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Methodological Considerations for Systematic Reviews

Ensuring the rigor in systematic reviews: Part 1, the overview

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Well-executed systematic reviews synthesize all the relevant evidence on a topic in order to answer a clinical question. The growth in the number of systematic reviews and evidence syntheses and the potential for poor methodical design in conducting these studies are significant concerns.[1,11] Over the next few journal issues, *Heart and Lung* will present a series of columns that highlight the process of conducting a well-executed systematic review. This first column begins with a general overview of systematic reviews.

The purpose of systematic reviews

Systematic reviews are valuable studies because a single study can inform clinicians about a body of research, alleviating the burden of reading and critiquing all the studies on that topic.[3] Combining studies in a systematic review is beneficial because the results show the effect sizes of an intervention on a larger number of participants.[3] Because of the review's clinical importance, the researcher's attention to detail is critical when conducting a systematic review. For instance, there can be challenges with the results of the review if it does not include unpublished research results,[8] or it includes the wrong research.[2,15] If this happens, the researcher's conclusions can be skewed, which, if unchecked, will have a potential negative impact on future research, clinical practice, and policy decisions.[6]

The growth in the number of systematic reviews has been exponential. In an analysis of systematic review publications, Niforatos et al[10] compared the growth in the numbers of randomized controlled trials (RCT) to the growth in numbers of systematic reviews and meta-analyses (SRMA) in the period 1995–2017. Results show that there was a 138% increase in published RCTs, compared with a 4676% increase in SRMAs published during the same period. It has also been reported that there is an increase in the repetition of systematic reviews on the same topic with no new meaningful clinical research on the topic.[4,13]

If a researcher chooses to undertake a systematic review, foremost in their mind should be the recognition that the process involves a rigorous methodology. It also takes time and several people. The researcher should allow at least a 12-month timeframe from idea formulation to completion.[16] Doing a systematic review is not a solo act, and the researcher must build their team. Both the Institute of Medicine and the Cochrane Collaboration recommend that the review team should be multidisciplinary, with experts in SR methodology, statistical proficiency, as well as information specialists trained in searching bibliographic databases.[3,14]

Systematic review rigor

The rigor of a systematic review is consequential because healthcare decision-makers rely on these reviews to inform healthcare and policy. Especially important is ensuring the study's "transparency, [thus] minimizing bias and conflicts of interest, and clarity of reporting".[14] Transparency through record keeping and documentation throughout the review ensures that the researcher is accountable at every step of the process. The first step is to develop a protocol that outlines the methods to be used in the systematic review. The protocol outlines the plan to systematically gather and synthesize the body of evidence on a topic to answer a very specific question. The design of a systematic review becomes straightforward when the research team follows established standards and guidelines.

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The standards and guidelines

While many review teams might feel confident that they can synthesize the evidence in a meaningful way, systematic reviews are not a haphazard exercise. The call for more rigorous systematic reviews is abundant in the literature,[5,7,17] so it is essential that research teams be aware, comprehend, and follow guidelines that dictate the precision needed to complete the review.

The Cochrane Collaboration is considered the gold standard for systematic reviews. Thus, the Cochrane Handbook (2019) offers a rigorous methodological guideline for all systematic review researchers, not only for Cochrane affiliated teams but any team that wants to undertake a systematic review. Also, of note, the Joanna Briggs Institute uses the systematic review methodology from the Cochrane Collaboration, but for reviews of qualitative, economic, and prevalence-related evidence.

Another well-known guideline is PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis).[9] PRISMA is a reporting guideline, which details the steps and items required for the proper and transparent reporting of the systematic review process. Since the original publication of PRISMA, the affiliated group has added several additional checklists, known as extensions, to facilitate the reporting of different types of reviews.[12] It is essential for researchers to not only look at the PRISMA checklists but refer to the "elaboration" documents, which give detailed explanations about the methods for each reporting item.

The National Academy of Medicine (formerly the Institute of Medicine) handbook includes guidance about building the team, developing a protocol, and the standards for formulating the review. The handbook emphasizes that because of the influence of any systematic review in making clinical and policy decisions, time must be spent in the initial stage of the project, to detail the steps and to define the review focus.[14] Establishing the expectations of the systematic review from the beginning helps the review team stay on task as well as breaks apart a large project into more manageable pieces. An additional value of the guideline is that it will outline the steps the researcher must take in their review.

The guidelines and standards mentioned above ensure a rigorous, evidence-based systematic review. However, journal-specific guidelines may have a preferred systematic review guideline that authors must follow.

The steps

The following six columns will look at the specific steps that are necessary for rigorous systematic reviews. Column 2 will cover framing the question and developing a protocol, and Column 3 will cover identifying relevant evidence. Column 4 and Column 5 will include how to screen results and extract data. Column 6 will discuss the systematic review write-up, and Column 7 will focus on peer-reviewing systematic reviews. Dictated by guidelines, these steps ensure that your systematic review, like any clinical study, is transparent and reproducible. As librarians who have worked on many successful (and unsuccessful) systematic review projects, we will take you through the next six columns with a focus on why professional, rigorous standards in systematic reviews are essential. We will take examples from our own experiences as well as highlight well-done systematic reviews.

Declaration of Competing Interest

None

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Ensuring the rigor in systematic reviews: Part 2, preparation is key: The question and the protocol

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Preparation is Key: The Question and The Protocol

The first column of this series provided an overview of the purpose of a systematic review and meta-analyses (SRMA) and outlined what makes an SRMA rigorous. The essential first step in ensuring the rigor of an SRMA is to be clear about three things. First, is there a need for the review, and what is its purpose? Second, is the review question clearly defined? Third, has the team developed a clear research protocol? This column will address the value of taking the time to consider all these questions so the review can begin with the rigor this type of study deserves.

Does a systematic review already exist?

Knowing that a well-done systematic review can take longer than a year,[2,3] it is necessary to consider the value and importance that the synthesis brings to the field. When a research team deliberates whether an SRMA is necessary on the topic, consider whether it will either inform policy or procedure, or highlight a research gap. If the answer is yes to any of these questions, then the effort and time devoted to embarking on the synthesis should make the research a critical addition to the literature. If the answer is no, save the team time!

At the conceptual stage of an SRMA project, questions to ask include: is there already a review that answers this question? How dated is it? Or is another research team already conducting a similar review? Use databases to search for reviews on the topic, locating previous SRMAs on similar topics. If an SRMA exists, how does it differ from what the team is proposing? If the researcher discovers that there is an existing SRMA that answers the same question, decide if an updated review makes sense.

Also, the researcher needs to ask, is there enough new research to conduct a new SRMA? If there is not enough evidence in the literature to synthesize, there are plenty of alternatives review types that might be a better fit. We recommend reading "A Typology of Reviews: An Analysis of 14 Review Types and Associated Methodologies" to find other types of reviews.[4]

It is essential to check systematic review protocol registries and repositories to see if a similar SRMA is currently in process. Two we suggest are PROPSERO (https://www.crd.york.ac.uk/prospero/) and the Open Science Framework (OSF) (https://osf.io/). If the research team discovers that another group is doing a similar evidence synthesis, decide whether to replicate the work or propose an opportunity for partnership. We recently worked with a research team who wanted to carry out an SRMA; however, a quick search in PROSPERO informed the group that another research team was working on an SRMA on the very topic. The group took time to reconsider the project and eventually did an SRMA looking at a similar, but not identical, topic—researching the same disease but a different intervention.

What is already known about the topic?

If there appears to be no similar review on the topic, the next question is: is there enough original research on the topic to warrant an SRMA? The team likely already knows of original research that would fit into the project, and that is a good starting point. Using known articles, begin with a scoping search (not to be confused with a scoping review[8]) to find additional articles on the topic and get a sense of the literature's breadth. If the team does not yet include an information professional, such as a librarian, now is the time to consult with one and consider adding them to the team (Cochrane[3,6]). Throughout the SRMA project, the librarian will continue to bring value as a guide to the methods as they have often conducted many before. In particular, at this stage of the SRMA project, the librarian will save the team time by efficiently conducting the scoping search.

The results of an expertly conducted scoping search reinforces the need for the SMRA in three ways. First, it might unearth a previously or recently completed SRMA on the topic rendering the project repetitious. Second, the scoping search will identify the potential extent of literature on the topic. Third, the scoping search may find additional "validation" articles that can be used to create the final SRMA search. A validation, or "gold standard," article helps build the search strategy to find all the evidence for your topic.

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What is the foundational question?

Central to an SRMA, is the question that the review is intending to answer. The rigor of the SRMA depends on a focused and well-defined question, but this can sometimes be a challenge.[6] Another reason to include a librarian on the research team is to take advantage of their skill in developing questions that are the basis for efficient searches. The widely known structure for a question includes the elements of PICO (Patient/Population, Intervention, Comparative/Control intervention, and Outcome). PICO defines for the team the data concepts or elements of the SRMA. Importantly, the PICO concepts will be the foundation for the scoping search and form the concepts for the more extensive search to locate the final set of evidence for inclusion in the SRMA. According to the Cochrane Handbook (Cochrane[3]), the review will broadly use PICO three times. The question is central to (1) the planning phase at the time of writing the SRMA protocol, (2) deciding the eligibility of studies for inclusion or exclusion in the review, (3) defining the specific aims of the data synthesis after data extraction from each of the studies included in the review.

