Paper 2: Tailored evidence synthesis approaches are required to answer diverse questions: a pragmatic evidence synthesis toolkit from JBI

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EA is the director of the synthesis science program for JBI. ZJ is the executive director of JBI. All authors are chairs and/or convenors of JBI methodology groups focussed on synthesis. EA is the current chair of the JBI Scientific Committee. CL, MS, AM, ZJ, ARW, CE and ZM are members of the JBI Scientific Committee. EA and ZM are editors of the *JBI Manual for Evidence Synthesis*; all authors are contributing co-authors to chapters within the manual. EA is the editor in chief, CS a senior associate editor, and MK and CE associate editors of *JBI Evidence Synthesis.* EA, THB, MK, YJ, CE, ARW, and ZM deliver the JBI systematic review training program. ZM is currently responsible for the development of JBI SUMARI software and JBI systematic review training program. ZM is supported by an NHMRC investigator grant APP1195676.

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Abstract

Evidence synthesis is critical in evidence-based healthcare and is a core program of JBI. JBI evidence synthesis is characterised by a pluralistic view of what constitutes evidence and is underpinned by a pragmatic ethos to facilitate the use of evidence to inform practice and policy. This second paper in this series provides a descriptive overview of the JBI evidence synthesis toolkit with reference to resources for 11 different types of reviews. Unique methodologies such as qualitative syntheses, mixed methods reviews and scoping reviews are highlighted. Key features include standardised and collaborative processes for development of methodologies and a broad range of tailored resources to facilitate the conduct of a JBI evidence synthesis, including appraisal and data extraction tools, software to support the conduct of a systematic review and an intensive systematic review training program. JBI is one of the leading international protagonists for evidence synthesis, providing those who want to answer health-related questions with a toolkit of resources to synthesize the evidence.

The first paper in this series introduced the JBI model of evidence-based healthcare (1); the model lays the conceptual foundation for the practical efforts towards knowledge translation that form the work programs of JBI. This second paper in this series provides an overview of the key features of JBI's program of evidence synthesis including its beginnings, introduction to the range of review methodologies and methods that are currently a part of the JBI evidence synthesis toolkit, the collaborative methods and process used in their development and an overview of the tools and support available for the conduct of a JBI evidence synthesis. The following paper in this series naturally follows the trajectory of evidence and knowledge translation from this initial handling by the science of synthesis, through to its practical implementation and use to inform clinical decision-making worldwide.(2)

1.1 JBI and evidence synthesis

Using the best available evidence to inform decision-making is the ethos that underpins the vision and mission of JBI and therefore, all of the organization's programs (see JBI model of evidence-based healthcare),(1, 3) including its ongoing investment in the conduct of systematic reviews and the science of synthesis. A key component of JBI's full program of evidence synthesis is its focus on the conduct of systematic reviews to inform healthcare decision-making; this work is disseminated in one of JBI's journals, *JBI Evidence Synthesis.* Concomitant with the conduct of reviews to guide practice is also the ongoing development of methodologies and methods, as well as updating of guidance and messaging, to conform with internationally accepted standards for authors conducting JBI reviews.(4)

As reflected in the JBI model,(1, 3) the organization has, at its core, aspired to a pragmatic focus across its work programs, including synthesis.(5) Methodology and methods emphasize actionable knowledge, where recommendations and implications for policy or practice are not a by-product of the review, but the intended primary output.(6) Methodologically, this is reflected in Peirce's pragmatic maxim whereby practical consequences are the guiding interest in methodological developments, and where recommendations have generalizable characteristics that inform issues of global health.(7) Importantly, the questions that spawn the majority of JBI systematic reviews arise directly from healthcare professionals. Indeed, healthcare professionals, intent on using the best available evidence to promote consistency in care and service delivery provided the seed for the beginnings of JBI and its programs of work. What began as an attractive proposition in the mid-1990's - using evidence to inform practice - initially following the seminal work of the then Cochrane Collaboration and adoption of their standards of reviews of effects of interventions, quickly evolved

