

DICTIONARY

for the
**Effective Public Health Practice Project
Quality Assessment Tool for Quantitative Studies**

INTRODUCTION

The purpose of this tool is to assess the methodological quality of relevant studies since lesser quality studies may be biased and could over-estimate or under-estimate the effect of an intervention. Each of two raters will independently assess the quality of each study and complete this form. When each rater is finished, the individual ratings will be compared. A consensus must be reached on each item. In cases of disagreement even after discussion, a third person will be asked to assess the study.

When appraising a study, it is helpful to first look at the design then assess other study methods. It is important to read the methods section since the abstract (if present) may not be accurate. Descriptions of items and the scoring process are located in the dictionary that accompanies this tool.

The scoring process for each component is located on the last page of the dictionary.

INSTRUCTIONS FOR COMPLETION

Circle the appropriate response in each component section (A-H). Component sections (A-F) are each rated using the roadmap on the last page of the dictionary. After each individual rater has completed the form, both reviewers must compare their ratings and arrive at a consensus.

The dictionary is intended to be a guide and includes explanations of terms.

The purpose of this dictionary is to describe items in the tool thereby assisting raters to score study quality. Due to under-reporting or lack of clarity in the primary study, raters will need to make judgements about the extent that bias may be present. When making judgements about each component, raters should form their opinion based upon information contained in the study rather than making inferences about what the authors intended.

A) SELECTION BIAS

Selection bias occurs when the study sample does not represent the target population for whom the intervention is intended. Two important types of biases related to sample selection are referral filter bias and volunteer bias. For example, the results of a study of participants suffering from asthma from a teaching hospital are not likely to be generalizable to participants suffering from asthma from a general practice. In volunteer bias, people who volunteer to be participants may have outcomes that are different from those of non-volunteers. Volunteers are usually healthier than non-volunteers.

Q1 **Are the individuals selected to participate in the study likely to be representative of the target population?**

The authors have done everything reasonably possible to ensure that the target population is represented (e.g.	Very Likely
Participants may not be representative if they are referred from a source within a target population even if it is in a systematic manner (e.g. patients from a teaching hospital for adults with asthma, only inner-city schools for adolescent risk.	Somewhat Likely

Participants are probably not representative if they are self-referred or are volunteers (e.g. volunteer patients from a teaching hospital for adults with asthma, inner-city school children with parental consent for adolescent risk) or if you can not tell.	Not Likely
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Q2 What percentage of selected individuals agreed to participate?

The % of subjects in the control and intervention groups that agreed to participate in the study before they were assigned to intervention or control groups.	%
There is no mention of how many individuals were approached to participate.	Not Reported
The study was directed at a group of people in a specific geographical area, city, province, broadcast audience, where the denominator is not known, e.g. mass media intervention.	Not Applicable

B) ALLOCATION BIAS

In this section, raters assess the likelihood of bias due to the allocation process in an experimental study. For observational studies, raters assess the extent that assessments of exposure and outcome are likely to be independent. Generally, the type of design is a good indicator of the extent of bias. In stronger designs, an equivalent control group is present and the allocation process is such that the investigators are unable to predict the sequence.

Q1 Indicate the study design.

Investigators randomly allocate eligible people to an intervention or control group.	RCT
<i>Cohort (two group pre and post)</i> Groups are assembled according to whether or not exposure to the intervention has occurred. Exposure to the intervention may or may not be under the control of the investigators. Study groups may not be equivalent or comparable on some feature that affects the outcome.	Two-group Quasi- Experimental
<i>Before/After Study (one group pre + post)</i> The same group is pretested, given an intervention, and tested immediately after the intervention. The intervention group, by means of the pretest, act as their own control group. <i>Case control study</i> A retrospective study design where the investigators gather 'cases' of people who already have the outcome of interest and 'controls' that do not. Both groups are then questioned or their records examined about whether they received the intervention exposure of interest. <i>No Control Group</i>	Case-control, Before/After Study or No Control Group

Note: The following questions are not for rating but for additional statistics that can be incorporated in the writing of the review.

(i) **If the study was reported as an RCT was the method of random allocation stated?**

The method of allocation was stated.	YES
The method of allocation was not stated.	NO

(ii) **Is the method of random allocation appropriate?**

The method of random allocation is appropriate if the randomization sequence allows each study participant to have the same chance of receiving each intervention and the investigators could not predict which intervention was next. e.g. an open list of random numbers of assignments or coin toss	YES
The method of random allocation is not entirely transparent, e.g. the method of randomization is described as alternation, case record numbers, dates of birth, day of the week.	NO

(iii) **Was the method of random allocation concealed?**

The randomization allocation was concealed so that each study participant had the same chance of receiving each intervention and the investigators could not predict which group assignment was next. Examples of appropriate approaches include assignment of subjects by a central office unaware of subject characteristics, or sequentially numbered, and sealed in opaque envelopes.	YES
The method of random allocation was not concealed or not reported as concealed.	NO

C) **CONFOUNDERS**

A confounder is a characteristic of study subjects that: is a risk factor (determinant) for the outcome to the putative cause, or is associated (in a statistical sense) with exposure to the putative cause

Note: Potential confounders should be discussed within the Review Group and decided a priori.

Q1 Prior to the intervention were there differences for important confounders reported in the paper?

The authors reported that the groups were balanced at baseline with respect to confounders (either in the text or a table)	NO
The authors reported that the groups were not balanced at baseline with respect to confounders.	YES

Q2 Were the confounders adequately managed in the analysis?