Has the team developed a clear research protocol? With a well-defined question in place, the research team should create a protocol and register or publish it as an announcement of the research team's intentions to undertake an SRMA. Developing the SRMA protocol ensures that the team makes decisions a priori, which helps to "reduce arbitrariness in decision-making when extracting and using data from primary research since planning provides an opportunity for the review team to anticipate potential problems" ([7], p. 1). Technically, the protocol serves as the outline and project plan that guides the research team through the SRMA process.

As with all well-done research, the protocol helps the research team establish the rationale for the project and becomes the road map for the SRMA. The protocol outlines and communicates for the team the study's directives. The protocol includes: the context and rationale for the review; identifies the primary outcomes of interest; the methods and search strategy; the inclusion/exclusion criteria; and the strategy for the synthesis of the data.[6] It also serves as the framework for the final paper and analysis due to the prescriptive writing style of an SRMA.[5]

Developing a sound protocol ensures that the research team is ready to invest their time and resources in the SRMA. Since the protocol defines the project scope, it is the guide for the team to know what is necessary to bring the project to completion. Outlining the process for the SRMA will identify the required resources and informs the team as to whether they are ready to undertake the project. For instance, logistically, an SRMA needs a research team larger than two and should include a project manager, at least two reviewers, an information professional or librarian, and, potentially, a statistician. In the protocol, be sure to include a timeline, with detail for each of the SRMA steps. The Cochrane Handbook[3] suggests a timeline to help with this (see Box 2.3.b in the handbook).

It is recommended that SRMA research teams register their protocol. As mentioned earlier, the most well-known repository is PROSPERO (https://www.crd.york.ac.uk/prospero/), which registers SRMA protocols from all over the world. The repository is searchable for reviews in progress. PROSPERO protocols are peer-reviewed, allowing for feedback on study design flaws and subsequently letting the review team modify their methods before the review gets underway.[1] Protocols can also be made available through open access registries, such as The Center for Open Science (https://www.cos.io/). Another avenue for protocol publication is professional organization websites if the project is linked to the organization, such as a guideline or policy supported by the organization.

Are you ready?

Before any research team embarks on an SRMA, they need to consider the time, effort, and resources needed to complete it. Including a librarian can streamline the effort to see if a similar SRMA exists and if there is enough information on the topic to justify the project. If the team decides to proceed, it is imperative to make sure the question is specific – another way the librarian can help. The next step is to develop a protocol. The protocol provides a guide for the research team at each stage of the project. While we have touched on some aspects of the search step of the SRMA, in column three will discuss the details for developing the search strategies to find the articles, which is the data necessary for any SRMA.

Declaration of Competing Interest

None.

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Ensuring the rigor in systematic reviews: Part 3, the value of the search

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ABSTRACT

The third column, in this seven part series, highlights: Systematic reviews must include published sources as well as consider including unpublished sources for data collection. Systematic reviews require rigorous search strategies, that are transparent and reproducible. Systematic reviews require adequate reporting of search methods

The value of any well-done systematic review and meta-analysis (SRMA) is to collect and synthesize all the research evidence to answer a given research question. A well-done SRMA saves its reader time by not having to read all the original research on a specific research question. This column will focus on the mechanics of building a reproducible and transparent search strategy to collect the body of research evidence (often articles). A transparent and reproducible search strategy is the hallmark of an SRMA and expected as part of the rigor.[8,11,22]

In the second column in this series [23], we discussed the merits of a protocol, which hinges on having a well-thought-out question to focus the intent of the SRMA. Once the question is clear, and the exclusion and inclusion criteria are well-defined in the protocol, the next step is to develop the search for evidence. In an SRMA, think of the studies found in the search as the research data, and then, as with any research, they are synthesized to become the findings of the study. The research team's goal is to cast a wide net to find all studies; that is, all the data on the topic.

Guidelines for the quality of the search recommend three criteria.[7,12] First, the search identifies all relevant records; second, the search must be transparent; and third the search must be reproducible.[2,10] The search should be comprehensive enough to capture all relevant articles, yet not so broad that there are too many irrelevant articles.[10] Achieving transparency and reproducibility is possible by documenting the steps that were taken during the search. As with all research, clear documentation of the search allows future research teams to build on the work of the SRMA, as well as to evaluate, appraise and critique it.

This column explains in more detail what sources to choose, how to ensure rigor in the search strategy, and how to keep track of the search strategy. These three elements are some of the project management factors from the protocol, adding to the methodological transparency that is the hallmark for SRMAs.

Selecting sources

The goal of an SRMA is to locate all the evidence that answers the research question. Collecting evidence begins with thinking about which citation databases, grey literature resources, and other information sources to search. It is essential to select multiple sources because one source may not contain all the information that answers the question. When thinking about where to find research evidence, the team chooses sources that include evidence on a topic both from a broad perspective, and well as from a specialty perspective. For example, we worked with a research team who was looking for non-drug alternatives to opioid prescriptions. The specialty database we searched was AMED (Allied and Complimentary Medicine Database), and for the broad perspective, we searched MEDLINE, EMBASE, and CINAHL.

A comprehensive study by Gusenbauer and Haddaway[7] measured the usability and functionality limitations of 28 database platforms commonly used in SRMAs and other evidence syntheses. They tested the databases from the user perspective to see if the resulting data

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set was useful for the user's query. The multidisciplinary cross-section of databases found that 14 database platforms are well-suited and are considered useful resources for SRMAs or other review types (for other review types see Grant and Booth[4]). Among these databases are Cochrane Library, Embase, APA PsycInfo (formerly PsycINFO), PubMed, Web of Science, and CINAHLPlus. In addition, we recommend other supplementary resources be considered depending on the topic and where the topic is typically published. These additional sources could include GoogleScholar, JSTOR, and Education Resources Information Center (ERIC). Keeping good notes is important for methodological rigor,[11,14] so the research team should document which databases are searched, and why, to ensure there is a trail of the decisions made. The research team includes this information both in the protocol and the final manuscript.

It is important to find evidence for the SRMA from all sources possible, therefore it is essential to search for resources that will discover grey literature on the topic.[2] Grey literature includes publications such as reports, theses, conference proceedings, clinical trial registrations, author preprints, and official documents from government departments and other organizations.[5] Grey literature can provide information on studies yet to be conducted, results yet to be peer reviewed, and studies that have not been published in traditional publishing sources. Looking for relevant grey literature helps ensure that even results not published in journals are considered for the SRMA. Look for grey literature in Google, Google Scholar, ClinicalTrials.gov, OpenGrey, ProQuest Dissertations and Theses, and medRxiv, to name just a few.[18] Finding the grey literature can be a challenge due to the different formats and diverse places it can be found. Despite any search challenges, it is important to include unpublished gray literature.

The research team should search for the data in multiple databases. Minimally the databases should include Embase, OVID MEDLINE (or PubMed), Web of Science, and Google Scholar.[1] We recommend that the first database represent the subject area of the topic. It is also helpful if the first database has the search history is a line by line format. After the search is conducted, the line-by-line format allows the team to see what search concepts were used and how they are combined to arrive at the final article set. This format allows the research team to review and discuss individual lines, concepts, and logical structure before everyone approves the search strategy.

It is essential to draft the search that retrieves relevant articles in one database before searching other the other selected databases. Focusing on one database to begin with allows the team to identify search errors before moving to other databases. Selecting the databases that lead to adequate data collection is the first step in the searching process. Now it is time for the team to think about how to pull together the search so that it is rigorous.

Ensuring search rigor

The best way for the research team to ensure search rigor is to include a librarian on the SRMA team.[8] The librarian has expertise and training in developing searches and navigating various databases ensuring maximum retrieval of articles that address the question. The skillset they bring to the SRMA increases the rigor of the evidence that is produced.[20,21]

The SRMA search strategy is based on the research team's clinical question. The search uses the concepts from the question, searching each concept individually, and finally combining the concepts to find results that answer the question. The concepts in the question are often referred to as PICO, an acronym for Patient/Population, Intervention, Comparison/Control, and Outcome. However, depending on the topic, other search concept acronyms might be more applicable.[2,13,16] Not all concepts are included in the search, but all are included in the screening phase. The librarian can be a good resource to help the team decide which concepts should be searched, and which should be left until the screening phase. For example, the concepts to include in a search to discover the effects of an intervention are typically the population of interest, the intervention, and sometimes the comparative intervention. Searching the outcome in this case inadvertently adds bias to the search by identifying specific outcomes. Instead of searching for the outcomes, screening for them lets the evidence reveal itself rather than predetermining it. We will discuss screening along with inclusion and exclusion criteria in a future column.

