

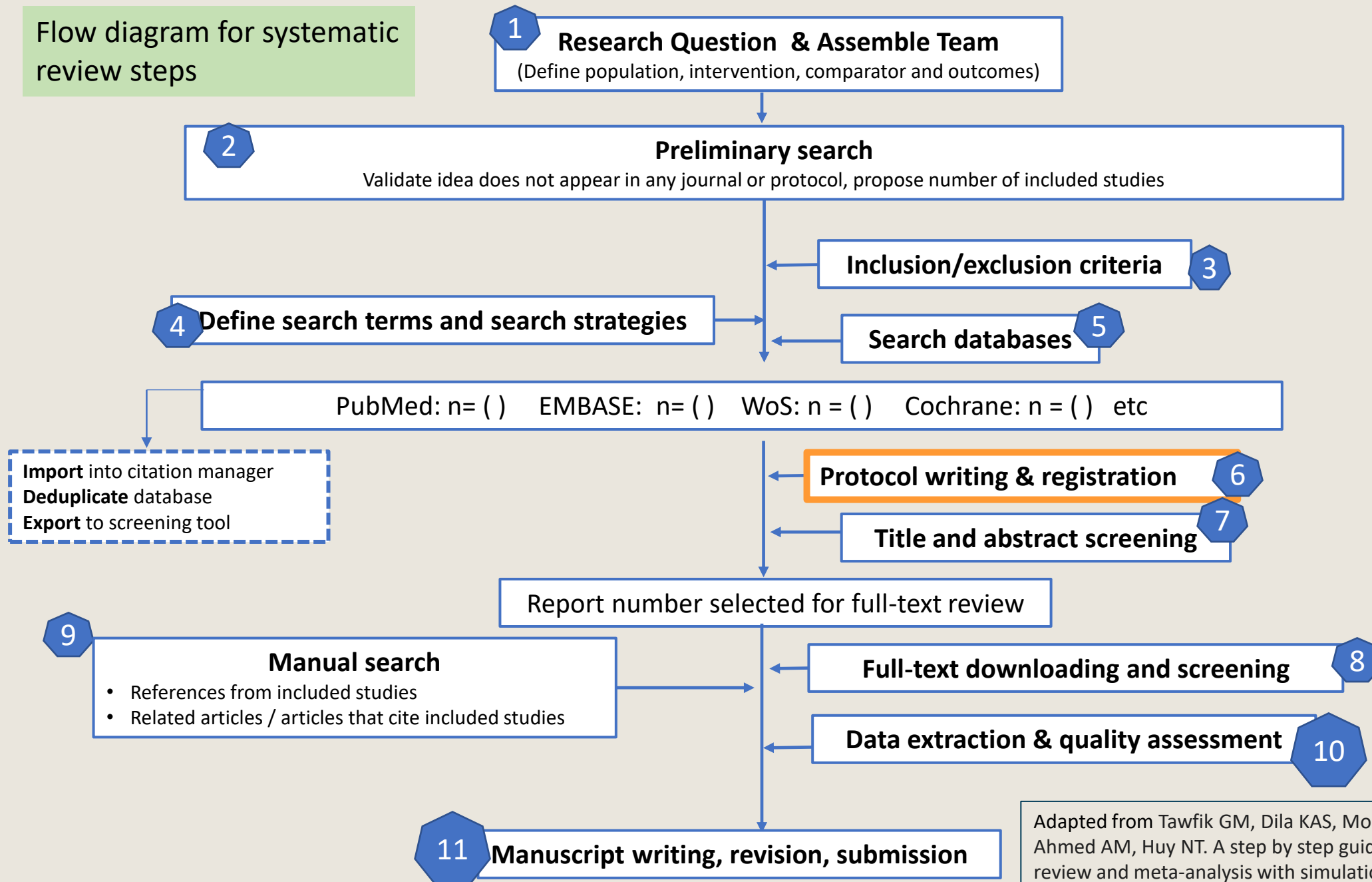
Developing a Systematic Review Protocol

Systematic Review Training

Center for Knowledge Management

VANDERBILT  UNIVERSITY
MEDICAL CENTER

Flow diagram for systematic review steps



Adapted from Tawfik GM, Dila KAS, Mohamed MYF, Tam DNH, Kien ND, Ahmed AM, Huy NT. A step by step guide for conducting a systematic review and meta-analysis with simulation data. Trop Med Health. 2019 Aug 1;47:46. doi: 10.1186/s41182-019-0165-6. [PMID: 31388330](https://pubmed.ncbi.nlm.nih.gov/31388330/)

What is a systematic review protocol?

