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Risk of bias in cross-sectional studies: Protocol for a scoping review of concepts and tools

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ABSTRACT

Cross-sectional studies are commonly used to study human health and disease, but are especially susceptible to bias. This scoping review aims to identify and describe available tools to assess the risk of bias (RoB) in cross-sectional studies and to compile the key bias concepts relevant to cross-sectional studies into an item bank. Using the JBI scoping review methodology, the strategy to locate relevant RoB concepts and tools is a combination of database searches, prospective review of PROSPERO registry records; and consultation with knowledge users and content experts. English language records will be included if they describe tools, checklists, or instruments which describe or permit assessment of RoB for cross-sectional studies. Systematic reviews will be included if they consider eligible RoB tools or use RoB tools for RoB of cross-sectional studies. All records will be independently screened, selected, and extracted by one researcher and checked by a second. An analytic framework will be used to structure the extraction of data. Results for the scoping review are pending. Results from this scoping review will be used to inform future selection of RoB tools and to consider whether development of a new RoB tool for cross-sectional studies is needed.

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Specifications table

Subject area:	Research Methods
More specific subject area:	Epidemiology, knowledge synthesis methods, study designs, risk of bias
Name of your protocol:	Risk of bias in cross-sectional studies: protocol for a scoping review of concepts and tools
Reagents/tools:	Not applicable
Experimental design:	Not applicable. This protocol describes a scoping review.
Trial registration:	Not applicable. This is not a trial. This scoping review is registered with the Open Science Framework (https://osf.io/y7vst/)
Ethics:	This work did not involve human subjects, animal experiments or data collected from social media platforms.
Value of the Protocol:	Scientific contribution: • Comprehensive summary of different methodological considerations for risk of bias in cross-sectional study designs. • Maps coverage for key bias considerations in existing risk of bias tools. • Identified gaps may be used to select tools for use and/or to inform future risk of bias tool development.

Description of protocol

A cross-sectional study is a type of observational research study that is used to examine a group of individuals at a specific point in time in order to understand their characteristics and behaviors. The objective of this scoping review is to identify tools used to evaluate the risk of bias (RoB) in cross-sectional studies of humans; and to identify, describe, and to compile the key items, domains or concepts relevant to RoB in cross-sectional studies into an item bank.

Methods

The proposed scoping review will be conducted in accordance with the JBI methodology for scoping reviews and reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) [1,2].

Review questions

1. What tools are used to assess the risk of bias in cross-sectional studies?
2. What risk of bias items, domains or concepts are included in tools intended for cross-sectional study designs?
3. How do risk of bias concepts vary when tools are intended to be applied to analytic studies of association or prevalence?

Inclusion criteria

The Cochrane definition will be used to consider RoB as a measure of how features of the design, conduct or analysis of a study may cause systematic error in the results of a study; That is, whether the prevalence or associated effects for an outcome in a cross-sectional study may be over- or under-estimated. Since tools may be described inconsistently using language on methodological quality, quality tools will be eligible if they are judged by reviewers to contain one or more items relating to internal validity of the study.

This review will consider records for inclusion if they meet the following criteria:

- Permit the assessment of RoB in human observational studies defined as cross-sectional studies, including analytic or prevalent/survey approaches;
- Describe or permit global assessment of RoB for multiple study designs and originally developed for application to cross-sectional study designs; or,
- Describe the application of a tool not originally designed for application to cross-sectional study designs which has been adapted or modified for application to cross-sectional study designs for the assessment of RoB; and,
- Published or available in English.

“Tools” may be described as checklists, scored instruments, ‘question/item-based‘ or ’domain-based’ according to groupings or categories of bias. Systematic reviews of RoB tools will also be included if they endeavoured to locate and/or include relevant tools/items/concepts for cross-sectional studies.

Records identified will be excluded if they 1) report tools intended for other study designs and are not intended for evaluation of cross-sectional study designs; or, 2) report single-study or multi-study tools modified for application to cross-sectional studies in a systematic review and the modified tool is not reported or cited.