Another element in designing a rigorous search is for the research team to identify articles that may be part of the set of final evidence used in the analysis of the SRMA. While this sounds preemptive, consider these as "gold standard" articles which become exemplars that serve the purpose of developing and validating the search. That is, with the search developed, the gold standard articles should be amongst the search result set. Identifying these articles ahead of time helps the librarian to frame the discussion on the topic and to develop the search in the databases. In addition, when thinking about what terms to use to build the search, a great tool to use as a starting point is the Yale MeSH Analyzer.[6] Using the PubMed ID for each of the gold standard articles, the MeSH Analyzer retrieves fields within the PubMed record, including title, abstract, subject headings, and author keywords. The information within these fields helps formulate the initial search strategy in the database. As the search progresses, the librarian tests to see if the gold standard articles appear in the result set. If they do not, the search strategy needs revision.

Using the subject headings identified by the Yale MeSH Analyzer,[6] the research team can now start to develop the search. SRMA guidelines recommend searching subject headings, also known as controlled vocabulary, as well as keywords.[11] Many biomedical and social science databases implement a system of subject headings to describe the aboutness of the articles more consistently. As a standard, most articles are indexed with subject headings soon after inclusion in the database. Searching with the subject headings expands the retrieval because they cover various synonymous terms that may be used in the articles. For example, the subject heading "myocardial infarction" in PubMed retrieves articles that may use the terms "myocardial infarction", "heart attack", or "cardiovascular stroke".

In addition to using subject headings, the team should be sure to search for keywords. The keyword search is the search for that *exact* word in the metadata fields of the citation record. The keyword search looks at the article title, abstract, as well as the author keywords listed in the metadata. It is important to know that for most databases keyword searching does not search the full text of the article. Keyword searching is essential because not all citation records in a database are indexed with subject headings, including very recent literature. Also, some articles may not be indexed with a term that the keyword easily captures.

Once the research team feels satisfied that each concept of the search is addressed with the appropriate subject headings and keywords in one database or source, translate the search in other databases and information sources that have been selected. Adequately translating a search means that the research team will want the search strategies to look similar in the databases. However, each database will have different subject headings that might be broader or more specific than the other databases.

It is important for the research team to have realistic expectations of what a search can retrieve. As with any research data collection process, the thoroughness of the search ensures that the research team finds all the evidence relevant to the question. The scope of the search can be either narrow (specific) or broad (sensitive).[15] A narrow search is one that is highly specific, meaning that it retrieves fewer articles with the potential of loss of some relevant articles. On the other hand, a broad search is highly sensitive, meaning that the search has retrieved more articles but there may be some that are not relevant. The research team must consider that the search strikes a balance between being narrow and broad in order to find as much

relevant evidence as possible. An additional step for finding articles that may not be retrieved from databases is to look at the citation list of the important articles in the final set. This citation chaining technique can reveal articles that may not have been found through the database search.

It is highly recommended that a librarian peer review the search strategies to avoid poorly designed search strategies.[2] Poor search design includes several basic errors that the research team should watch out for. These include search errors such as how the concepts are included and combined in the search, lack of use of spelling variations or spelling errors in keywords, and missing concepts in the search. Search errors undermine the SRMA because research is not valid if the data collection is flawed. Cochrane recommends using an information specialist or a librarian as the peer reviewer.[2] The CADTH organization (https://www.cadth.ca/resources/finding-evidence/press) has developed PRESS,[12] a tool that can be used to peer review the search.

Keeping track

Adequate reporting of search methods in a final published systematic review is notoriously overlooked.[3,9,17] When this happens, the SRMA loses credibility because the reader does not know where the evidence came from. If you are reading a randomized control trial article, you would not presume that the trial is double-blinded just because the author said so, you would want to know the "how," or what the methodological rigor is behind the blinding. A systematic review should also answer the how in the search methods. For instance, we realize that finding evidence is dependent on the databases and resources that the research team has access to, as well as the resources they choose to use or not use. Keeping track of the decisions behind what the team uses and does not use allows them to report the choices during the manuscript write-up. Acknowledging these decisions is important for transparency for readers to learn why the team collected the data they did, which subsequently led to the reported results.

It is important to keep detailed records of how the evidence was found, and what choices were made to find it. PRISMA guidelines require that the search methods writeup includes a description of all information sources in the search, including databases with dates of coverage, and the date last searched.[11] The updated PRISMA 2020 requires that the search strategy for *all* databases, registers, and websites be available so that the search can be reviewed by manuscript peer reviewers and readers to ensure quality and transparency.[19] When we search, we save the searches in each database so that we can rerun the search in case there are new results that should be included in the analysis. This should be done close to when the team is finalizing the manuscript for publication. We also record the search history after completing each search run so that there is a record of the exact numbers of the search results for that precise moment in time. The easiest way for recording the search history is to take a screenshot.

Conclusion

The rigor of the research team's SRMA is contingent upon a meticulously designed search. The research team needs to have a searchable question that is easily broken down into concepts. Next, the research team needs to decide where to search, how to search, and how to informally validate the search. The research team needs to know how to expertly use citation indexes, literature databases, and grey literature sources. Throughout this process, it is vital for the team to record the decisions made and how the evidence was found.

Even the best search strategy will only get the team so far; the next step is screening articles to ensure they answer the question of the SRMA. In column four, we will discuss the importance of developing inclusion and exclusion criteria for the SRMA, as well as using these criteria for the screening and selection of process.

Declaration of Competing Interest

None.

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Ensuring the rigor in systematic reviews: Part 4, screening the results

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Previous columns in this series have emphasized that the rigor of a systematic review and meta-analysis (SRMA) begins with a focused question as the basis for a reproducible search that systematically finds all the available evidence in the form of published articles on a topic. After completing the comprehensive database and grey literature searches, the next step is for the team to screen the found articles to determine the ones that belong in the evidence synthesis. Screening the evidence, also known as study selection or simply *screening*, means to apply a rigorous process of deciding if the evidence, or the study's article, answers the question posed at the outset of the SRMA. Screening, as with all the SRMA steps, is guided by the protocol. At this stage of the SRMA, the team refers to the protocol's pre-established inclusion and exclusion criteria to determine if the evidence should continue to the data extraction and synthesis phases. In keeping with the rigor necessary for SRMAs, screening is systematic and transparent. This column will explain the considerations during the evidence screening phase to determine which evidence, or studies, will move to the next SRMA phase of data extractionInclusion and exclusion

In Part 2 of this series,[1] we addressed the need for a protocol, likening it to a road map for the project. A protocol describes the steps in the SRMA project plan.[2] The steps include developing the research question, developing a database search strategy, and including concepts to search and limits that will refine the final study results that answer the question. An important step in this process is determining the inclusion and exclusion criteria.[3] The inclusion and exclusion criteria are the concepts that need to be in the final set of articles included in the evidence synthesis to answer the SRMA research question. Some inclusion and exclusion criteria are easily limited or filtered within the database, such as publication date, but some are not, such as demographics of study participants. When a concept cannot be filtered in the search, the research team will need to become the "human filter" to include or exclude any evidence.[4]

The research team can work with the librarian to determine which terms the database can pick up as inclusion or exclusion criteria.[3] Working with the librarian helps ensure that the team does not add concepts or limits to a search that could eliminate relevant results.[5] A simplistic example is a research team that is only interested in studies with adults over 18 years of age. At first, this limit might seem easy since databases make limiting by age relatively easy. So, the database search could eliminate any article that focuses on children under the age of 18. However, a study might look at children and adults for two separate arms of the study or define the patients as "adults without children" or "adult children." Unfortunately, the database cannot separate the research team's idea of an "adult-only" study from those articles that mention children or studies that separately looked at adults and children. This finer inclusion or exclusion nuance is when the "human filter" is necessary. In this case, the search strategy should not have either a "child" or "adults only" limit. Instead, the screeners become the human filter, identifying and eliminating articles focusing only on "children" during the screening phase.

It is essential for the search to be as exhaustive as possible to include all potentially relevant articles. Therefore, it is typical that the results of the search include a margin of error and risk-aversion; thus, the initial set of articles to screen could be large and potentially seem overwhelming. However, including a large set of articles at the outset allows the research team greater latitude to be the human filter, adding precision to the inclusion or exclusion of relevant studies. It is better to err on the side of not having the database filter with too much exactitude, to give the team greater control over whether to include or exclude a study.

The progressive steps of screening

The screening of the articles found by the search typically occurs in two steps. The first step is the title and abstract screening allowing the team to exclude irrelevant articles quickly, winnowing the large

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number of citations resulting from the search just by looking at the article title, and, if necessary, the article abstract.[6] Any article that is not excluded moves to the second step in the screening process. The second step is screening the full text, allowing the team to look more closely at the details of the study to determine if the study be included in the final synthesis.

These two steps use the inclusion and exclusion criteria outlined in the SRMA protocol.[3] The inclusion and exclusion criteria usually include study characteristics, such as participants, settings, interventions, comparators, and outcome measures. Also, criteria should include publication characteristics such as publication date, language, and article type.[7] Some criteria are easily determined in the title and abstract screening step, such as if the article is original research. However, more detailed information may not be apparent to the screener until screening the full text, such as the study's specific results.