Systematic Review Protocol

- **What it does:** *explicitly documents rationale & purpose, and plan up front as to how systematic review will be executed*
- **Ultimate goals:** *provide transparency, replicability, mitigates risk of selective reporting*
- **Ensures consistent conduct by and accountability of the review team**
- Registered or published protocols can **reduce redundant efforts** by other teams
 - ❑ Databases of registered SR protocols (such as Prospero) define specific formats for protocol submission
- PRISMA – P can guide you

Centre for Reviews and Dissemination at the University of York (UK)

Systematic :

- entire process is based on a method or plan (*protocol – just like a protocol undertaken in a lab, outlining step by step processes*)
- Characterized by order; methodical

Wordsmyth Advanced Dictionary. 2023.
www.wordsmyth.net/?level=3&ent=systematic
7 March 2023

Summary of the parts of protocol:

https://www.york.ac.uk/media/crd/Systematic_Reviews.pdf

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Identify the report as a protocol of a systematic review
Update	1b	If the protocol is for an update of a previous systematic review, identify as such
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number
Authors:		
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments
Support:		
Sources	5a	Indicate sources of financial or other support for the review
Sponsor	5b	Provide name for the review funder and/or sponsor
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol
INTRODUCTION		
Rationale	6	Describe the rationale for the review in the context of what is already known
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)
METHODS		
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated
Study records:		
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review

PRISMA-P

The most common checklist of protocol requirements

PRISMA – P can guide you through the process of Is checklist of generally agreed upon required elements

Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2 , Kendall's τ)
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)

* It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L. PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. *BMJ*. 2015 Jan 2;349(jan02 1):g7647.



PRISMA : Preferred Reporting Items for Systematic Reviews and Meta-Analyses *for systematic review protocols (PRISMA-P)*

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Identify the report as a protocol of a systematic review
Update	1b	If the protocol is for an update of a previous systematic review, identify as such
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number
Authors:		
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments
Support:		
Sources	5a	Indicate sources of financial or other support for the review
Sponsor	5b	Provide name for the review funder and/or sponsor
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol
INTRODUCTION		
Rationale	6	Describe the rationale for the review in the context of what is already known
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)
METHODS		
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated
Study records:		
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review

Items 1-11a

What is it:

- 17 items considered to be “essential and minimum components of a systematic review or meta-analysis protocol”
- **template & guidance to aid in the preparation of systematic review protocols**

Aims: to improve quality of SR protocols

What it is *not*: “an assessment tool to gauge the appropriateness of the methods of a systematic review protocol”

<http://prisma-statement.org/Extensions/Protocols>

Development of the 2015 PRISMA-P:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA; PRISMA-P Group. *Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement*. Syst Rev. 2015 Jan 1;4(1):1. doi: 10.1186/2046-4053-4-1. [PMID: 25554246](https://pubmed.ncbi.nlm.nih.gov/25554246/); PMCID: PMC4320440.

PRISMA-P (cont.)

Items 11b-17

Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2 , Kendall's τ)
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

PRISMA-P example: Smoking cessation interventions for U.S. adults...