Differences between groups for important confounders were controlled in the design (by stratification or matching) or in the analysis.	YES
No attempt was made to control for confounders.	NO

Q3 Were there important confounders not reported?

describe	YES
All confounders discussed within the Review Group were reported.	NO

D) BLINDING

The purpose of blinding the outcome assessors (who might also be the care providers) is to protect against detection bias.

Q1 Was (were) the outcome assessor(s) blinded to the intervention or exposure status of participants?

Assessors were described as blinded to which participants were in the control and intervention groups.	YES
Assessors were able to determine what group the participants were in.	NO
The data was self-reported and was collected by way of a survey, questionnaire or interview.	Not Applicable
It is not possible to determine if the assessors were blinded or not.	Not Reported

E) DATA COLLECTION METHODS

Some sources from which data may be collected are:

Self reported data includes data that is collected from participants in the study (e.g. completing a questionnaire, survey, answering questions during an interview, etc.).

Assessment/Screening includes objective data that is retrieved by the researchers. (e.g. observations by investigators).

Medical Records / Vital Statistics refers to the types of formal records used for the extraction of the data.

Reliability and validity can be reported in the study or in a separate study. For example, some standard assessment tools have known reliability and validity.

Q1 **Were data collection tools shown or known to be valid for the outcome of interest?**

The tools are known or were shown to measure what they were intended to measure.	YES
There was no attempt to show that the tools measured what they were intended to measure.	NO

Q2 **Were data collection tools shown or known to be reliable for the outcome of interest?**

The tools are known or were shown to be consistent and accurate in measuring the outcome of interest (e.g., test-retest, Cronback's alpha, interrater reliability).	YES
There was no attempt to show that the tools were consistent and accurate in measuring the outcome of interest.	NO

F) WITHDRAWALS AND DROP-OUTS

Q1 **Indicate the percentage of participants completing the study.**

The percentage of participants that completed the study.	%
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The study was directed at a group of people in a specific geographical area, city, province, broadcast audience, where the percentage of participants completing, withdrawing or dropping-out of the study is not known, e.g. mass media intervention.	Not Applicable
The authors did not report on how many participants completed, withdrew or dropped-out of the study.	Not Reported

G) ANALYSIS

If you have questions about analysis, contact your review group leader.

- Q1. The components of a recognized formula are present. There's a citation for the formula used.
- Q2. The appropriate statistically significant difference between groups needs to be determined by the review group before the review begins.
- Q3. The review group leader needs to think about how much the study has violated the underlying assumptions of parametric analysis?
- Q5. Whether intention to treat or reasonably high response rate (may need to clarify within the review group).

H) INTERVENTION INTEGRITY

Q1 What percentage of participants received the allocated intervention or exposure of interest?

The number of participants receiving the intended intervention is noted. For example, the authors may have reported that at least 80 percent of the participants received the complete intervention.	%
describe	Not Reported
describe	Not Applicable

Q2 Was the consistency of the intervention measured?

The authors should describe a method of measuring if the intervention was provided to all participants the same way.

describe	Yes
describe	No
describe	Not Reported

Q3 Is it likely that subjects received an unintended intervention (contamination or cointervention) that may influence the results?

The authors should indicate if subjects received an unintended intervention that may have influenced the outcomes. For example, co-intervention occurs when the study group receives an additional intervention (other than that intended). In this case, it is possible that the effect of the intervention may be over-estimated. Contamination refers to situations where the control group accidentally receives the study intervention. This could result in an under-estimation of the impact of the intervention.

describe	Yes
describe	No
describe	Can't Tell

Component Ratings for Study

A) SELECTION BIAS

Strong

Q1 = Very Likely AND Q2 = 80-100% Agreement
OR
Q1 = Very Likely AND Q2 = Not Applicable

Moderate

Q1 = Very Likely AND Q2 = 60 - 79% Agreement
OR
Q1 = Very Likely AND Q2 = Not Reported
OR
Q1 = Somewhat Likely AND Q2 = 80-100%
OR
Q1 = Somewhat Likely AND Q2 = 60 - 79% Agreement
OR
Q1 = Somewhat Likely AND Q2 = Not Applicable

Weak

Q1 = Not Likely
OR
Q2 = Less than 60% agreement
OR
Q1 = Somewhat Likely AND Q2 = Not Reported

B) ALLOCATION BIAS

Strong

Study Design = RCT

Moderate

Study Design = Two-Group Quasi-Experimental

Weak

Study Design = Case Control, Before/After Study, No Control Group

C) CONFOUNDERS

Strong

Q1 = No	AND Q2 = N/A	AND Q3 = No
Q1 = Yes	AND Q2 = Yes	AND Q3 = No

Moderate

Q1 = Yes	AND Q2 = Yes	AND Q3 = Yes
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Weak

Q1 = Can't Tell		
Q1 = Yes	AND Q2 = No	AND Q3 = Yes
Q1 = Yes	AND Q2 = No	AND Q3 = No
Q1 = No	AND Q2 = N/A	AND Q3 = Yes

D) BLINDING

Strong

Q1 = Yes

Weak

Q1 = No

Q1 = Not Reported

Not Applicable

E) DATA COLLECTION METHODS

Strong

Q1 = Yes AND Q2 = Yes

Moderate

Q1 = Yes AND Q2 = No

Weak

Q1 = No AND Q2 = Yes

OR

Q1 = No AND Q2 = No

F) WITHDRAWALS AND DROP-OUTS

Strong

Q1 = 80-100%

Moderate

Q1 = 60-79%

Weak

Q1 = Less than 60%

OR

Q1 = Not Reported

Not Applicable