One way to expedite the screening process is for the team to develop an exclusion hierarchy that quickly identifies studies under no circumstances to include in the final SRMA synthesis.[8,9] View the hierarchy as a sequential checklist. The hierarchy prioritizes exclusion criteria, with the more easily identified criteria at the top of the hierarchy, progressively moving to less easily identified criteria toward the hierarchy's bottom. With easily identified criteria at the top of the hierarchy, irrelevant articles are quickly screened out often during the title and abstract screening step. For instance, the hierarchy's first criteria may be to exclude any studies with the pediatric population. Using the adult-only study example from above, either the title or the abstract might identify the type of patients studied. Suppose by reviewing the article title and abstract, the reviewer determines that the study includes a pediatric population. In that case, the article is screened out and does not go to the full text screening phase. The hierarchy is also vital because it becomes a guide for all screeners to be consistent with their article exclusion reasons. It is often the case that a significant number of studies are excluded in the title and abstract screening phase, whittling the number of studies to be reviewed in the full text screening step.

The second step of screening is when the team examines the full text of the articles. The team continues to apply the same hierarchy of exclusion criteria but looking at the article's more granular details. During this step, to ensure consistency for elimination reasons, determining the elimination criteria is based on the hierarchy. For instance, building on the example above, the top priority in the hierarchy is to exclude studies with pediatric populations. The next priority might be to exclude articles where the intervention does not match the question the SRMA is trying to answer. The team will look at the full text to review the details of the intervention, such as the dosage amount. In this case, an article is eliminated if the medication dosage is inconsistent with the SRMA research question. If an article includes correct intervention criteria, or dosage in this example, the next criteria priority in the hierarchy might be outcome measures. The team will continue this process of verifying each criterion as they move down the hierarchy, excluding the article when it does not meet the criterion. Making a note of the reason for exclusion is an essential reporting criterion according to the PRISMA guidelines.[10,11] At the full text screening step, PRISMA requires that researchers include a reason for excluding all articles.

Before starting this detailed two-step screening process, we recommend that the team decides on a manageable number of articles to "test screen" and then reconvening as a group to talk through the process. Test screening allows the team to make sure each screener understands the exclusion criteria and the hierarchy. After test-screening, reconvening allows discussion if there is a deviation in the reviewers' screening decisions and why. This discussion also allows for any uncertainties in the process to be clarified, potential refinement to occur, and strong inter-rater (inter-reviewer) reliability.[12] Test screening is a crucial step to do early in the screening phase of the SRMA as it is easier to course correct at the beginning, rather than when many hundreds of articles have already been reviewed and excluded or included. The team may decide to do test-screening and reconvene more than once, depending on the discussions' utility and clarity after each meeting.

The reviewers

To ensure rigor and transparency, SRMA standards from groups such as Cochrane Collaboration and Institute of Medicine recommend including at least two screeners for study selection.[3,13] The rationale for this is that dual screening minimizes bias, reduces human error, and can help identify ambiguous inclusion criteria.[14] Each reviewer screens the articles independently, so they do not influence each other's decisions. Any disagreement between the two screeners about the inclusion and exclusion of a study is adjudicated by another reviewer, potentially a senior member of the team. If the team is smaller, it is often the case that the team members make the final decision together through discussion.

Including a mix of subject matter expertise and non-subject matter experts can be advantageous to the screening team. Experts have in-depth knowledge of the subject yet may bring preformed ideas, which brings biases about the relevance and validity of the studies. Including a second reviewer who is not a subject matter expert can temper this, offering a different perspective.[15] Regardless of the individual reviewers' expertise, all reviewers involved in the screening process should be knowledgeable about the inclusion and exclusion criteria of the screening. Furthermore, each reviewer should have command of what is meant by each of the inclusion and exclusion criteria, ideally developed through the test screening described above.

Screening tools

Software tools can make the screening process trackable and can potentially reduce bias. The research team needs to decide on the process for screening and provide training as necessary. All reviewers should use the same software to make screening decisions, enabling easy comparison between each reviewer's screening decisions. Which software to use is another decision that is best made at the protocol stage. The decision might be influenced by what software the research team's institution or their library has available, team members' knowledge of the tools available, and potentially available funding if there is an associated cost. Some teams may use software specially designed for SRMAs such as Covidence (Veritas Health Innovation, Melbourne, Australia), Review Manager (RevMan) (The Cochrane Collaboration, Copenhagen), or DistillerSR (Evidence Partners, Ottawa, Canada). Others might use a familiar tool such as MSExcel (Microsoft Corporation) or EndNote (Clarivate Analytics, Philadelphia, PA) to help with the screening process.[16] The SR Toolbox (http://systematicreviewtools.com/advancedsearch.php) is an excellent resource as it provides a list of tools for consideration and explains their utility.

In Part 2[1] of this series, the importance of a comprehensive description of the search methodology was outlined. It is equally important to describe the methods used during the screening phase, including the inclusion and exclusion criteria.[10,11] Throughout the article screening process, be sure to keep records of the studies that are eliminated during each phase. PRISMA recommends using a flow diagram, accompanied by descriptive text, to describe the process of screening and study elimination during the SRMA.[10,11] The flow diagram includes the number of studies excluded after both screening phases (title and abstract screening, full text screening) and how many studies are in the final synthesis. It is also recommended that reasons for exclusion be included for studies that were excluded at the full text screening stage

review.[10,11] As a measure of rigor and transparency, ensure that the list of articles that made it to the final analysis is available, as well as the list of excluded articles.[17] When the SRMA is submitted for publication, the publisher may require these details as an appendix or supplemental material.

Conclusion

Screening, or study selection, is the final step of data collection, so there must be transparency and reproducibility. The team should be aware of the considerations of the entire screening process before embarking. The research team's inclusion and exclusion criteria form the basis of a hierarchy for article screening and need to be developed in advance. The screening process needs at least two reviewers to reduce bias and, ideally, a tool to track the data selection process. The rigor of the screening phase is essential because it leads to the data extraction phase. If the team does not have the right data, they cannot accurately synthesize the evidence to answer the question posed by the SRMA. The team needs to understand how screening builds toward the final evidence synthesis. In the next column, we will discuss the data extraction basics.

Declaration of Competing Interest

None.

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Ensuring Rigor in systematic reviews: Part 5, quality appraisal, data extraction, synthesis

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Introduction

While previous columns in our systematic review series discussed the protocol and evidence collection,[3,4] this column focuses on how the research team will use the collected evidence – typically in the form of published articles/papers that describe primary research studies. In this next stage of the systematic review or meta-analysis (SRMA) process, the research team will assess the studies' methodological quality found in the data collection phase using an appraisal tool. Once the research team has appraised the evidence, relevant data is extracted from each study to develop a synthesis of the evidence that answers the research question. This column will focus on the quality assessment of the studies and data extraction in preparation to create the evidence synthesis.

Quality Assessment

After the research team has the final selection of primary research articles that meets the inclusion criteria to answer the SRMA research question, the next step is to determine the quality of included research. Determining the quality of the primary research included in the SRMA is essential because it forms the basis of this research effort's findings. The strength of the SRMA is only as good as the strength of the evidence used to create that synthesis. It is recommended that only studies that meet minimal adequacy standards be included in SRMAs.[20] The SRMA protocol must have a clear description of how the team will review the quality of the primary research.[19]

Research quality is assessed by the team critically appraising each included study's strengths and weaknesses to determine the overall quality of study design and execution. Note that quality appraisal is also known as critical appraisal[17] or risk of bias.[13] Evidence of deficiencies in the study's quality raises the possibility of bias, where bias refers to the study's tendency to "exaggerate or underestimate the 'true' effect of an intervention or an exposure" [19] (p37).

The effort to undertake the quality appraisal allows the research team to ascertain a general overview of the quality of the research on the topic. Like many of the SRMA process steps, set aside time to do a detailed and transparent assessment. Quality assessment requires carefully reading each primary research article to determine if the methods and results are believable, logical, and valid. A thorough appraisal for each study may take several hours to complete.[2]

The research team can either develop their own quality appraisal checklist or refer to one of the many published checklists or tools. There are many tools out there,[18] however there is little guidance as to which is best to use.[21] For that reason, the researcher should be sure to choose a quality appraisal tool that considers the context of the review.[7] Some commonly used checklists include CASP (https://casp-uk.net/casp-tools-checklists/), JBI (https://joannabriggs.org/critical-appraisal-tools), and the Center for Evidence-Based Medicine (https://www.cebm.ox.ac.uk/resources/ebm-tools/critical-appraisal-tools). It is also advisable to look at other similar topic reviews to see what checklists that research team used.[2]

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To mitigate confusion or ambiguity, when the research team begins the quality assessment work, the tool or checklist should be piloted. Completing quality assessment with a sample of studies with several reviewers helps determine that there is agreement, and maximizes the tool's validation and reliability for the review's purpose.[7] Once the tool is validated with a small sample set, the research team appraises all the studies. It is recommended that two researchers on the team appraise each included study[30] to mitigate vague or ambiguous reporting.[7] In the event of disagreement between reviewers' appraisal, consensus can be reached through discussion and agreement or by a third member on the team.