Smoking cessation interventions for U.S. adults with disabilities: Protocol for a systematic review

Jonathan Schulz, Andrea Villanti, Gary Atwood, Sean Regnier, Lindsey Mullis, Tyler Erath, Au

To enable PROSPERO to focus on COVID-19 submissions, this registration record has undergone automated checks for eligibility and is published exactly as submitted. PROSPERO has never reviewed, and usual checking by the PROSPERO team does not endorse content. Therefore, any published records should be treated as any other PROSPERO registration. Further detail is p

Citation

Jonathan Schulz, Andrea Villanti, Gary Atwood, Sean Regnier, Lindsey Mullis, Tyler Erath, Au
Smoking cessation interventions for U.S. adults with disabilities: Protocol for a systematic review
2022 CRD42022337434 Available from: https://www.crd.york.ac.uk/prospERO/display_record.php?ID=CRD42022337434

Review question

What is the evidence for smoking cessation interventions tailored to meet the needs of U.S. adults with disabilities?

Searches

Databases to search: CINAHL Plus, Embase, MEDLINE, and PsycINFO
Studies will be limited to those conducted in the U.S. and published in English with no date re

Types of study to be included

Studies will provide empirical data on tobacco cessation using a range of study designs, including controlled trials, cluster-randomized controlled trials, quasi-experimental studies, single-subject and cohort studies. Qualitative studies, formative research without outcome data on smoking interventions focusing on prevention rather than smoking cessation will be excluded.

Condition or domain being studied

Tobacco cessation interventions tailored for people with disabilities.

Participants/population

Participants in the studies must be aged 18 or above and living in the U.S. Participants must be living with a disability (e.g., cognitive, communication, hearing, independent living, intellectual/developmental, visual). Interventions focusing on tobacco cessation for people with psychiatric disabilities will be excluded as reviews on this population already exist.

Intervention(s), exposure(s)

Eligible studies will be behavioral or pharmacological interventions at the individual or group level. Interventions focusing on tobacco smoking prevention will be excluded.

Comparator(s)/control

Control conditions include no intervention; delayed intervention beginning after follow-up; or general tobacco, smoking cessation, or health education provided to all participants. Studies with no control or comparators will be excluded.

Main outcome(s)

Eligible outcome measures include change in smoking behavior (e.g., cigarettes per day) and smoking cessation or abstinence. Examples of outcomes include 7-day point prevalence abstinence, self-reported quitting, or biological measures (e.g., exhaled carbon monoxide, cotinine). The primary outcome will be smoking status at 6 months follow-up.

Additional outcome(s)

Secondary outcomes will include adverse outcomes (e.g., psychological distress), social validity outcomes, and quality of life outcomes.

PRISMA-P example: Smoking cessation interventions for U.S. adults... (cont.)

Data extraction (selection and coding)

Two authors will review the title and abstract of all studies to determine initial eligibility. Articles will be included in full text review if at least one reviewer suggests inclusion. Once titles and articles are screened, two authors will review the full text to determine if the article should be included. If the two reviewers disagree on any article, a third reviewer will discuss with the two reviewers whether the article should be included in the next stage. At the full text review stage, reviewers will provide reasons for exclusion. Data related to general study information (e.g., title, authors, funding), methods (e.g., study design, intervention characteristics, setting, participants, outcomes), and conclusions will be extracted using a data extraction template in Covidence (Veritas Health Innovation, Melbourne, Australia). We will revise and add any additional categories as necessary during the process. Two reviewers will extract data from all records and extracted data will be checked for consensus. Disagreements on extracted data will first be discussed between the two extracting reviewers and arbitrated by a third researcher, if necessary.

Risk of bias (quality) assessment

The revised version of the Cochrane tool (RoB 2) will be used to assess risk of bias in randomized studies. The ROBINS-I tool will be used to assess risk of bias in nonrandomized studies. Two reviewers will assess risk of bias in all studies.

Strategy for data synthesis

We will create summary tables and graphs related to key outcomes and study characteristics based on the data extracted. Data to be summarized includes general study characteristics (e.g., study design, setting, participant characteristics, theoretical basis, and intervention elements) and outcomes. A summary of findings table will be created for each study following the GRADE approach. We will evaluate the evidence systematically to provide information on the effects of interventions by synthesizing information across studies, if possible.

Analysis of subgroups or subsets

Subgroup analyses will be conducted if studies are similar enough to be grouped together and if the data available are appropriate for synthesis. Elements to be assessed for comparability include intervention types and type of disability.

