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A Guide for Developing a Protocol for Conducting Literature Reviews

Purpose	This tool provides guidance on developing a protocol for conducting literature reviews. It discusses the importance of developing a protocol to guide literature reviews and describes the key elements in a protocol.
Format	This tool provides step-by-step instructions on how to develop a protocol for conducting a literature review.
Audience	This tool is designed primarily for researchers. It can be adapted by other NIDILRR-funded grantees and the general public.
Resources	Resources are listed in the Additional Resources section at the end of this document and include examples of published protocols.

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Contents

Why Is It Important to Develop a Protocol for Conducting a Literature Review?	1
How to Develop a Review Protocol	1
Additional Resources	4
Example Protocols and Templates.....	4
Systematic Review Standards Guide and Templates.....	4
Scoping Review Framework.....	5
Additional Examples and Templates.....	5
Bibliography	5

Why Is It Important to Develop a Protocol for Conducting a Literature Review?

A review protocol provides a step-by-step guide for conducting literature reviews, which may include systematic reviews, scoping reviews, and meta-analysis. It is necessary for the review team to develop the protocol *before* starting the literature review so that the process is clear and consistent throughout. In particular, the protocol should contain specific guidelines to identify and screen relevant articles for the review as well as outline the review methods for the entire process. A review protocol is important for reducing bias in the review process and limiting overlap with existing reviews. It also provides an outline for the review process that helps with planning and anticipating challenges that may come up in the review.¹ After the review is completed, the protocol can help the review team or other researchers to follow the same process to update the literature review when new research becomes available.

How to Develop a Review Protocol

In this section, we describe the key elements of a review protocol.

1. Background/Purpose

This section answers the question “why do this review”? It also addresses the importance of the review and provides context about the reasons the researchers are conducting it. The background should provide information about current gaps in the literature and describe the intervention, how the intervention might work, and why it is important to investigate.

2. Objectives/Review Question

The objectives of the review include the research question and the goals of the review. This section should include a statement about the population and outcomes on which the review focuses.

3. Methods

The methods section should outline the process for conducting the review. The level of detail should be sufficient so that others may replicate the review. Key components of the methods section are described below.

a. Selection Criteria

This section will help the review team determine which articles to include in the review. Selection criteria can be broken down into inclusion and exclusion criteria to help further clarify the requirements for eligibility. The selection criteria should be described clearly in the protocol. Items to consider when designing selection criteria include:

¹ <http://training.cochrane.org/resource/writing-protocol>

Type of intervention: Consider the types of intervention to be included in the review, and briefly describe the components of interventions to include and exclude.

Type of Outcome: Consider possible outcomes, including potential consequences such as risks or toxicities as well as benefits, and identify primary and secondary outcomes that are most relevant to the targeted intervention and study population.

Population of studies: Consider the characteristics of participants in the studies included in the review (e.g., age, gender, education) based on the population that the intervention is directed toward.

Type of studies: Consider the study designs to include (e.g., randomized controlled trial [RCT], non-RCT studies, etc.). There should be a clear justification for the study designs selected.

Type of publication: Consider whether the review will include published research studies only or if it will also include gray literature.

Publication date: Consider whether the studies in the review will be limited to a specific time frame.

Language: Consider whether the review will be limited to studies in English or include studies written in other languages.

Location: Consider whether there are limits on where the study took place.

b. Search Strategy

The protocol should provide a list of the databases and other sources used during literature searches to identify potentially relevant studies. This section will also include the search strategy, such as keywords and criteria for the searches.