Common elements in quality appraisal checklist tools include four factors.[19] For each study, the research team first decides if the methods were appropriate to answer the research question.[11] Second, they determine if the results are valid and therefore accurate.[2] The research team will establish the study's accuracy by reviewing the study's methodological rigor to identify flaws in how the research was conducted that would invalidate the findings.[11] Third, they appraise the study's reliability to determine the trustworthiness of the study findings. For the research team to determine whether the findings are accurate, they should test the calculations presented in the study.[6,11] Fourth, and finally, they look for the applicability of the findings, or are the results beneficial, and can the results be translated into practice.[2] Based on these four factors, often using the scale provided by the appraisal checklist, the research team can determine the strength of the research quality as evidence in support of the SRMA research question.

There are systematic review software tools that research teams can use to appraise the quality of studies. One of these is Covidence (https://www.covidence.org/), a fee-based software tool. In the absence of having access to a critical appraisal software tool, we recommend using a spreadsheet-style table to compile individual appraisals to compare all studies' quality quickly. Each row represents one study, and each column represents one of the quality items under review. Use the scoring system from the appraisal checklist, weight the studies, ensuring those with higher quality get a higher weighting.[20] Reporting the individual studies' research quality is part of the transparency of SRMA methods.[30] At this stage, reporting the reasons for the studies' inclusion ensures full transparency of the critical appraisal process. While every study will have weaknesses, the team needs to decide whether to include lesser quality primary studies. If lesser quality studies are included, the team will need to address the rationale behind that decision and the potential impact on the SRMAs findings. If the team decides that any studies are of inferior quality, consider excluding them from the final synthesis, thus avoiding unnecessary data extraction.

While the quality appraisal elements we have mentioned refer to appraising quantitative research, there is an increasing number of qualitative literature syntheses occurring,[9,10] For this reason, the Cochrane Qualitative Research Methods Group has adapted the broad quality appraisal principles mentioned above to credibility, transferability, dependability, and confirmability.[12] Also, there are scoring tools for appraising mixed-methods primary studies.[25,26]

The next stage of the SRMA is pivotal to the purpose of the research project and will begin to inform the team about the data details as it relates to the central SRMA question. Because the research team is reading primary research articles carefully during quality appraisal, some teams consider conducting the quality assessment and study data extraction simultaneously. Again, test this dual-process, and decide what works for everyone on the team.

Data extraction

After establishing the quality of the studies to be included in the SRMA, the team extracts the specific characteristics from each of the studies. Data extraction means examining each primary study to extract the same characteristic. These data characteristics are recorded in a grid format so that the same data is compared across all the included primary studies. This extracted data provides the raw material that forms the synthesis and analysis of the SRMA.

Many researchers use a data extraction form in the format of a table or a spreadsheet. A typical way to set the spreadsheet up is with each study existing in a row, and the data characteristics in corresponding cells. Another commonly used method is to create a database using a survey tool where each of the data characteristics is extracted into a field within the survey.[2] In addition, there are systematic review software tools that are designed to extract data. As already mentioned, one of these is Covidence (https://www.covidence.org/), others include Rayyan (http://rayyan.qcri.org), and RevMan (https://training.cochrane.org/online-learning/core-software-cochrane-reviews/revman/revman-non-cochrane-reviews). Whether the team uses a spreadsheet, database, or an online tool, the data characteristics that are extracted should be the same across all studies to ensure consistency of the mined data points.

When creating the data extraction template, think about the column input in two distinct groupings.[11] First, extract the study's methodologic characteristics such as the article citation information, study design, study aims, population, setting, and, if relevant, publication location. Second, using the research question as a guide, extract relevant content-specific characteristics and details such as interventions, comparative interventions, outcomes assessed, and possible implications for policy or practice. As with all steps in the SRMA process, we recommend beginning the data extraction with a few studies, and then reconvening as a team to determine if the data extraction points are suitable, if more data points needs to be added, or if there needs to be clarification for consistency.

As the data is extracted and the table is developed, shared characteristics and patterns across studies begin to emerge.[2] The straightforward format of a data extraction table aids in the development of both the synthesis and the manuscript as well as the data displays, such as matrices, graphs, charts, or networks.[29] These data displays will aid in the visualization of patterns and relationships across studies.

Synthesis

The power of a synthesis is the efficient access to a body of knowledge that will potentially aid decision support to healthcare policymakers and practitioners.[27,28] Integration and synthesis depend on a well-designed research question, and a team with wide methodological and topical expertise.[5] The synthesis draws from the data characteristics found within the tables developed during data extraction. Summarizing the findings can be accomplished by either a quantitative or a qualitative method, and sometimes both.[14]

SRMA methodological rigor remains essential in the synthesis phase. The research team must be transparent in how the data is synthesized, including how the data is pooled, insights gained from the process, and citing methodological checklists, tools, and instruments used in the SRMA process.[15]

The quantitative synthesis uses the numerical values within each study to summarize or combine the data points via statistical analysis.[15] This statistical analysis, also known as meta-analysis, pools the numerical data from studies that have addressed similar research questions and administered the same interventions with similar types of participants.[1] The pooling of data can estimate the true effect of the intervention. Results are usually presented as p-values and displayed on a forest plot. Even if the team's SRMA incorporates a quantitative analysis, a narrative synthesis is essential to highlight other study elements not revealed through the data. For instance, a narrative synthesis is necessary when outcomes data characteristics cannot be pooled into a statistical analysis. Instead, these facts are

reported through a descriptive synthesis rendering comparisons across the studies.[14]

On the other hand, a qualitative synthesis is the summary or interpretation of the data by identifying "themes, concepts, frameworks, or theories and inter-related concepts"[15] (p4). Qualitative synthesis involves the synthesis of findings across studies using a comparative analysis.[14]

For the narrative synthesis of both quantitative or a qualitative SRMAs, the research team can view the synthesis in three steps.[24] First, they will organize the description of the studies into logical categories, such as interventions (to determine intervention effectiveness) or outcomes (to determine how outcomes may be achieved). Second, they will analyze the findings within the categories to explore the relationships, differences, and common themes within each of the categories. Third, and lastly, they will amalgamate the findings across the studies describing and summarizing the information that the review has uncovered.[24] This methodology is flexible enough to consider variations in study quality, populations, intervention, and settings.

Conclusion

Quality appraisal, data extraction, and evidence synthesis aggregates the studies' evidence the team has identified to answer their original research question. The time and energy that was dedicated to the early steps in the SRMA process are starting to materialize. This column is a broad overview into the process of now stitching together the data characteristics and synthesizing the body of literature on the topic. There are more detailed review documents that guide researchers in the specifics of quality appraisal and data extraction.[8,13,16,22] We also highly recommend becoming familiar with the PRISMA 2020 statement.[30] Throughout the series we have focused on transparency and reproducibility via scrupulous notetaking. Column six will illustrate the benefits of these efforts as we closely examine the SMRA writeup with special emphasis on the requirements of reporting guidelines.

Declaration of Competing Interest

None

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Ensuring rigor in systematic reviews: Part 6, reporting guidelines

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Introduction

Each column in this series has described the rigorous process required to produce a valid and reliable systematic review or meta-analysis. The importance of this rigor is bounded by consensus-based reporting guidelines. In this column, we will focus on the systematic review or meta-analysis (SRMA) manuscript through the lens of several more-often-used reporting guidelines. All reporting guidelines for evidence syntheses, including systematic reviews, can be found on the Equator Network (https://www.equator-network.org/). Standards for reporting of SRMAs recognize the importance of transparency and reproducibility of the process. In this column, first, we will summarize the nuances of three specific guidelines. Next, we will describe in more detail what should be included in each section of the manuscript and will refer to the specific location in each of the guidelines where the information is found. As suggested throughout this series, the research team's detailed research log documenting the steps and decisions along the way will make drafting the manuscript less complicated.[1] This column will continue to illuminate the reasoning behind our suggestions.

Outline of the tools, and why you would use each-why and when

An SRMA must adhere to a reporting guideline to describe the methods, to account for the final data, and to develop a narrative that synthesizes the results of the study similar to a clinical trial or observational study. Reporting guidelines ensure high standards for documentation of the methods and results, reduce reporting bias, and ensure transparency.[2] Following these guidelines is of utmost importance to ensure that SRMAs are accurate, thorough, and trustworthy enough to appropriately inform healthcare decisions. Throughout this series we have pointed to standards for conducting systematic reviews, such as the Institute of Medicine[2] and Cochrane Collaboration.[3] Similarly, there are other standards that offer guidance on conducting evidence syntheses with various foci such as economic evidence syntheses[4] or conducting mixed methods systematic reviews.[5] While this guidance sets basic standards for conducting SRMA research, the reporting guidelines are foundational for how teams present the information in a manuscript.

While standards are useful to refer to as the research team advances through the project, attention should also be paid to reporting guidelines as the manuscript begins to take shape. We bring your attention to three major reporting guidelines each providing its own checklist, or rubric. These checklists help ensure that appropriate and complete details about the research are described. Peer reviewers often consider the guidelines when reviewing the team's manuscript. The three guidelines are: PRISMA,[6] MOOSE,[7] and ENTRQ.[8] Because the approach to the evidence synthesis study design is to some extent universal, the guidelines are similar. In Table 1, we have created a comparison chart of the elements required for you to compare the similarities and differences with ease.