Contact details for further information

Jonathan Schulz
jonathan.schulz@uvm.edu

Organisational affiliation of the review

Vermont Center on Behavior and Health

Review team members and their organisational affiliations

Dr Jonathan Schulz. Vermont Center on Behavior and Health
Dr Andrea Villanti. Rutgers Center for Tobacco Studies
Gary Atwood. Dana Medical Library
Dr Sean Regnier. University of Kentucky
Lindsey Mullis. University of Kentucky
Dr Tyler Erath. Vermont Center on Behavior and Health
Austin Nugent. University of Kentucky

Type and method of review

Systematic review

Anticipated or actual start date

06 June 2022

Anticipated completion date

30 November 2022

Funding sources/sponsors

NA

Conflicts of interest

Language

English

Country

United States of America

PRISMA-P example: Smoking cessation interventions for U.S. adults... (con't)

Stage of review		
Review Ongoing		
Subject index terms status		
Subject indexing assigned by CRD		
Subject index terms		
Adult; Disabled Persons; Humans; Smoking; Smoking Cessation; Smoking Prevention		
Date of registration in PROSPERO		
09 July 2022		
Date of first submission		
28 June 2022		
Stage of review at time of this submission		
Stage	Started	Completed
Preliminary searches	Yes	Yes
Piloting of the study selection process	Yes	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No
<i>The record owner confirms that the information they have supplied for this submission is accurate and complete and they understand that deliberate provision of inaccurate information or omission of data may be construed as scientific misconduct.</i>		
<i>The record owner confirms that they will update the status of the review when it is completed and will add publication details in due course.</i>		
Versions		
09 July 2022		
09 July 2022		

PRISMA-P

History of the development of the PRISMA Statement

Moher et al. *Systematic Reviews* 2015, 4:1
<http://www.systematicreviewsjournal.com/content/4/1/1>



RESEARCH Open Access



Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement

David Moher^{1*}, Larissa Shamseer¹, Mike Clarke², Davina Ghera³, Alessandro Liberati⁴, Mark Petticrew⁴, Paul Shekelle⁵, Lesley A Stewart⁶ and PRISMA-P Group

Abstract

Systematic reviews should build on a protocol that describes the rationale, hypothesis, and planned methods of the review; few reviews report whether a protocol exists. Detailed, well-described protocols can facilitate the understanding and appraisal of the review methods, as well as the detection of modifications to methods and selective reporting in completed reviews. We describe the development of a reporting guideline, the Preferred Reporting Items for Systematic reviews and Meta-Analyses for Protocols 2015 (PRISMA-P 2015). PRISMA-P consists of a 17-item checklist intended to facilitate the preparation and reporting of a robust protocol for the systematic review. Funders and those commissioning reviews might consider mandating the use of the checklist to facilitate the submission of relevant protocol information in funding applications. Similarly, peer reviewers and editors can use the guidance to gauge the completeness and transparency of a systematic review protocol submitted for publication in a journal or other medium.

PRISMA-P Elaboration and explanation



BMJ 2014;349:g7647 doi: 10.1136/bmj.g7647 (Published 2 January 2015) Page 1 of 25

RESEARCH METHODS & REPORTING

Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation

Larissa Shamseer¹, David Moher¹, Mike Clarke², Davina Ghera³, Alessandro Liberati (deceased)⁴, Mark Petticrew⁵, Paul Shekelle⁶, Lesley A Stewart⁷, the PRISMA-P Group

¹Ottawa Hospital Research Institute and University of Ottawa, Canada; ²Queen's University Belfast, Ireland; ³National Health and Medical Research Council, Australia; ⁴University of Modena, Italy; ⁵London School of Hygiene and Tropical Medicine, UK; ⁶Southern California Evidence-based Practice Center, USA; ⁷Centre for Reviews and Dissemination, University of York, UK

Abstract

- act as a guard against arbitrary decision making during review conduct
- enable readers to assess for the presence of selective reporting against completed reviews,
- when made publicly available, reduce duplication of efforts and potentially prompt collaboration
- created as a result of the development of PROSPERO, the launch of an open-access journal focusing on SRs (BioMed Central's Systematic Reviews) and the development of PRISMA guidelines,

Moher D, Shamseer L, Clarke M, Ghera D, Liberati A, Petticrew M, Shekelle P, Stewart LA; PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst Rev*. 2015 Jan 1;4(1):1. doi: 10.1186/2046-4053-4-1. PMID: 25554246; PMCID: PMC4320440.

