The revised JBI critical appraisal tool for the assessment of risk of bias for analytical cross-sectional studies

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ABSTRACT

Cross-sectional studies are a useful observational study design that provide a snapshot of a population's health status at a specific moment in time. Analytical cross-sectional studies are often included in systematic reviews investigating the etiology or risk of diseases, and descriptive cross-sectional studies are often used to determine the prevalence of a disease. As required of all studies that meet eligibility criteria for a systematic review, analytical cross-sectional studies should be subjected to appropriate critical appraisal of their methodological quality to determine the risk of bias. The JBI Effectiveness Methodology Group is currently undertaking a comprehensive revision of the entire suite of JBI critical appraisal tools to align with recent advances in risk of bias assessment. This paper presents the revised critical appraisal tool for risk of bias assessment of analytical cross-sectional studies. Applying tools such as the revised JBI tools within systematic reviews allows end users to make informed decisions using the evidence. We discuss major changes from the previous iterations of this tool and justify these changes within the context of the broader advancements to risk-of-bias assessment science. We also offer practical guidance for the use of this revised tool, and provide examples for interpreting the results of risk-of-bias assessment for analytical cross-sectional studies to support reviewers including these studies in their systematic reviews.

Keywords: bias assessment; cross-sectional studies; methodology; risk of bias; systematic review

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Introduction

Systematic reviews provide a rigorous, transparent, and comprehensive synthesis of relevant studies to answer a specific, explicitly articulated question.[1] While many systematic reviews are focused on answering a question addressing the effectiveness of a health care intervention (ie, does it work?), there are different types of questions that can and need to be systematically reviewed. This need has spawned methods for many different types of systematic reviews.[2] Systematic reviews of etiology and risk, for example, assess the association between specific, measurable variables and the development of a health outcome.[3] Meanwhile, systematic reviews of prevalence and/or incidence[4] answer questions related to the burden of disease over a specific time period.[5] As these types of systematic reviews diverge quite markedly from the questions posed in systematic reviews of effectiveness, the designs of the studies included are not necessarily experimental, which are typically included in systematic reviews of the effectiveness of interventions. The study designs that are usually sourced to address the questions presented in

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systematic reviews of etiology and risk include cohort studies, case-control studies, and cross-sectional studies (commonly presented as surveys).[3,5]

Cross-sectional studies are an observational research design and provide data regarding a specific population captured at a specific point in time.[6-8] The nature in which data are collected in cross-sectional studies differentiates them from the more rigorous observational study designs, such as cohort and case-control studies. In cohort and case-control study designs, participants are typically followed over time, or retrospectively through time, to determine changes in their health outcomes.[9] Additionally, while cohort studies include eligible participants based on exposure status (ie, exposed vs unexposed) and case-control studies include eligible participants based on outcome status (ie, presence or absence of outcome), cross-sectional studies do not impose similar demands for how eligible participants are included.[8] Instead, cross-sectional study designs aim to select individuals in a way that ensures they are representative of the entire population.[7,8,10] This approach allows for the information collected from the study sample to be generalized to the whole population, effectively creating a sample that serves as a cross-section of the population.[7-9] These studies play a crucial role in epidemiological research, as they provide a basis for generating hypotheses about disease etiology and identifying associations that warrant further investigation through longitudinal research.[9,11]

Cross-sectional studies can be categorized into 2 types for providing different types of data: descriptive and analytical.[7,8] Descriptive cross-sectional studies measure the prevalence or incidence of a health outcome in a population of interest. By providing this snapshot, descriptive cross-sectional studies can identify both existing and new cases of diseases as they occur.[11] For instance, a descriptive cross-sectional study may reveal the prevalence of people with mental disorders between the years 2020 and 2022.[12] This ability to capture information about disease burden at a particular moment makes cross-sectional studies invaluable for public health planning and resource allocation.[7,11] Meanwhile, analytical cross-sectional studies collect data not only on the prevalence or incidence of a health outcome, but also on potential exposures that participants may have been subject to in order to assess associations between them. These studies further identify potential differences between the groups of participants that have been exposed and those that remain unexposed regarding the health outcome of interest. In this paper, we refer to analytic cross-sectional studies aiming to investigate the relationship between an exposure and an outcome.