Originally, MOOSE[7] and ENTREQ[8] were early attempts to offer reporting guidance for evidence syntheses of non-experimental study designs, whereas the earlier version of PRISMA[9] was primarily reporting guidance for experimental studies. In 2020, however, PRISMA[6] was updated and explicitly states that it is suitable as a reporting guideline for any type of evidence synthesis. We have

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Table 1
Comparison of elements of commonly used SRMA reporting guidelines.

	PRISMA[6]	MOOSE[7]	ENTREQ[8]
Title	1. Title		
Abstract	2. Abstract		
Introduction	3. Rationale in context of existing knowledge 4. Objectives or questions the review addresses	1. Problem definition 2. Hypothesis statement 3. Description of study outcome(s)	1. Aim
Methods	5. Inclusion and exclusion criteria 6. Information sources 7. Full search strategies for all databases, registers, websites 8. Selection process for inclusion or exclusion 9. Data collection process, including how many reviewers 10. Data items – outcomes and variables 11. Study risk of bias assessment 12. Effect measures 13. Synthesis methods 14. Report of bias assessment 15. Certainty assessment	4. Type of exposure or intervention used 5. Type of study design used 6. Study population 7. Qualifications of searchers 8. Search strategy 9. Efforts to include all studies 10. Databases and registries searched 11. Search software used 12. Use of hand searching 13. List of citations located, and those excluded 14. Method for addressing non-English publications 15. Method for handling abstracts and unpublished studies 16. Description of any contact with authors 17. Description of relevance of studies included to test the hypothesis 18. Rational for selecting and coding data 19. Documentation about coding	2. Synthesis methodology 3. Approach to searching 4. Inclusion criteria 5. Data sources 6. Electronic search strategy 7. Study screening methods 8. Study characteristics 9. Study selection results 10. Rationale for appraisal 11. Appraisal items 12. Appraisal process 13. Appraisal results 14. Data extraction 15. Software 16. Number of reviewers 17. Coding
Results	16. Study selection 17. Study characteristics 18. Risk of bias in studies 19. Results of individual studies 20. Results of synthesis 21. Reporting bias 22. Certainty of evidence	20. Assessment of confounding 21. Assessment of study quality 22. Assessment of heterogeneity 23. Description of statistical methods 24. Appropriate tables and graphs 25. Graphic summarizing study estimates 26. Table giving descriptive information for each study 27. Results of sensitivity 28. Indication of statistical uncertainty 29. Quantitative assessment of bias 30. Justification for exclusion 31. Assessment of quality of included studies	18. Study comparison 19. Derivation of themes 20. Quotations
Discussion & Conclusion	23. Discussion of results, limitations of evidence included and the review process, and implications for practice, policy, future research	34. Guidelines for future research	21. Synthesis output
Other information	24. Registration and protocol 25. Support, financial and non-financial 26. Competing interests 27. Availability of data, code, and other materials	35. Disclosure of funding sources	

included all three because we know of manuscript peer reviewers who have questioned research teams as to why they did not use MOOSE[7] or ENTREQ[8] when doing their SRMA. Thus, before embarking on any SRMA be sure to check the journal's author guidelines for the preferred reporting guideline.

Below we have described the purpose of each guideline as well as a summary of what each requires. Table 1 briefly identifies the sections and elements for each guideline in juxtaposition to the others therefore we recommend referring to the specific guideline and elaboration documents for complete details. Note that PRISMA also has "extensions," which outline additional reporting guidelines including protocols (PRISMA-P), scoping reviews (PRISMA-ScR), and health equity focus reviews (PRISMA-E). For a full list of PRISMA extension consult http://www.prisma-statement.org/.

PRISMA

PRISMA, which stands for the preferred reporting items for systematic reviews and meta-analysis, is the most widely-know reporting guideline for systematic reviews.[6] The guideline was updated in 2020 and includes a 27-item checklist comprising the minimum set of reporting items to ensure transparency of the research efforts. The core reporting structure checklist includes title and abstract (with its own specific abstract checklist), and introduction. The checklist, moreover, requires reporting of the methods used including the search, assessment, and synthesis; results, including risk of bias and synthesis results; discussion; and other information such as protocol registration, competing interests, and availability of data.

The PRISMA 2020[6] update explicitly states that the reporting guideline is not only for synthesizing randomized control trials but is inclusive for synthesizing all study designs including observational and qualitative. This means that researchers can consult and use these reporting guidelines for any evidence synthesis.

MOOSE

MOOSE, which stands for meta-analyses of observational studies in epidemiology is, as stated, the reporting guideline for evidence synthesis of observational studies.[7] This guideline emphasizes the valuable and valid evidence which comes from studies beyond randomized control trials. Synthesizing observational studies is important because these studies are more likely to assess harm, include underrepresented, vulnerable, minority, or heterogeneous populations, report effectiveness rather than efficacy, and represent "typical" situations rather than controlled experimental conditions.[10] A close look at the reporting guidelines shows a similar structure as PRISMA, but there are highly specific reporting details unique to this guideline. The MOOSE checklist includes 35-items in its reporting

structure. The core reporting structure checklist includes an introduction stating the problem definition and hypothesis; the methods section that includes the search strategy, synthesis, and assessment methods; the results section; the discussion section, and the conclusion.

ENTRQ

ENTREQ is the reporting guideline for research teams undertaking an evidence synthesis of qualitative research.[8] ENTREQ stands for enhanced transparency in reporting the synthesis of qualitative research. Synthesis of qualitative studies, often called a meta-synthesis, creates a more in-depth description of studies that explore the same phenomenon of interest. While it is recognized that qualitative research is not generalizable, the synthesis of qualitative research does not reinterpret original findings but instead draws conclusions based on common elements across studies in order to provide guiding recommendations.[11] The ENTREQ checklist includes 21-items that comprise the minimum expectation for these types of reviews. The core reporting structure checklist includes stating the synthesis aim, the methods used, including the search, data extraction and coding, results, and discussion.

Reproducibility & transparency & transferability

The purpose of adhering to the reporting guidelines is to ensure clarity in describing the SRMA process. As with all research, transparency in methods is paramount. By following reporting guidelines, peer reviewers and, ultimately, readers follow the team's process from inception to conclusion. The overall reporting structure for an SRMA has all the essential elements seen in presenting any scientific research. Besides a title and abstract, all evidence synthesis guidelines follow the same framework of introduction, methods, results, discussion, and conclusion. As shown in Table 1, each reporting guideline may differ in the specific elements within each category of the framework. Below is a summary of the types of information that should be included when writing a systematic review manuscript. However, a research team should refer to the latest version of the specific guideline and elaboration document.

Title and Abstract

The title should reflect both the subject of the review and the review study type; the abstract should follow the format recommended by the author guidelines. PRISMA's abstract checklist,[12] an excellent guide for preparing abstracts for any purpose, includes summarizing the background, methods, results, and discussion of the SRMA. A well-constructed descriptive title and abstract truly representing the content is critical to the discoverability of research on a topic.

Introduction

All three reporting guidelines require that researchers use this section to describe the research problem and rationale for the study. With the rapid increase in the number of SRMAs being published,[13] it is imperative that researchers closely examine previous evidence syntheses to evaluate the uniqueness of their identified research question thus avoiding duplication of effort.[14,15] The introduction should clearly outline the novelty of the study and how it both fits into and adds to the body of evidence, especially within the landscape of currently published SRMAs. The introduction usually concludes with a reiteration of the foundational question that the evidence synthesis is attempting to answer. We refer you back to the more detailed discussion about determining the novelty and developing the question in Part 2 of this series.[16]

Methods

All three reporting guidelines specify what to include when reporting methodology. A description of the SRMA methods ensures that peer reviewers, and ultimately readers, can evaluate the transparency in the research study approach, which, when well done, is an indicator of reproducibility. As stated in detail in Part 3 of this series,[17] librarians, as part of the research team, contribute by writing the search methods. Librarians are extremely experienced with the language required to describe the selection of databases and information sources, as well as the syntax that appropriately describes search term selection and relationships deployed to identify included studies. PRISMA[6] recommends that along with their manuscript, the research team submit the search strategy utilized for each information source. Librarians excel in supplying detailed and carefully annotated search strategies to accompany the manuscript.

As noted in Table 1, the manuscript reporting guidelines require describing the team's inclusion and exclusion criteria. We recommend taking extra care to provide the reasons behind decisions that might require further explanation. For instance, we worked with a team doing an SRMA on extracorporeal membrane oxygenation (ECMO). As this technology evolved in the early 2000s, the researcher described in the manuscript why there were few studies included before the year 2000. Next, when describing the process of screening identified papers, PRISMA[6] specifically requires the number of reviewers screening each study be reported. We have detailed screening and reviewers in Part 4 of this series.[18] And finally, the methods writeup should specify how studies were appraised, how and what data was extracted from the studies, and how that data was synthesized. Of note, PRISMA[6] requires researchers to report any software used in the SRMA, such as Covidence (Veritas Health Innovation, Melbourne, Australia).