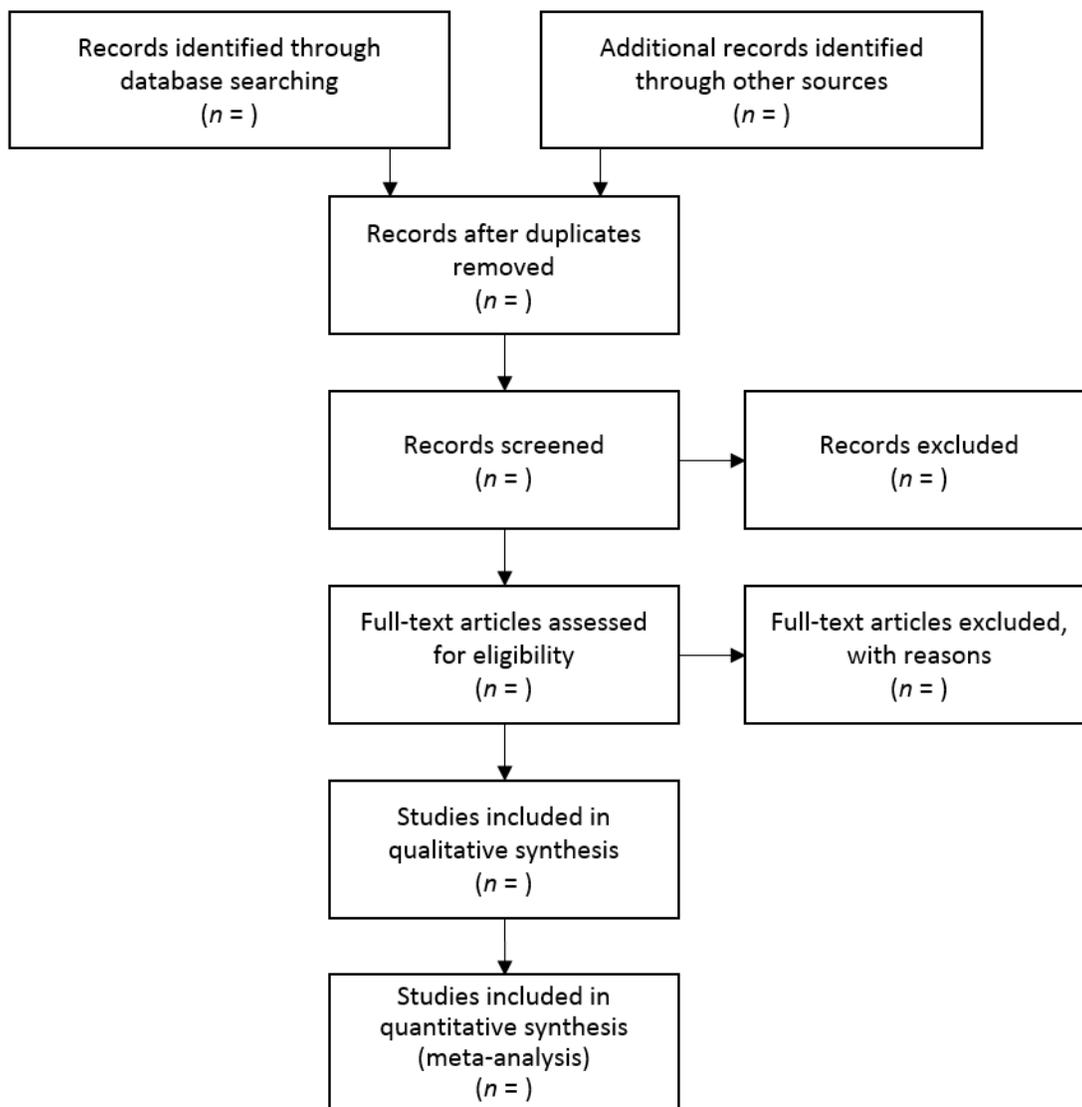
c. Data Collection

This section will include a description of the process for selecting studies and extracting data from eligible studies. It should include variables and definitions for each variable for which data will be collected from eligible studies. The researchers can include these variables on the data extraction template. This section should also provide details about how many members of the review team will review each article and how disagreements over the data extracted will be resolved. For example, two reviewers can extract data and then reconcile disagreements in extracted data using a standard data extraction template. The review team may also choose to reconcile differences using a third reviewer.

d. Displaying Data

It is important to consider how data will be presented in the final report. A flow diagram can help to lay out the data in a clear, organized way. It should include information such as the number of studies identified, reviewed, included, and excluded. Many journals require certain flow charts to appear in articles submitted for publication. One example called the PRISMA Flow Diagram appears below. For more information about creating a PRISMA flow diagram, please visit <http://guides.lib.unc.edu/prisma>.

PRISMA Flow Diagram Example



From: Moher, D., Liberati, A., Tetzlaff, J., Altman, D. G., & The PRISMA Group. (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA statement. *PLoS Med*, 6(7), e1000097. doi:10.1371/journal.pmed100009

Tables are also an effective way to present the primary data gathered on the articles being reviewed. An example of such a table is presented below.

Sample Table: Characteristics of Included Studies

Study	Setting	n	Population	Intervention	Primary outcome	Jadad score
Anderson, 1998	Primary care	200	Age 18–70, otherwise healthy, with cough or fever	erythromycin 333 mg po tid vs. amoxicillin 500 mg po tid	Days till resolved (symptom score < 3/10)	4
Billings, 2000	Emergency department	125	Age 16–60, "no serious comorbidities"	azithromycin 500 mg day 1, 250 mg days 2–5 vs, cephalexin 500 mg po tid	Symptom score at 14 days	4

From: <http://ebp.uga.edu/courses/Chapter%209%20-%20Meta-analysis%20of%20treatment/8%20-%20Presenting%20the%20results.html>

e. Analysis and Synthesis

The review team should determine how to analyze the data extracted for the review. If a software program is used for the analysis, it should be described and a rationale should be provided for its use. Reviewers should use a standard approach to assess the body of evidence used in the review by considering study limitations, consistency of effect, imprecision, indirectness, and publication bias.² The analysis section should also include a description of how risk bias in included studies will be assessed. This section will also address how the review team will handle missing data. Reviews should contain a section on limitations. This might include the difficulties with search terms or lack of uniformity of outcome measures, for example. This is a critical contribution for the reader.

Additional Resources

Example Protocols and Templates

Systematic Review Standards Guide and Templates

- The Campbell Collaboration: https://www.campbellcollaboration.org/images/pdf/plain-language/C2_Protocols_guidelines_v1.pdf
- The Cochrane Collaboration: http://endoc.cochrane.org/sites/endoc.cochrane.org/files/public/uploads/CMED_protocol_template.pdf

²http://ph.cochrane.org/sites/ph.cochrane.org/files/public/uploads/Guide%20for%20PH%20protocol_Nov%202011_final%20for%20website.pdf

Scoping Review Framework

- The Joanna Briggs Institutes: http://joannabriggs.org/assets/docs/sumari/Reviewers-Manual_Methodology-for-JBI-Scoping-Reviews_2015_v2.pdf

Additional Examples and Templates

- World Health Organization: http://www.who.int/hrh/education/Rec1_CPDforfacultyteachingstaff.pdf
- Wiley Online Library: <http://onlinelibrary.wiley.com/doi/10.1002/9781444316544.app1/pdf>

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