by necessity. Initial standards for conduct and reporting for systematic reviews in healthcare had long been focussed on reviews assessing the effectiveness of an intervention or a therapy using experimental methodologies. (8, 9) This is still reflected in the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) 2020 statement, which remains principally geared towards reporting these types of reviews.(10) However, many of the questions that required answering to inform real practice issues, were not limited to treatment or intervention for a condition, nor were there ample randomized controlled trials available to inform all of the questions. Very quickly, it became clear that new methodologies and methods of synthesis would be required to deal with the natural progression, expansion and demand for additional evidence to inform practice; this realization highlights another key feature of the JBI program of synthesis – a pluralistic view of evidence.(11) This feature is apparent within and between the JBI methodologies, visible with the consideration and inclusion of observational studies (where appropriate) to inform questions of effectiveness (with realization of the added complexities this involves in synthesis and its implications) through to the inclusion of qualitative evidence and also expert opinion as recognized sources of 'evidence to inform practice' respectively.(12, 13) To further solidify this pluralistic stance, JBI stresses the importance for considerations of the Feasibility, Appropriateness, Meaningfulness and Effectiveness (FAME) of interventions, treatments, strategies and recommendations in its approach to synthesizing evidence to inform decision-making.(3)

1.2 JBI evidence synthesis

A JBI systematic review is a review product that adheres to JBI standards of conduct and reporting and indeed, is published by JBI. Irrespective of where a reviewer decides to publish their final work, the JBI methodologies, methods and tools are available, and are frequently adopted by reviewers across many diverse fields in health and beyond. Despite the range of available methodologies and methods across the JBI program of synthesis, fundamentally, the core steps and processes involved across all of them are similar.(4) This section highlights some of the unique features of the JBI program that are reflected in Table 1.

JBI has been one of the leading international protagonists for synthesis of qualitative evidence.(13) These reviews focus on analysing human experience and cultural, social and organizational phenomena (for example exploring and explaining why interventions are, or are not, effective in different settings and from the perspective of different stakeholders).(13) While there are a multitude of recognizable approaches to qualitative synthesis, the JBI approach was developed specifically to guide healthcare practice. This overriding ethos is reflected in the methodology and

the methods that are focussed on maximizing standardization, transparency and credibility. All of the relevant findings from primary studies are extracted verbatim (with illustrations), remaining as close as possible to the author's original interpretations. Findings are then categorized, based on similarity of meaning, and further integrated to construct synthesized findings that provide a practical and actionable response to the review question. An extension of these methods is identifiable in the methodology developed to synthesize expert opinion and policy.(12) Driving this methodology was recognition of diverse knowledge needs of health professionals when a synthesis of randomized controlled trials, or other quantitative methods were inappropriate or insufficient. In particular, when evidence is needed on experiences such as family members experiences with having a relative in intensive care,(14) reaffirming practice in healthcare is multifaceted. Similarly, mixed methods research has infiltrated evidence synthesis methods that promote transparent amalgamation of the findings following methods of synthesis of quantitative data with synthesized qualitative evidence assessing experiences with the same intervention for example. Depending on the type of question being addressed, the JBI mixed methods methodology may demand integration of the two types of evidence at different points in the review process.(15)

Much of the methodological guidance developed by JBI has centred on the appropriate handling of data derived from observational studies, or non-experimental studies. This is not just with regards to their use to inform questions of effectiveness, as mentioned, but also where these types of studies are in fact the most appropriate research designs to answer specific questions that align to three review types: reviews of etiology and risk, reviews of prevalence and cumulative incidence, and reviews of diagnostic test accuracy. In these types of reviews, heterogeneity, whether it is methodological, clinical and/or statistical, is expected.(16) For example, most studies assessing prevalence of a condition are cross-sectional in design. The JBI program has developed tools to assess the quality of prevalence studies and to conduct meta-analyses for this type of data (proportional).(17-19)

JBI has also been a pioneer in the development of synthesis methodology for evidence of costs and economic evaluations, including cost effectiveness, cost utility, or cost benefit.(20) An extension of the canonical clinical effectiveness review, health economic evaluation reviews require methods for the additional consideration of costs relative to clinical benefits or consequences of healthcare interventions or programs.(21) Some of the innovations of JBI include the development of a critical appraisal tool to evaluate the rigor of these types of primary research studies, and highlighting the necessity of high quality sensitivity analyses in the synthesis of health economic evidence.

Finally, scoping reviews can be used to determine the scope or range of evidence around a topic and to map concepts or definitions.(22) Considering their intent, scoping reviews offer more 'flexibility'

in the approach to synthesis, in that there are no predefined analytic methods for analysis and presentation of data. The end point should be determined by the question the review is addressing, and also importantly, facilitate user experience and understanding of the field or topic.