There have recently been well-documented advancements[13-15] proposed in the field of risk of bias assessment science, including the requirement to assess bias at specific levels (result level and outcome level, as opposed to study level) and to focus only on concepts related to internal validity (as opposed to external validity or quality of reporting). The JBI critical appraisal instruments are, therefore, being revised to reflect these advances in risk of bias assessment.[13-16] This paper presents the revised critical appraisal tool for risk of bias assessment of analytical cross-sectional studies, accompanied by practical guidance for its use and a discussion of the major changes made.

Methods

The JBI Scientific Committee tasked the JBI Effectiveness Methodology Group (a working group of researchers) in 2021 to revise the current JBI critical appraisal tools for quantitative study designs. The overall aim of this work was to improve their relevance and longevity while adhering to the updated perspectives in risk-of-bias science.[13-16] This revision also aligns the revised critical appraisal tool for analytical cross-sectional studies with the reporting requirements established by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 statement,[17] and methodological requirements for using Grading of Recommendations, Assessment, Development and Evaluation (GRADE) when assessing certainty in the evidence.[18]

The methods used to develop the revised critical appraisal tool for analytical cross-sectional studies have been comprehensively documented in previous publications.[16,19] To summarize the methods, the Effectiveness Methodology Group organized the questions of the previous critical appraisal tool for analytical cross-sectional studies into constructs of validity (internal, statistical conclusion, comprehensiveness of reporting, external) through roundtable discussions and a mapping exercise. Each question related to the construct of internal validity was then further categorized into a specific domain of bias. Finally, each question was separated by the level in which it is to be assessed (study, outcome, or result). The rationale and justification for the key changes

made from the previous tool (and the entire suite of revised tools) have been fully documented in the previous publications of this series.[16,19-21]

How to use the revised tool

Assessment methods

As with the other revised tools in this series, the methods for using this tool remain consistent. Reviewers should consider each signaling question as presented and respond to that question with "yes," "no," "unclear," or "not applicable." This response should be based on the methodological safeguards the study has employed, or lack thereof, that are directly relevant to the question being asked. There will always be a level of subjective interpretation for any risk of bias assessment, regardless of the tool used. We acknowledge that it is not uncommon for different review teams, or even members within the same review team, to arrive at different judgments regarding how a question should be answered. For example, question 1 of the revised tool for risk of bias assessment of analytical cross-sectional studies asks, "Were the criteria for inclusion in the sample clearly defined?" What constitutes being "clearly" defined is, ultimately, subjective and context-dependant. These thresholds need to be established by the review team, and universally understood by members of the review team, prior to commencing risk of bias assessment of the studies included in a systematic review. To circumvent differences in interpretation of these questions, we strongly encourage review teams to pilot this tool on a sample of included studies so these thresholds can be defined early. The thresholds should then be clearly communicated, so any reader of the review can transparently determine how these judgments were made.

Previous guidance from this series has discussed other common issues with the methods and presentation of risk of bias assessment, including the appropriateness of excluding studies at high risk of bias,[21] and the utility of providing an overall risk-of-bias judgment.[21] Additionally, guidance for suggested methods of presentation have also been outlined in the previous papers on this series,[16,19-21] as well as other frequently asked questions regarding risk-of-bias assessment.

The revised JBI critical appraisal tool for analytical cross-sectional studies

The criteria and considerations that should be made when using the revised JBI critical appraisal tool for analytical cross-sectional studies are shown in Table 1. This tool is also available to download as supplemental digital content at: http://links.lww.com/SRX/A98.

Question 1: Were the criteria for inclusion in the sample clearly defined?