Types of sources

This scoping review will consider records of any study design for inclusion. As there is a limited number of RoB tools published in peer-reviewed literature, four approaches will be used to search for and locate eligible RoB tools relevant to cross-sectional studies:

1. **Bibliographic database search:** This approach will be used to identify published RoB tools and relevant systematic reviews of RoB tools. For the search of bibliographic databases, an experienced medical information specialist developed and tested search strategies through an iterative process in consultation with the review team.

2. **Prospective scan of PROSPERO registrations:** This approach will be used to identify RoB tools identified in 1000 prospectively registered systematic review protocols in the PROSPERO database. In order to identify currently used tools, all records will be searched for proposals including the term "cross-sectional" and systematic reviews indicating the proposed inclusion of cross-sectional studies in the analysis will be retained. Applicable RoB tools will be identified from the details in the "Risk of bias (quality) assessment" section of the registration.
3. **Outreach to key knowledge users:** This approach will be used to gather information regarding RoB tools being applied in practice for cross-sectional studies. A group of users in the field of nutrition will be selected as they commonly use or assess cross-sectional research. The email-based outreach will briefly ask participants to reply if they are willing to share a citation or the name of a relevant RoB tool they use or are aware of.
4. **Experiential knowledge of content experts:** This approach will supplement the other approaches by collecting the experiential knowledge of key content experts to identify additional tools not represented they are aware of.

Bibliographic database search strategy

An experienced medical information specialist developed and tested the search strategies through an iterative process in consultation with the review team. A full search strategy for OvidMEDLINE® ALL, including Epub Ahead of Print, In-Process & Other Non-Indexed Citations, and Embase Classic+Embase will be searched on the Ovid platform, followed by a search of Web of Science (see Appendix I). The strategies utilize a combination of controlled vocabulary (e.g.,"Cross-Sectional Studies", "Bias","Checklists") and keywords (e.g.,"cross-sectional design", "quality rating","tool"). The search strategy will be adapted for each included information source. The search strategy will aim to locate both published and unpublished tools. Results will be limited to the publication years 2011 to the present. Results will be downloaded and deduplicated using EndNote version 20.4.1 (Clarivate Analytics, PA, USA) and uploaded to Covidence systematic review software for screening (Veritas Health Innovation, Melbourne, Australia. Available at www.covidence.org). The database search will be updated prior to completion of the scoping review.

Evidence selection

Following the search, all identified database records will be collated and uploaded into Covidence systematic review software (Veritas Health Innovation, Melbourne, Australia. Available at www.covidence.org) and EndNote and duplicates removed. Following a pilot test, titles and abstracts will then be screened by two independent reviewers for assessment against the inclusion criteria for the review. Potentially relevant records will be retrieved in full and tracked through Covidence. The full text of selected citations will be assessed in detail against the inclusion criteria by one reviewer and included records will be confirmed by a second independent reviewer.

The included study lists of all eligible systematic reviews will be screened to identify potentially relevant RoB tools. All records identified through systematic reviews, the environmental scan, expert working group and PROSPERO registry search will be retrieved in full, assessed in detail against the inclusion criteria by one reviewer and confirmed by a second independent reviewer. All non-database records will be tracked using an MS Excel spreadsheet (Microsoft Corp. (2018).

Following a detailed assessment, a super-set of unique RoB tools relevant to cross-sectional studies will be created once de-duplication of records and tools across the approaches is complete.

Reasons for exclusion of full-text records that do not meet the inclusion criteria will be recorded and reported in the scoping review. Any disagreements that arise between the reviewers at each stage of the selection process will be resolved through discussion or with a third reviewer. The results of the search will be reported in full in the final scoping review and presented in a PRISMA flow diagram [3].