In recognition of the importance of transparent and reproducible processes to assist in the formulation of implications and recommendations from the results of a systematic review a working group of the JBI Scientific Committee (see section 1.3) created ConQual to assess the confidence in synthesized findings derived from a JBI qualitative synthesis.(23) ConQual has been designed specifically for reviews following the meta-aggregative approach and was developed prior to the finalisation of CERQual, established by the GRADE working group.(24) While both approaches are similar in their aims, the approaches differ in their judgements of certainty or confidence and coherence.

Table 1: The JBI evidence synthesis toolkit: JBI methodologies of synthesis and available guidance.

Review Type	**Aim**	**Reference**
Experiential (Qualitative)	To investigate the experience or meaningfulness of a particular phenomenon	Lockwood C, Porrit K, Munn Z, Rittenmeyer L, Salmond S, Bjerrum M, Loveday H, Carrier J, Stannard D. Chapter 2: Systematic reviews of qualitative evidence. In: Aromataris E, Munn Z (Editors). *JBI Manual for Evidence Synthesis.* JBI, 2020. Available from https://synthesismanual.jbi.global. https://doi.org/10.46658/JBIMES-20-03
Effectiveness	To evaluate the effectiveness of a certain treatment/practice in terms of its impact on outcomes	Tufanaru C, Munn Z, Aromataris E, Campbell J, Hopp L. Chapter 3: Systematic reviews of effectiveness. In: Aromataris E, Munn Z (Editors). *JBI Manual for Evidence Synthesis.* JBI, 2020. Available from https://synthesismanual.jbi.global. https://doi.org/10.46658/JBIMES-20-04
Expert opinion/policy	To review and synthesize current expert opinion, text or policy on a certain phenomena	McArthur A, Klugarova J, Yan H, Florescu S. Chapter 4: Systematic reviews of text and opinion. In: Aromataris E, Munn Z (Editors). *JBI Manual for Evidence Synthesis.* JBI, 2020. Available from https://synthesismanual.jbi.global. https://doi.org/10.46658/JBIMES-20-05
Prevalence and/or Incidence	To determine the prevalence and/or incidence of a certain condition	Munn Z, Moola S, Lisy K, Riitano D, Tufanaru C. Chapter 5: Systematic reviews of prevalence and incidence. In: Aromataris E, Munn Z (Editors). *JBI Manual for Evidence Synthesis.* JBI, 2020. Available from https://synthesismanual.jbi.global. https://doi.org/10.46658/JBIMES-20-06

Costs/Economic Evaluation	To determine the efficiency of a particular approach/treatment strategy, particularly in terms of cost effectiveness, utility or benefit	Gomersall JS, Jadotte YT, Xue Y, Lockwood S, Riddle D, Preda A. The systematic review of economic evaluation evidence. In: Aromataris E, Munn Z (Editors). *JBI Manual for Evidence Synthesis.* JBI, 2020. Available from https://synthesismanual.jbi.global. https://doi.org/10.46658/JBIMES-20-07
Etiology and/or Risk	To determine the association between particular exposures/risk factors and outcomes	Moola S, Munn Z, Tufanaru C, Aromataris E, Sears K, Sfetcu R, Currie M, Lisy K, Qureshi R, Mattis P, Mu P. Chapter 7: Systematic reviews of etiology and risk. In: Aromataris E, Munn Z (Editors). *JBI Manual for Evidence Synthesis.* JBI, 2020. Available from https://synthesismanual.jbi.global. https://doi.org/10.46658/JBIMES-20-08
Mixed methods	To investigate whether and how an intervention (or practice) works and inform complex clinical decision-making	Lizarondo L, Stern C, Carrier J, Godfrey C, Rieger K, Salmond S, Apostolo J, Kirkpatrick P, Loveday H. Chapter 8: Mixed methods systematic reviews. In: Aromataris E, Munn Z (Editors). *JBI Manual for Evidence Synthesis.* JBI, 2020. Available from https://synthesismanual.jbi.global. https://doi.org/10.46658/JBIMES-20-09
Diagnostic Test Accuracy	To determine how well a diagnostic test works in terms of its sensitivity and specificity for a particular diagnosis	Campbell JM, Kulgar M, Ding S, Carmody DP, Hakonsen SJ, Jadotte YT, White S, Munn Z. Chapter 9: Diagnostic test accuracy systematic reviews. In: Aromataris E, Munn Z (Editors). *JBI Manual for Evidence Synthesis.* JBI, 2020. Available from https://synthesismanual.jbi.global. https://doi.org/10.46658/JBIMES-20-10
Umbrella	To summarise the available evidence derived from systematic reviews	Aromataris E, Fernandez R, Godfrey C, Holly C, Khalil H, Tungpunkom P. Chapter 10: Umbrella Reviews. In: Aromataris E, Munn Z (Editors). *JBI Manual for Evidence Synthesis.* JBI, 2020. Available from https://synthesismanual.jbi.global. https://doi.org/10.46658/JBIMES-20-11
Scoping	To explore and systematically map the literature available on a topic	Peters MDJ, Godfrey C, McInerney P, Munn Z, Tricco AC, Khalil, H. Chapter 11: Scoping Reviews (2020 version). In: Aromataris E, Munn Z (Editors). *JBI Manual for Evidence Synthesis*, JBI, 2020. Available from https://synthesismanual.jbi.global. https://doi.org/10.46658/JBIMES-20-12
Psychometric	To evaluate the measurement properties of a certain test(s), normally to determine the	Stephenson M, Riitano D, Wilson S, Leonardi-Bee J, Mabire C, Cooper K, Monteiro da Cruz D, Moreno-Casbas MT, Lapkin S. Chapter 12: Systematic reviews of measurement properties. In: Aromataris E, Munn Z (Editors). *JBI Manual for Evidence Synthesis.* JBI, 2020. Available