Shamseer L, Moher D, Clarke M, Ghera D, Liberati A, Petticrew M, Shekelle P, Stewart LA; PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. *BMJ*. 2015 Jan 2;350:g7647. doi: 10.1136/bmj.g7647. Erratum in: *BMJ*. 2016 Jul 21;354:i4086. PMID: 25555855.

PRISMA-P Guidance

RESEARCH METHODS & REPORTING

Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation

Larissa Shamseer¹, David Moher¹, Mike Clarke², Davina Ghera³, Alessandro Liberati (deceased)⁴, Mark Petticrew⁵, Paul Shekelle¹, Lesley A Stewart¹, the PRISMA-P Group

PRISMA-P (Preferred Reporting Items for Systematic review and meta-analysis protocols) 2015: elaboration and explanation

Section and topic

ADMINISTRATIVE INFORMATION

Section and topic	Item No	Description
Title:		
Identification	1a	Identify the report as a protocol
Update	1b	If the protocol is for an update
Registration	2	If registered, provide the name
Authors:		
Contact	3a	Provide name, institutional affiliation, and email address of corresponding author
Contributions	3b	Describe contributions of protocol authors
Amendments	4	If the protocol represents an amendment, describe the amendment and, otherwise, state plan for documentation
Support:		
Sources	5a	Indicate sources of financial or other support
Sponsor	5b	Provide name for the review funder
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and other support

INTRODUCTION

Rationale	6	Describe the rationale for the review
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)

METHODS

Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and other factors (such as language, publication status) to be used as criteria for eligibility for the review
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, and grey literature sources) with planned dates of coverage
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including search terms and filters, and whether the search was repeated
Study records:		
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review

Objectives

Item 7. Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)

Example 1

"The aim of this systematic review is to evaluate the effectiveness and harms of perioperative pregabalin in the management of postoperative pain for the diverse patients undergoing various surgical procedures. To this end, the proposed systematic review will answer the following questions:

1. When compared with standard multimodal analgesia, what are the comparative effectiveness and harms of the co-administration of pregabalin in the perioperative pain management of adult patients?
2. Is there a definitive opioid-sparing advantage of pregabalin (for example, lower risk of nausea, vomiting, somnolence, opioid use, and other opioid-related adverse effects) in the perioperative pain management of adults?
3. For questions 1 and 2 above, what clinical outcomes are most important to patients and clinicians? What are the results?"⁷²

Explanation


Among the most crucial pieces of information to include in a review protocol are the question(s) the reviewers plan to investigate, or simply, the review's objectives. Along with the review's rationale (Item 6), this information provides the reader with context and understanding for why the review is being carried out and what the reviewers hope to achieve. Several key components, namely the planned population, intervention, comparator, and outcome (that is, PICO elements) at minimum should form the basis for developing a specific, well designed review question. Additional elements such as setting, study design, and time frame (that is, length of follow-up) may also be included in the review question, but if not, should certainly appear in the review's eligibility criteria (Item 8). Guidance is available to help researchers develop a research question.^{74 75} Reviews may focus on one PICO element more than others given the planned scope of the review; authors should clearly state this emphasis in the protocol.