Data extraction

Data will be extracted from tools included in the scoping review by one reviewer and checked by a second reviewer. The data extracted will focus on descriptive information, characteristics of the tool, items and domains used to evaluate risk of bias and any psychometric properties reported, including:

- citation, tool name;
- reported study design(s) intended for use/application (single or multiple study designs);
- tool development and testing: reported methods used to develop the tool, reported reliability, validity or usability testing, including whether the tool was developed or tested in a particular clinical area;
- characteristics of the tool including but not limited to: use of domains/items/rating probes, format for completing the item or overall rating, whether rating summaries of quality or bias are used (e.g. poor/good/moderate) or if scoring is calculated;
- discrimination between concepts of quality, risk of bias, and reporting quality;
- how and why an existing tool was modified for application to cross-sectional studies; and,
- declared organization supporting the tool development, any sponsors or reported funding.

Data extraction will be standardized using a framework reported for RoB tools by the National Toxicology Program of the United States Department of Health and Human Services [4]. The extraction framework focuses on key bias domains (*selection, exposure, outcome, confounding, loss-to-follow-up, analysis, selective reporting, conflict of interest and other*), the topic(s) within each domain, the questions and available response options. The extraction framework will be adapted if necessary for considerations specific to cross-

sectional studies during a pilot to assess the feasibility of the process for extracting data from each included record. Any modifications will be detailed in the full scoping review. Any disagreements that arise between the reviewers will be resolved through discussion or with a third reviewer. All extracted information will be compiled into detailed evidence tables in Microsoft Excel.

Data analysis and presentation

Results will be presented in tables and figures (if applicable) and described in detail. A narrative summary will accompany the charted results and will describe how the results relate to the scoping review objective and questions. The final evidence product will be an item bank of risk of bias concepts relevant to cross-sectional studies.

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Supplementary material *and/or* additional information

Supplementary material

Search strategy

MEDLINE
Database: Ovid MEDLINE(R) ALL ⟨1946 to November 17, 2021⟩

1 Cross-Sectional Studies/ (398,684)
2 ((cross-section* or crosssection*) adj2 (study or studies or design?)).ti,kw,kf. (48,153)
3 1 or 2 [CROSS-SECTIONAL STUDIES] (412,208)
4 Cross-Sectional Studies/st [standards] (41)
5 Research Design/st [standards] (12,411)
6 Evidence-Based Medicine/mt, st [methods,standards] (9222)
7 or/4–6 [RESEARCH DESIGN STANDARDS] (21,297)
8 3 and 7 [CROSS-SECTIONAL STUDIES - RESEARCH DESIGN STANDARDS] (320)
9 exp bias/ (72,351)
10 bias$2.ti,kw,kf. (38,345)
11 ((assess* or apprais* or estimat* or grade? or grading) adj3 (bias* or quality)).tw,kw,kf. (118,427)
12 ((susceptib* or risk?) adj3 bias*).tw,kw,kf. (33,354)
13 ((rate or rated or rates or rating) adj2 quality).tw,kw,kf. (7834)
14 Research Design/ (116,838)
15 (research adj3 (appropriate* or design? or method* or protocol? or strateg* or valid*)).tw,kw,kf. (132,941)
16 (methodological* adj3 (appropriate* or consider* or decision? or design? or issue? or quality or valid*)).tw,kw,kf. (33,428)
17 ((design? or report* or study or studies) adj3 (appropriate* or quality or valid*)).tw,kw,kf. (160,543)
18 "Reproducibility of Results"/ (431,267)
19 reproducib*.ti,kw,kf. (18,259)
20 (reliabilit* or reliabl*).ti,kw,kf. (60,000)
21 (replicable or replicat*).ti,kw,kf. (58,248)
22 Valid*.ti,kw,kf. (142,161)
23 Confound*.ti,kw,kf. (5461)
24 Data Accuracy/ (3315)
25 ((calculat* or data or measur* or statistic*) adj3 (accurat* or accurac* or appropriate* or objective)).tw,kw,kf. (141,906)
26 ((calculat* or data or measur* or statistic*) adj3 (correct* or exact* or precis*)).tw,kw,kf. (50,759)
27 or/9–26 [QUALITY] (1,285,786)
28 3 and 27 [CSS - QUALITY] (38,988)
29 Checklists/ (7539)
30 (checklist* or check list*).ti,kw,kf. (8020)
31 (tool or tools).ti,kw,kf. (100,645)
32 (instrument or instruments).ti,kw,kf. (37,759)
33 (framework? or frame work?).ti,kw,kf. (58,639)
34 ((assess* or apprais* or grade? or grading or quality) adj3 (criteri* or guide or guideline? or guidance? or standard?)).ti,kw,kf. (7910)
35 or/29–34 [TOOLS/FRAMEWORKS] (215,219)
36 28 and 35 [CSS - QUALITY ASPECTS - TOOLS] (1844)
37 8 or 36 [CSS - QUALITY ASPECTS - TOOLS/STANDARDS] (2136)
38 limit 37 to yr="2010-current" (1713)