	reliability and validity of a particular test or assessment.	from https://synthesismanual.jbi.global. https://doi.org/110.46658/JBIMES-20-13

Adapted from: Munn *et al.(11))*

1.3 Methods and processes

Development of the JBI methodologies and methods of synthesis and the accompanying guidance(4) has followed a consistent process. As mentioned, the questions that direct JBI syntheses arise from health professionals and researchers across the globe. Historically, questions were being posed for which JBI had no appropriate nor developed methodological guidance of synthesis available. Increase in demand coupled with identifiable expertise has been the common impetus for JBI to invest and convene a JBI international methodology group to develop guidance for conduct of a JBI review.(25)

The organizational decision to convene a methodology group aligned to evidence synthesis is made by the international JBI Scientific Committee. This committee provides oversight of the JBI program of methodological development and comprises a chair and a range of ex-officio positions from across JBI, including program directors, editors in chief of journals, and chairs of methodology groups. Members of the committee also include health professionals, researchers, methodologists and systematic reviewers from the JBI Collaboration with regional (Australia, Europe, Americas, Asia, Africa) representation from across the globe.(26) Editors and educators also contribute to discussions of the committee and similarly take their direction from the committee regarding publication and delivery of programs respectively.

The methodology groups are aligned to each type of evidence synthesis, 11 in total (see Table 1). They are organized as individual committees with a chair and convenor and generally operate in a cyclical fashion of prioritization, development and revisitation. Groups meet regularly to iteratively discuss issues, conduct projects and collaborate in writing and research. Where available, existing research and current methods for evidence synthesis are used as the starting point for the development of JBI guidance; more frequently, multiple exemplar reviews that may address a question aligned to the work of each group are also assessed in detail to help determine application and output of diverse methods used by reviewers previously. Face to face meetings of the various groups occur annually and coincide with the annual scientific meeting of JBI. Concurrently, these meetings are further utilized to design and perform surveys, workshops, and pilot tools to test aspects of methodology and gain further feedback and evaluation of synthesis methods (for example

a critical appraisal tool or extraction instrument) from the broader pool of health professionals and researchers who attend. All of these opportunities are used to inform and consolidate guidance for conduct and reporting. Each methodology group is required to provide updates of progress and any challenges at regular meetings of the JBI Scientific Committee for discussion and debate. In some cases, the investigations of the methodology groups recommend adoption of methodology and methods developed by other groups rather than de novo development, for example following the lead of Cochrane in the case of reviews of diagnostic test accuracy(27) and that of the COnsensus based Standards for the selection of health Measurement INstruments (COSMIN) initiative for reviews of measurement properties.(28) Ultimately, any guidance developed or presented is always provided to the JBI Scientific Committee for ongoing oversight, feedback and finally for ratification, prior to publication as formal guidance for a JBI evidence synthesis methodology in the *JBI Manual for Evidence Synthesis.*(4)

Any innovations or changes to JBI methodology and methods of synthesis are messaged to the JBI collaboration including authors, and also importantly educators, peer reviewers and editors. Authors are expected to adhere to the available guidance that dictates the scope of submissions to the journal, *JBI Evidence Synthesis*. Members of methodology groups are expected to contribute regularly to peer review for the journal and also provide advice to the editors when requested. Standard journal processes of independent peer review by members of the JBI collaboration and other experts in synthesis as well as review by expert editors also contribute to ensuring adherence to JBI guidance.