List of registries for systematic review protocols

- 1) [International Prospective Register of Systematic Reviews \(PROSPERO\)](#) – the first website created for the *international* prospective registration of systematic review protocols; **created in 2011**. **Only accepts systematic, rapid, and umbrella reviews** – does not accept scoping reviews or literature scans. Submissions can include any topic where there is health-related outcome. PROSPERO is funded by the National Institute for Health Research in England. **Protocol submissions undergo a quality assessment check** and processing can take several months. **Registration is FREE**. Is the largest database of systematic review protocols (**more than 100,000**).
- 2) [Research Registry – Registry of Systematic Reviews/Meta Analyses](#) – **started in 2015**; accepts protocols of any kind but includes a subsection dedicated to systematic reviews and meta-analyses. **Selling point is that it is “more comprehensive than any other registry in the world” in terms of types of study protocols accepted**. Is provided by the International Journal of Surgery Publishing Group and the IDEAL Collaboration (a consortium coordinated by the Nuffield Dept of Surgical Sciences at the Univ. of Oxford). Protocol submissions do not undergo assessment until after registration; registered protocols are published immediately upon submission. **Cost: 99£**. Currently **has more than 7,900 protocols**.
- 3) [International Platform of Registered Systematic Review and Meta-Analysis Protocols \(INPLASY\)](#) – just **started in 2020**. Accepts only **systematic reviews**. The site is funded from the **fees paid by authors**. **Protocols undergo a quality assessment** and are published within 48 hours. Each protocol is assigned a DOI number and protocol metadata fields align with the [PRISMA-P checklist](#). Registration fee is \$20; each **update to the protocol is \$9**. Currently has **close to 4,500 protocols**.
- 4) [Cochrane Library](#) Cochrane Library contains protocols for systematic reviews in healthcare and clinical interventions. Run a search on your topic and select the "Cochrane Protocols" tab.
- 5) [Joanna Briggs Institute \(JBI\) Systematic Review Register](#) – for use solely by JBI affiliated entities, contains protocols of systematic and scoping reviews in healthcare research. **Serves as awareness tool**
- 6) [Open Science Framework Registry](#) OSF Registry includes protocols for all types of research projects with no restriction on the discipline.

-
- 1) [Collaboration for Environmental Evidence](#) CEE contains protocols for systematic reviews and systematic maps in environmental science, policy and practice
 - 2) [Campbell](#) provides a list of its registered protocols which span the social sciences - Business and Management, Climate Solutions, Crime and Justice, Disability, Education, International Development, Knowledge Translation and Implementation, Methods, and Social Welfare

Journals that publish protocols as stand alone

 **BMC** Part of Springer Nature

 **Systematic Reviews**

Submission guidelines:

- Proposed or ongoing research not yet at data extraction stage
- Prospective registration in PROSPERO or Open Science Framework is highly encourage
- PRISMA-P checklist

Faieta JM, Devos H, Vaduvathiriyam P, York MK, et al. Exercise interventions for older adults with Alzheimer's disease: a systematic review and meta-analysis protocol. Syst Rev. 2021 Jan 4;10(1):6. doi: 10.1186/s13643-020-01555-8. PMID: 33397453; PMCID: PMC7779651.

Sunde E, Harris A, Nielsen MB, et al. Protocol for a systematic review and meta-analysis on the associations between shift work and sickness absence. Syst Rev. 2022 Jul 16;11(1):143. doi: 10.1186/s13643-022-02020-4. PMID: 35842678; PMCID: PMC9287923.

BMJ Open

Aims and scope: "All research study types are considered, from study protocols through phase I trials to meta-analyses. This includes specialist studies and studies reporting negative results."

 Hindawi

Emergency Medicine International

For authors: "You can make your protocol public before publication of your article if you choose, which will not harm the peer review process of your article and may allow you to get comments about your methods to adapt or improve them before you submit your article"

Beyramijam M, Khankeh HR, Farrokhi M, Ebadi A, Masoumi G, Aminizadeh M. Disaster Preparedness among Emergency Medical Service Providers: A Systematic Review Protocol. Emerg Med Int. 2020 Oct 26;2020:6102940. doi: 10.1155/2020/6102940. PMID: 33274079; PMCID: PMC7683168.