Additional information

In a cross-sectional study, a sample of individuals is selected from a larger population and data is collected from each individual in the sample. This data can then be analyzed to draw conclusions about the population as a whole (5). Researchers may use cross-sectional studies for population-based surveys, to estimate the prevalence of outcomes and/or intervention/exposures or to measure association between the intervention/exposure and outcome by calculating an odds ratio [5,6].

The strengths of this design are that studies can be conducted relatively more resource efficiently when compared to other study designs, they can provide information that can be used to plan subsequent research studies (hypothesis generating), as well as provide data to support planning, monitoring and evaluation of health services or public health programs [6]. They often employ survey questionnaires which can be quick and simple approaches to collect prevalence data [7]. At the population level, the resulting prevalence estimates can be informative and generalizable. However, there are several limitations associated with cross-sectional studies. Causal relationships cannot be derived from a one-time measurement of intervention/exposure and outcome and there are no temporal elements within the design to strengthen estimates or sufficiently determine trends [6,7]. It can be difficult to plan and conduct a high-quality cross-sectional study as this design is prone to real or potential bias related to difficulties obtaining representative samples, inaccuracies in collected information, unclear temporal relationships and the possibility of reverse causality. Like other observational study designs, a major limitation is the inability to account for unobservable confounding when associations of interest are identified [6,8–10].

When trying to answer research questions, knowledge users may use or synthesize evidence from cross-sectional studies. Including a risk-of-bias (RoB) assessment is crucial to understanding relationships among interventions, exposures and the parameters of interest, and interpreting study findings. Although several tools exist for assessing the RoB in cross-sectional studies, there is no consensus on a 'gold standard' tool.

Recent reviews of RoB tools have shown that existing tools may apply to one or more study design, but vary in their approach to scoring or rating, the included RoB concepts, and their response options, and variably include additional items related to generalizability, precision or reporting [11,12]. Previous research concluded that many RoB tools are developed explicitly for experimental research and do not adequately address key biases common in observational research [13,14]. Many tools developed broadly for multiple observational study designs are not specifically applicable to cross-sectional studies or fail to sufficiently assess important aspects of bias common in cross-sectional studies [14–16]. While multi-study RoB tools cover a breadth of methodological bias concepts, using design-specific RoB tools can help ensure that all relevant sources of bias are considered and evaluated appropriately. These design-specific tools may be more applicable, user-friendly and easier to interpret where there is no control group present [15].

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

CRediT authorship contribution statement

Shannon E. Kelly: Conceptualization, Methodology, Validation, Writing – original draft, Writing – review & editing, Visualization. **Karima Benkhedda:** Conceptualization, Methodology, Writing – review & editing. **Stephen P.J. Brooks:** Conceptualization, Methodology, Writing – review & editing. **Amanda J. MacFarlane:** Conceptualization, Methodology, Writing – review & editing. **Linda S. Greene-Finestone:** Conceptualization, Methodology, Writing – review & editing. **Becky Skidmore:** Methodology, Validation, Writing – original draft, Writing – review & editing. **Tammy J. Clifford:** Supervision, Methodology, Writing – review & editing. **George A. Wells:** Conceptualization, Methodology, Supervision, Writing – review & editing.

Data availability

No data was used for the research described in the article.

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