Category: Internal validity
Domain: Bias related to selection and allocation
Appraisal: Study level

Reviewers should check for descriptions of the inclusion and exclusion criteria that the authors applied to determine participant eligibility into the study. These descriptions should be explicit and provide sufficient detail that is critical to the nature of the study. The inclusion and exclusion criteria should be developed prior to the recruitment of the study participants and may include aspects such as age of eligible participants, occupants per household, presence or absence of comorbidities, and other useful demographic information to determine whether potentially eligible participants from the broader population were eligible for inclusion into the study.

Question 2: Were objective, standard criteria used for measurement of the condition?

Category: Internal validity
Domain: Bias related to selection and allocation
Appraisal: Outcome level

It is useful to determine if patients were included in the study based on a specified diagnosis or definition regarding the health condition of interest. For example, if it was a requirement that participants were only eligible if they were experiencing depression, reviewers should check to determine whether this diagnosis was through objective, standard criteria, such as from the Diagnostic and Statistical Manual of Mental Disorders, as opposed to a self-diagnosis of depression. Characteristics are another useful approach to matching groups, and studies that did not use specified diagnostic methods or definitions should provide evidence on matching by key characteristics.

Question 3: Was the exposure measured in a valid and reliable way?

Category: Internal validity
Domain: Bias related to classification of the exposure
Appraisal: Study level

Reviewers should determine that the study has provided a clear description as to how the exposure was measured and determined (ie, ascertained). For exposure determination to be valid, an appropriate

Table 1: JBI critical appraisal tool for analytical cross-sectional studies

RoB assessor:		Date of appraisal:	Record number:			
Study author:		Study title:	Study year:			
Internal validity		Choice: comments/ justification	Yes	No	Unclear	N/A
Bias related to selection and allocation						
1	Were the criteria for inclusion in the sample clearly defined?		☐	☐	☐	☐
2	Were objective, standard criteria used for measurement of the condition?		Yes	No	Unclear	N/A
	Outcome 1		☐	☐	☐	☐
	Outcome 2		☐	☐	☐	☐
	Outcome 3		☐	☐	☐	☐
	Outcome 4		☐	☐	☐	☐
	Outcome 5		☐	☐	☐	☐
	Outcome 6		☐	☐	☐	☐
	Outcome 7		☐	☐	☐	☐
Bias related to classification of the exposure						
3	Was the exposure measured in a valid and reliable way?		☐	☐	☐	☐
Bias related to assessment, detection, and measurement of the outcome						
4	Were the outcomes measured in a valid and reliable way?		Yes	No	Unclear	N/A
	Outcome 1		☐	☐	☐	☐
	Outcome 2		☐	☐	☐	☐
	Outcome 3		☐	☐	☐	☐
	Outcome 4		☐	☐	☐	☐
	Outcome 5		☐	☐	☐	☐
	Outcome 6		☐	☐	☐	☐
	Outcome 7		☐	☐	☐	☐
Bias related to confounding factors						
5	Were confounding factors identified?		☐	☐	☐	☐
6	Were strategies to deal with confounding factors stated?		Yes	No	Unclear	N/A
	Outcome 1		☐	☐	☐	☐
	Outcome 2		☐	☐	☐	☐
	Outcome 3		☐	☐	☐	☐
	Outcome 4		☐	☐	☐	☐
	Outcome 5		☐	☐	☐	☐
	Outcome 6		☐	☐	☐	☐
	Outcome 7		☐	☐	☐	☐
Statistical conclusion validity						
7	Was appropriate statistical analysis used?					
	Outcome 1		Yes	No	Unclear	N/A
	Result 1		☐	☐	☐	☐
	Result 2		☐	☐	☐	☐
	Result 3		☐	☐	☐	☐
	Outcome 2		Yes	No	Unclear	N/A
	Result 1		☐	☐	☐	☐

Table 1: (*continued*)

