes OpenSIGLE, Chinese, Indian, African, Korean etc sources and 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,²⁷ 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** contains indexing and abstracts for more than 8,300 journals, with full text for more than 4,500 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 1,000 titles. The database contains unmatched full text coverage in biology, chemistry, engineering, physics, psychology, religion & 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 1,300 generic drug patient education sheets with more than 4,700 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 behavioural sciences. The database provides abstracts of journal articles and citations to book reviews drawn from over 1,800+ 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 and 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's designed to find the 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 4,000 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 5 patent offices
- “Articles-in-Press” from over 3,000 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 favourite 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 analysing 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 behaviours 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 8 individually or altogether using a single strategy. CENTRAL - The Cochrane Central Register of Controlled Trials (Clinical Trials) – filters controlled clinical trials from the major healthcare 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 Randomised 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 U.S. spelling without any limits put on them or put into combined sets.

PsycINFO (Ovid)

As with CINAHL, there is no specific heading for Randomised 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 U.S. spelling) without any limits put on them or put into combined sets.

TRIP database

Search – as Phrase (within single quotation marks)

- 'randomised 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 Randomised 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 optimised 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 randomised 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, randomised 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.

Controlled Trials (CCT)

CCT provides access to databases that house RCT data for the following regularly updated organisations:

- 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

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 randomised 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 randomised 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 randomised 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.⁶²

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:⁶²

- 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)
- CONnaissance 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 4 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
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[WordIndexed] Searches the language the article was written in.	LA Spanish

Tag	Description	Example
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 U.S.-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

Typing in 'expert opinion' will be a very broad search term and locate a large number of hits, so this needs to be refined. Use the 'Limits' screen to filter according to 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, 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 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”.



While experts remain at odds over the issue of when life begins, most agree it's sometime after work.