Results

In the SRMA manuscript, the results section takes a narrative approach to describing studies included in the final synthesis – as shown in the reporting requirements for each of these three guidelines. However, reporting guidelines require a table showing the citations of included studies with descriptive information for each study. Some of the teams we have worked with include tables that also show the data elements extracted from each study which forms the basis for the final synthesis. This kind of table graphically represents the comparison of the studies that ENTREQ[7] and PRISMA[6] specifically require. The need for a detailed research log becomes apparent because guideline requirements also emphasize reporting a list of citations that initially appear to meet the inclusion criteria but were excluded along with the justification for exclusion. MOOSE[7] refers to this as a "reject log" in the form of a citation list, as does PRISMA.[6] The well-known graphic summary of included and excluded studies in the SRMA manuscript is the PRISMA flowchart. The flowchart describes the numbers in the results for the entire process, from the initial search result numbers to those in the final synthesis. A downloadable and editable flow diagram series can be found on the PRISMA website (http://prisma-statement.org/prismastatement/flowdiagram.aspx). Note that various flow charts exist specifically for different types of information sources that were used in the search process. As described in more detail in Part 5 of this series,[19] it is in the results section that the research team summarizes and synthesizes the data from the studies, mapping it back to the central SRMA question.

Discussion & conclusion

PRISMA[6] and MOOSE[7] recommendations for the discussion and conclusion focus on the implications of the synthesis of results within

the context of the past/current practice or policy landscape and recommendations for integration of what is learned into future practices or policies. ENTREQ[7] recommends that the discussion point out any biases identified in the included studies. Both PRISMA[6] and MOOSE[7] identify the results section as a logical place to report biases. Clearly, there can be blurring on what belongs in what section in these three reporting guidelines. Thus, a close examination of the appropriate reporting guideline is recommended.

Other information

We would like to note two items in the PRISMA[6] requirements that show the evolution of the SRMA process revealing wide recognition that transparency in this type of study is essential. First is that teams be required to register a protocol of their intent to conduct a systematic review. We worked with a team that had a manuscript rejected because they did not have a registered protocol. Review the intended journal for guidelines about this requirement. There is more detail about the value of protocols in Part 2 of this series.[16] Second is the availability of the data, code, and other items that have been a part of the team's development of the final manuscript. The PRISMA[6] guidance document acknowledges that there are often page, table, figure, and word limits imposed by journals, so including all the detail that the reporting guideline requires may not be possible in the manuscript. When space is an issue, a viable option is providing appendices that the journal can include as online supplements. If the journal does not do this, there are publicly accessible repositories such as Open Science Framework (https://osf.io/) where these documents can be stored and made publicly available. Alternatively, some of the detail may be available in the protocol so the manuscript can point to the publicly accessible protocol repository.

Conclusion

Reporting guidelines clarify and provide a framework to the research team as they write their manuscript. There are three described here, with the most current and oft used one being the PRISMA guideline.[6] Since each journal may have different reporting guideline requirements, research teams should identify and review the recommended guideline, including checklists and any elaboration documents. The team should be very familiar with the reporting guideline *before* they begin the study, and then keep referring to the checklist to ensure that all elements are included. Early familiarity with the reporting guideline encourages a high level of detail in the team's research log, safeguarding that the manuscript will come together with greater ease. The guideline structure helps the team to conform to the expectations of a well-done SRMA thus avoiding the challenges and surprises that can happen at the point of manuscript submission and peer review. Column 7 will focus on the critical appraisal and peer review process of SRMAs. We will illustrate how reporting guidelines are integral to these processes and thus continue to enhance the quality and rigor of the SRMA final publication.

Declaration of Competing Interest

None.

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Ensuring rigor in systematic reviews: Part 7, critical appraisal of systematic review quality

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ABSTRACT

Methodological transparency and reproducibility are essential for systematic reviews. Peer review of systematic review manuscripts ensures researchers achieve transparency and reproducibility. Using critical appraisal and quality assessment tools is a methodological way for peer reviewers to conduct a thorough critique to assess the rigor and transparency of the systematic review.

Introduction

This series has focused on the process for conducting a well-executed systematic review. Throughout, we highlighted the significance of ensuring transparency and reproducibility, thus rigorously producing a systematic review and meta-analysis (SRMA). In this last column, we continue to focus on rigor via this study design's peer review and critical appraisal process. The need to carefully evaluate SRMA quality is essential for several reasons. First, research teams can step back and assess the quality of the rigor of their manuscript before submission. Next, post submission, journal peer reviewers can cast a critical eye on manuscripts ensuring that researchers follow the rigor of the SRMA study design closely enough to warrant being published. Finally, health care professionals can use critical appraisal to determine SRMA quality and rigor before making process and policy decisions. This column describes the importance of critical appraisal and peer review using selected tools to determine the quality of the SRMA. The tools that we will outline are: AMSTAR,[1] JBI systematic review critical appraisal tool,[2] ROBIS,[3] and PRESS.[4]

Importance of peer review and critical appraisal

Our fifth column[5] focused on the importance of assessing the quality of the included studies in an SRMA because the strength of the SRMA is only as good as the strength of the evidence used to create that synthesis. Similarly, SRMA peer review and critical appraisal is essential because of the SRMA status as a comprehensive overview of the research on a specific health care topic or concern, and they are widely used to inform clinical practice and policy development.[6–8]

Furthermore, peer review and critical appraisal are essential as the publication rates of SRMAs are growing exponentially.[9] SRMAs indexed in PubMed from 1995 to 2017 saw a 4679% increase rate in the number of publications.[10] Similarly, the growth of SRMA publications during the same years within the rheumatology specialty was 3718%.[11] In comparison, the rates of change of RCTs indexed in PubMed were 138% for all RCTs[10] and 212% rheumatology RCTs.[11] This marked publication rate difference is an indication that practitioners and policymakers need to critically appraise any SRMA publication because the study design of SRMAs only requires that authors following guidelines. In contrast, original studies such as RCTs undergo scrutiny for rigor by review boards like the IRB.

Peer review and critical appraisal - tools

This series has previously highlighted three reporting guidelines, PRISMA,[12] MOOSE,[13] and ENTREQ,[14] to help researchers with the study methods essential for SRMA process rigor.[15] These guidelines help teams navigate the process with checklist-style rubrics that ensure transparency of the process in the manuscript writeup. This column adds four tools that enable reviewers to critically reflect on the quality of the information reported and reflect on how the

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manuscript stays true to the SRMA process rigor. Essentially, these tools offer the framework for reviewers to critically appraise the manuscript and determine any risks of bias inherent in the study. It is essential to mention that there is no universally accepted set of tools, so we have included tools that include robust criteria that reflect the reporting guidelines described in Column 6.[15] Below we will review the development and purpose of these tools and provide a snapshot view of the appraisal criteria asked in each. Importantly, we suggest using these tools together since each has a slightly different purpose. PRESS[4] assesses the quality of the data collection via the search strategy. AMSTAR[1] and the JBI[2] tool both evaluate the methodological quality of systematic reviews. ROBIS[3] assesses the risk of bias in systematic reviews.

PRESS

PRESS[4] (Peer Review of Electronic Search Strategies) is a tool reviewers can turn to when critically appraising the manuscript or article search strategy during the data collection phase of the SRMA. In alignment with our third column,[16] the PRESS checklist determines the validity of the search strategy used to gather the data that forms the basis for the SRMA, and so is invaluable to critically appraise the strengths of data collection. Developed in 2009,[17] with an update in 2015,[4] the PRESS checklist identifies critical elements to look for in the increasingly complex search strategies for systematic reviews. Throughout this series, we have identified librarians' integral role as part of the SRMA team and the inclusion in the peer review and critical appraisal stage is vital. Librarians have extremely unique searching skills and experiences that make them essential in the search strategy critiquing process. We have our searches peer-reviewed via PRESS by other librarians at our institution to ensure that our search is representative of the protocol, follows the guidelines of the database/platform, and does not include any syntax or typographical errors. A list of librarians willing to become SRMA manuscript peer reviewers can be found in Librarian Peer Reviewer Database (https://sites.google.com/view/mlprdatabase/home). Notwithstanding the essential role of the librarian as a SRMA peer reviewer, the PRESS tool is intended for everyone involved in peer review and critical appraisal, including researchers, journal editors, manuscript peer reviewers, and funding bodies.[17]

AMSTAR2

AMSTAR2[1] (A MeaSurement Tool to Assess systematic Reviews) was originally published in 2007[18] as a critical appraisal tool that enables reviewers to reflect on the transparency, reproducibility, and methodological quality of the manuscript or study under review. It was developed to allow reviewers to appraise SRMAs, particularly as it was evident that SRMAs were increasingly including non-randomized studies. The 2007[18] version included 11 domain items, and in 2017, AMSTAR2[1] was amended to include 16 domains ensuring rigor of methods used to create a SRMA. Domain items include: appraising the study for evidence of a protocol registration, the adequacy of the literature search, justification for excluding studies, individual study risk of bias, considerations of risk when interpreting results, assessment of each included study's publication bias, and the appropriateness of meta-analytical methods. The tool uses a rating scheme of *high, moderate, low*, and *critically low* regarding the confidence of the information for each of the domains reviewed in the study.[1] AMSTAR2 includes a comprehensive user guide and allows reviewers to identify the weaknesses in critical domains. The quality of using AMSTAR2 rests on the inter-rater reliability and usability testing that was done as part of the instrument development. Even though the quality of SRMAs varies, in an evaluation of the use of several tools to appraise this study design, AMSTAR2 was found to be the most endorsed appraisal tool for SRMAs for assessing the study's reliability, usability, and applicability.[19]