RoB assessor:		Date of appraisal:		Record number:			
Study author:		Study title:		Study year:			
Internal validity		Choice: comments/ justification		Yes	No	Unclear	N/A
	Result 2			☐	☐	☐	☐
	Result 3			☐	☐	☐	☐
	Outcome 3			Yes	No	Unclear	N/A
	Result 1			☐	☐	☐	☐
	Result 2			☐	☐	☐	☐
	Result 3			☐	☐	☐	☐
	Outcome 4			Yes	No	Unclear	N/A
	Result 1			☐	☐	☐	☐
	Result 2			☐	☐	☐	☐
	Result 3			☐	☐	☐	☐
	Outcome 5			Yes	No	Unclear	N/A
	Result 1			☐	☐	☐	☐
	Result 2			☐	☐	☐	☐
	Result 3			☐	☐	☐	☐
	Outcome 6			Yes	No	Unclear	N/A
	Result 1			☐	☐	☐	☐
	Result 2			☐	☐	☐	☐
	Result 3			☐	☐	☐	☐
	Outcome 7			Yes	No	Unclear	N/A
	Result 1			☐	☐	☐	☐
	Result 2			☐	☐	☐	☐
	Result 3			☐	☐	☐	☐
Comprehensiveness of reporting							
8	Were the study subjects and the setting described in detail?			☐	☐	☐	☐
Overall appraisal:		Include: ☐	Exclude: ☐	Seek Further Info: ☐			
Comments:							

N/A, not applicable; RoB, risk of bias.

determination measure should be used that is relevant to the topic under investigation. For example, an author may have performed a cross-sectional study to determine whether there are associations between exposure to burning insect repellents (eg, mosquito coils) and adverse skin reactions. It would be expected that authors first clearly identify how they defined what constituted exposure to these coils and then how this was determined in the participants. If exposure was defined as "use of 1 mosquito coil per day," how was this determined (ie, measured)? Self-report by participants in a survey is typical and expected; however, a more valid determination measure may be used to confirm this survey response. For example, the authors can consider using more rigorous methods of confirmation, such as spot checks or collection of coil waste at set intervals, although these methods are not typical of most cross-sectional studies.

Reliability refers to the processes included in a study to check the repeatability of measurements of the exposures. These usually include intra-observer reliability and inter-observer reliability. The absence of these metrics, however, does not necessarily preclude this criterion being scored as either "unclear" or "no." For assessment of both validity and reliability in the context of analytical cross-sectional studies, reviewers should use their judgment regarding the nature of the exposure measure, as well as the context

of the research question, and provide clear description and reasoning for their judgment.

Question 4: Were the outcomes measured in a valid and reliable way?

Category: Internal validity
Domain: Bias related to assessment, detection, and measurement of the outcome
Appraisal: Outcome level

To assess validity, reviewers should read the methods section of the paper to determine whether the outcome of interest has been assessed based on appropriate (ideally, objective) criteria relevant to the nature of the topic under investigation. Consider the previous example of a cross-sectional study investigating mosquito coils and adverse skin reactions (eg, eczema). It would be considered appropriate that determination of eczema in the participants would be achieved through a trained health professional, or perhaps participants had received a formal diagnosis regarding eczema. In this example, if the outcome was assessed using such techniques, then the answer to this question is likely to be "yes." If the presence of eczema in the participants was determined through self-report alone, the risk of overreporting or underreporting is increased, and objectivity of the outcome measure is compromised. Importantly, reviewers should determine whether any measurement tools used (where appropriate) were validated instruments, as this has a significant impact on outcome assessment validity.

It is also important to consider whether those involved in collecting data were trained or educated in the use of the instrument/s. If there was more than 1 data collector, were they similar in terms of clinical or research experience? Did they have similar levels of familiarity with the tool used to collect data, or level of responsibility in the piece of research being appraised? If not, then the response to this question may be "no."

Question 5: Were confounding factors identified?