JBI EVIDENCE SYNTHESIS

Information for authors:

- Prior to conducting SR
- Prospero registered
- PRISMA-P statement

Mares MA, Maneze D, Elmir R, et al. Health literacy and self-management in people with coronary heart disease: a systematic review protocol. JBI Evid Synth. 2022 Oct 1;20(10):2599-2604. doi: 10.11124/JBIES-21-00257. PMID: 36081391.

Frameworks for devising and structuring systematic review key questions

PICO (Population, Intervention, Comparator, Outcome)

- Schiavenato M, Chu F. PICO: What it is and what it is not. *Nurse Educ Pract.* 2021 Oct;56:103194. doi: 10.1016/j.nepr.2021.103194. Epub 2021 Sep 2. [PMID: 34534728](#).

PECO (Population, Exposure, Comparator, Outcomes)

- Morgan RL, Whaley P, Thayer KA, Schünemann HJ. Identifying the PECO: A framework for formulating good questions to explore the association of environmental and other exposures with health outcomes. *Environ Int.* 2018 Dec;121(Pt 1):1027-1031. doi: 10.1016/j.envint.2018.07.015. Epub 2018 Aug 27. [PMID: 30166065](#); [PMCID: PMC6908441](#).

SPIDER (Sample, Phenomenon of Interest, Design, Evaluation, Research type)

- Cooke A, Smith D, Booth A. Beyond PICO: the SPIDER tool for qualitative evidence synthesis. *Qual Health Res.* 2012 Oct;22(10):1435-43. doi: 10.1177/1049732312452938. Epub 2012 Jul 24. [PMID: 22829486](#).

PICOTS (Patient Population, Intervention, Comparator, Outcomes, Timing)

- Samson D, Schoelles KM. Developing the Topic and Structuring Systematic Reviews of Medical Tests: Utility of PICOTS, Analytic Frameworks, Decision Trees, and Other Frameworks. In: Chang SM, Matchar DB, Smetana GW, Umscheid CA, editors. *Methods Guide for Medical Test Reviews* [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2012 Jun. Chapter 2. [PMID: 22834028](#).

FINER Criteria (Feasible, Interesting, Novel, Ethical, Relevant)

- Thomas J, Kneale D, McKenzie JE, Brennan SE, Bhaumik S. Chapter 2: Determining the scope of the review and the questions it will address. In: Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, Welch VA (editors). *Cochrane Handbook for Systematic Reviews of Interventions* version 6.3 (updated February 2022). Cochrane, 2022. Available from www.training.cochrane.org/handbook.

Frameworks for devising and structuring systematic review key questions (cont.)



Thomas J, Kneale D, McKenzie JE, Brennan SE, Bhaumik S. Chapter 2: Determining the scope of the review and the questions it will address. In: Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, Welch VA (editors). *Cochrane Handbook for Systematic Reviews of Interventions* version 6.4 (updated August 2023). Cochrane, 2023. Available from www.training.cochrane.org/handbook.



Whitlock EP, Lopez SA, Chang S, et al. Identifying, selecting, and refining topics. In: Agency for Healthcare Research and Quality. *Methods Guide for Comparative Effectiveness Reviews* [posted April 2009]. Rockville, MD. Available at: <https://effectivehealthcare.ahrq.gov/products/cer-methods-guide/overview/>.



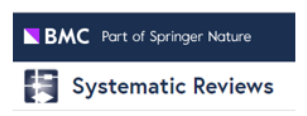
Module recap

Systematic Review Protocol

- **What it does:** *explicitly documents rationale & purpose, and plan up front as to how systematic review will be executed*
- **Ultimate goals:** *provide transparency, replicability, mitigates risk of selective reporting*
- **Ensures consistent conduct by and accountability of the review team**

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

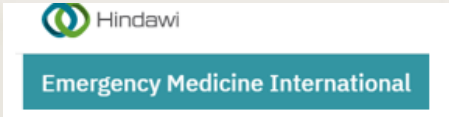
PROSPERO
International prospective register of systematic reviews



Journals that publish protocols as stand alone

BMJ Open

JBI EVIDENCE SYNTHESIS



Presented by
Center for Knowledge Management

VANDERBILT  UNIVERSITY
MEDICAL CENTER