The JBI critical appraisal checklist for systematic reviews

The JBI[2] systematic review appraisal tool is part of the larger series of critical appraisal checklists available from JBI (see https://jbi.global/critical-appraisal-tools). This checklist was developed in 2017 for the critical appraisal of systematic reviews or umbrella reviews (which are a review of reviews) used to support practice decisions.[2] There are 11 items in the checklist, allowing reviewers to rate each item either as *yes* or *no, unclear,* or *not applicable.*[2] Reviewers can then decide in an overall appraisal of the manuscript or article they are reviewing to either include, exclude, or seek further information. The checklist contains detailed information about each criterion aiding reviewers as they evaluate and apply the rating. A unique question in this tool is, "Were the specific directives for new research appropriate?[2] This shows that the tool has both an educational purpose and use for further primary and secondary research on the topic. JBI's call for using critical appraisal for education also extends to the recommendation that this tool be used as a discussion aid in journal clubs.

ROBIS

ROBIS[3] was developed in 2016 as a tool to assess the risk of bias in systematic reviews covering interventions, diagnoses, prognoses, and etiologies. The tool is also designed for guideline developers and researchers undertaking reviews to aid in avoiding the risk of bias in their study.[20] The developers noted that while there are protocols like PRISMA[21] and guidelines like MECIR (Methodological Expectations of Cochrane Intervention Review)[22] there was no formal tool to assess if the researchers appropriately reduced bias within their review.[3] The developers recommend using this tool in addition to AMSTAR.[1] Of note, this tool is valuable in distinguishing the difference between an SRMA with biased methodology and an SRMA that contains biased original studies.[3] The ROBIS tool allows reviewers to appraise manuscripts or articles through three phases. The first phase, relevancy, concerns the issue of the research question truly matching the purpose of the guide or policy that the conclusion is informing. The second phase identifies concerns with the review process and is most like AMSTAR[1] as it includes several domains that critique the methodology of the systematic review manuscript or paper. The third phase summarizes the risk of bias concerns identified in the second phase. Specifically, the tool addresses "potential concerns for reviews' eligibility criteria, methods of identifying studies, data collection, study appraisal, appropriate synthesis, and interpretation."[23] The tool itself includes "signaling questions" to help reviewers judge each element in the manuscript or paper enabling them to judge the risk of bias inherent in the study. More detailed information about the elements in each phase can be found in the Whiting et al.[3] article outlining details of the ROBIS tool.

Peer review and critical appraisal - key elements

When research teams, peer reviewers, and decision-makers critically appraise an SRMA, there are five key elements to consider regardless of the tool they decide to use. Reviewers should assess for: evidence of a pre-existing protocol; the clarity of the research question; data collection methods; appraisal of included studies; and the description of the research synthesis of findings. While there are no specific criteria in each of the appraisal checklists, screening by more than one reviewer is recommended SRMA methodology described by both PRISMA[12] and Cochrane Collaboration[14,22] as a way to assure reviewers that the risk of bias in study selection has been mitigated.

Protocol

The importance of researchers establishing the SRMA methodology should be agreed upon before the review starts. Adherence to the methods reduces the risk of bias when the review is underway.[1] During the appraisal process of an SRMA, AMSTAR checklist asks the reviewer to determine if "the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?"[1] Methodology rigor and transparency are achieved if the team has a publicly accessible or published protocol.[24] See column 2[25] for more detail about the protocol and its registration. Peer review of SRMAs includes looking to see if the researchers mention a preexisting protocol and acknowledgement of adhering to the predefined methods as well as the justification for any deviations from the planned method.

Research question

An SRMA must focus on a well-defined research question typically using the standard PICO (Population, Intervention, Comparative Intervention, and Outcome) format.[26] While all appraisal checklists include specific criteria about question formulation, the JBI checklist[2] asks reviewers, "Is the review question clearly and explicitly stated?" A clear research question defines the scope of the study and forms the basis for a detailed search to find the evidence. Question clarity informs the reviewer whether the researcher's inclusion and exclusion criteria were appropriate. Ultimately, the well-formed question allows the reviewer to critically assess if the review has achieved its objectives.

Data collection

The importance of adequate, transparent, and accurate data collection is central to reviewers who critique manuscripts and published articles. For this reason, all critical appraisal checklists mentioned signaling questions about data collection. PRESS[4] is the most specific checklist and asks detailed signaling questions about the search, including successfully translating the research question into a search strategy and the subsequent methodology used to develop the search. The tool directs reviewers' attention to whether the researchers used appropriate controlled vocabulary, subject headings, and keywords. The tool asks reviewers to consider appropriate use of controlled vocabulary terms, text words/keywords, and both Boolean and positional operators (AND, OR, NOT, adjacency, etc.). Misuse of any of these will dramatically affect the resulting set. It is recommended that research teams use the checklist to appraise their search strategy in the primary database before translating the search strategy to additional databases. We recommend that manuscript peer reviewers and others who use SRMAs to make policy or practice decisions appraise search strategies from each identified resource. Search strategy appraisal is critical because databases and their platforms have different controlled vocabularies, different search fields, and highly specific individual syntax rules. PRISMA guideline[21] requires that each database search strategy be included in the manuscript, typically as supplementary materials.

Critical appraisal of included studies

It is essential for research teams conducting an SRMA to use a critical appraisal tool most appropriate for the types of studies included in the SRMA. Thus, reviewers need to verify which critical appraisal tool was used by the research team to determine if it was appropriate and how many reviewers used it. The JBI checklist[2] addresses this, asking reviewers, "Were the criteria for appraising studies appropriate?" and "Was critical appraisal conducted by two or more reviewers independently?" Equally important is the risk of bias, which verifies the methodologies and reporting of selected studies. The ROBIS checklist[3] asks reviewers, "Was risk of bias (or methodological quality) formally assessed using appropriate criteria?" and furthers the question with "Were efforts made to minimize error in risk of bias assessment?" Critically applying these appraisal questions to an SRMA demonstrates the importance of reviewing how the researchers mitigated bias in their study.[3] The AMSTAR2 checklist[1] addresses the risk of bias both for meta-analysis and quantitative synthesis. A research team should not include a biased study in their SRMA. The emphasis on the appraisal is reflective of the IOM statement that "if the SR's assessment of the quality of a body of evidence is to be credible and true to scientific principles, it should be based on agreed-on concepts of study quality."[27] It is critical that reviewers appraise the inclusion methods because the potential weight given to SRMAs may influence eventual health care policies and practice decisions.

Research synthesis

The research synthesis contextualizes the SRMA findings in terms of strength, power, and the potential for implementation into practice and policy. The ROBIS checklist includes several very specific signaling questions including, "Was the synthesis appropriate given the nature and similarity in the research questions, study designs, and outcomes across included studies?"; "Was between-study variation minimal or addressed in the synthesis?"; and "Did the interpretation of findings address the concerns identified in [all previous steps in the SRMA]."[3] Reviewers appraising a SRMA should look for how the research team describes the heterogeneity of studies and the deviations in findings or studies.

Reviewers should also critically examine the researchers' discussion and interpretation of the findings, how they might be implemented in practice and policy, and finally, what gaps still exist in this research landscape. The JBI checklist[2] offers a question for reviewers to appraise if the reported data in the SRMA supports the recommendations for policy and practice.

Conclusion

Throughout this 7-part series regarding rigor in systematic reviews, the focus has been to emphasize that researchers undertaking a systematic review and meta-analysis (SRMA) ensure methodological transparency and reproducibility. Producing a quality SRMA that synthesizes a body of literature is highly regarded as it saves clinicians and policymakers' valuable time. The manuscript peer review is the final detailed critique essential to assessing the study's quality and appraisal of the researcher's efforts to achieve transparency and reproducibility. Although there is no universally mandated critical appraisal tool, this column has highlighted four well-known checklists to guide anyone reviewing an SRMA manuscript or published article in the appraisal of the study's quality. In the peer-review process, we recommend including librarians who are experts in this study design and, importantly, the rigor of the search strategy, which is central to the data collection upon which the reliability and validity of the SRMA hinges. As peer-reviewers it may be beneficial to consider more than one checklist, using them in combination to assess the transparency, validity, and reliability of the study under review. And, as peer reviewers, practitioners, and policymakers, it is essential that a critical appraisal be done before implementing the conclusions and recommendations of any systematic review.

We hope this series has shed light on the rigorous process required for a well-done systematic review and meta-analysis. While it may seem a formidable process, it is essential to know that librarians trained in information retrieval and synthesis can guide research teams in conducting this study and also be called upon to be part of the peer-review process.

Conflict of Interest

None.

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