Category: Internal validity
Domain: Bias related to confounding factors
Appraisal: Study level

A confounder is an additional variable that is linked, or contributes to, to the occurrence of both the exposure and the outcome, and can create a misleading association between the exposure and outcome. Authors of a high-quality study will identify the potential confounders and measure them, where possible. Potential confounding factors can be identified statistically using the variance inflation factor statistic for each independent variable considered. However, this is rarely performed in research due to the need to identify all known and unknown factors that each may or may not serve as a confounder. Other strategies to identify potential confounders include listing common demographic factors (eg, age, sex) or factors known to be associated with the exposure (eg, type of work, if investigating exposure to agricultural fertilizers) and the outcome (eg, smoking status if the outcome of interest is lung cancer). These can be sourced from existing studies and reviews on the topic to better understand what confounders should be investigated. If potential confounders likely to be associated with the exposure and the outcome are not identified in the study (eg, the authors have not identified smoking as a potential confounder for the outcome of lung cancer), then reviewers should answer this question as "no."

Question 6: Were strategies to deal with confounding factors stated?

Category: Internal validity
Domain: Bias related to confounding factors
Appraisal: Outcome level

Strategies to deal with the effects of confounding factors are often incorporated within the data analysis of analytical cross-sectional studies using statistical adjustment. As opposed to other observational study designs (eg, cohort studies or case-control studies), techniques such as matching or stratifying sampling of participants is not possible, due to the inherent differences associated with how participants are sampled in analytical cross-sectional studies. When dealing with statistical adjustment, reviewers should assess the statistical analysis used in the study. Most studies will use some form of multivariable regression analysis to account for the confounding factors measured. Reviewers should look for a broad description of the statistical methods utilized. Ideally, each factor controlled for in these adjusted analyses will be presented transparently, which will allow reviewers to determine whether all potential confounders identified have been appropriately addressed.

Question 7: Was appropriate statistical analysis used?

Category: Statistical conclusion validity
Appraisal: Result level

Inappropriate statistical analysis may cause errors of statistical inference regarding the existence and the magnitude of the association. Low statistical power and the violation of the assumptions of statistical tests are 2 important threats that weaken the validity of inferences about the statistical relationship between the exposure and outcome. Reviewers should check the following aspects: whether the assumptions of the statistical tests were considered and not violated; whether appropriate effect sizes were used; and whether appropriate statistical methods were used given the nature of the data and the objectives of statistical analysis (eg, association between variables, prediction, survival analysis). These should be considered when reviewers assess this question and used to justify their decision to score this criterion as "yes," "no," or "unclear."

Question 8: Were the study subjects and the setting described in detail?

Category: Comprehensiveness of reporting
Appraisal: Study level

It is important for readers of the study, and readers of the review, to determine whether the results presented are relevant to the population of interest for the systematic review and to inform any groups (similar studies to combine) for evidence synthesis. Although the study authors should have provided specific eligibility criteria regarding the population characteristics (assessed in questions #1 and #2), reviewers should also determine whether similar detail is provided regarding the study setting (eg, location, time period) and details of the actual participants (eg, participant demographics) enrolled in the study (not just eligible for the study).

Conclusions

Cross-sectional studies are commonly included in systematic reviews, particularly analytical cross-sectional studies, assessing the risk factors associated with a disease, or descriptive cross-sectional studies when estimating global disease burden. As with all studies included in a systematic review of the literature, there is a critical need to assess these studies for their risk of bias. The revised critical appraisal tool for the assessment of risk of bias for analytical cross-sectional studies will facilitate this assessment according to recent advancements of risk-of-bias science. The new tool permits judgments at the result, outcome, and study level, and clearly identifies the signaling questions related to internal validity (and hence, bias) and those that do not. This revised tool will ensure that reviewers are appropriately assessing these studies on the risk of bias in their future reviews.

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Author contributions

THB and SH wrote the manuscript. THB, EA, JCS, JLB, KS, MK, CT, SM, XLL, and ZM contributed to the concept and design of this work. THB, EA, JCS, JLB, KS, MK, SM, XLL, and ZM reviewed the draft and provided feedback.

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