1.4 Tools of the trade

JBI has also developed a range of tools and resources to accompany the JBI evidence synthesis toolkit and facilitate authors to undertake a systematic or scoping review.

1.4.1 JBI Manual for Evidence Synthesis

The *JBI Manual for Evidence Synthesis*(4) is an online publication which is updated regularly, following the processes detailed above. Currently, the content of the manual has focussed on both conduct and reporting of JBI reviews and protocols and its contents are currently being translated into other languages. The advent of PRISMA 2020(10), and the expansion of international standards for the minimal reporting requirements for systematic reviews in general, has better aligned to the transparent reporting requirements previously and currently demanded of JBI reviews.(29) In light of this, future iteration of the *JBI Manual for Evidence Synthesis* will revert to guidance for conduct only.

1.4.2 Appraisal tools

Among the most popular items to emerge from the JBI program of synthesis are the JBI critical appraisal tools.(19, 30-32) The JBI appraisal tools are checklists developed primarily around study designs that will be encountered during conduct of any JBI systematic review. Most tools have approximately nine-13 signalling questions that align to domains of bias and issues pertinent to methodological quality in quantitative research design and dependability and credibility in qualitative research studies and issues of quality across both.(33) Each checklist is freely available and is accompanied by detailed guidance regarding interpretation and application of the signalling questions in context. Use of these appraisal tools is required in any JBI systematic review, however they are regularly used by reviewers beyond the JBI collaboration and also by evidence-based practitioners applying their appraisal skills to critique evidence without necessarily conducting a systematic review. Versions are available in different languages. All these tools are integrated into the software JBI SUMARI which facilitates the conduct of JBI reviews.(34)

1.4.3 Education

JBI and its collaborating entities(26) regularly deliver a comprehensive systematic review training program. This program is organized into three modules, the first includes an introduction to JBI, evidence-based healthcare, evidence synthesis, and the first key steps of any evidence synthesis, from question development through to searching for evidence. The second module then addresses the remaining steps in the conduct and reporting of a systematic review of quantitative evidence (predominantly effects), whilst the third module repeats the process for systematic reviews of qualitative evidence. The program is delivered both online and face-to-face as an intensive workshop and is centred on use of the JBI's SUMARI software to facilitate the conduct of a review.(35) As a practical guide to the conduct of a systematic review, participants are also facilitated through the beginnings of their protocol development. The teaching program is supported by the JBI international trainers' network, which consists of approximately 250 trainers certified to teach this program by the JBI Train-the-Trainer program, held in different regions worldwide to encourage local evidence synthesis capacity development across the globe. This group works together to develop and update materials on an annual basis.(35)

1.4.4 Software

Concurrent with the development of methodologies and methods for synthesis has been the development of software to facilitate the conduct of a systematic review – JBI SUMARI.(34) Responding to different review questions requires different methodologies, ten of which have been included in JBI SUMARI. JBI SUMARI started with the development of a software to guide the

conduct of qualitative evidence synthesis and over the intervening 15 years has evolved into a full web interface to help review authors through all of the stages of the review process, from question and protocol development to finalizing the synthesis and writing the review report.(34) This support includes auto generation of text, appropriate for the specific type of review being conducted, that specifies the core details of the methods that will be used, including detailing JBI recommended practices for searching, appraisal and synthesis. The JBI appraisal tools are integrated, and the system is explicitly designed to facilitate dual independent conduct of review processes, including study selection and appraisal. JBI SUMARI accommodates statistical meta-analysis (both comparative and proportional) as well as meta-aggregation for qualitative evidence.

1.5 Conclusion

Evidence synthesis is a core program for JBI and is fundamental to support the trajectory of research through to its support of decision-making in healthcare and beyond. The JBI evidence synthesis toolkit includes methodologies and methods for 11 different types of reviews. The most appropriate methodology for any reviewer will depend on the question being addressed in the review and that the methods are appropriate for the data that will be extracted and ultimately synthesised. At their core, many of the methods employed across the range of available review options are similar and all demand transparent and rigorous conduct and reporting. Future developments for the program are currently focussed on the methods and tools used for risk of bias assessment and further innovations for umbrella reviews and mixed methods syntheses. These methodologies and methods have been developed using standardised and collaborative processes with researchers from across the globe and have also led to the concomitant development of manuals, software, appraisal tools, and educational programs to support the conduct of systematic reviews.

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