

ROBIS: Tool to assess risk of bias in systematic reviews

Phase 1: Assessing relevance (Optional)

ROBIS is designed to assess the risk of bias in reviews with questions relating to interventions, aetiology, diagnosis and prognosis. State your overview/guideline question (target question) and the question being addressed in the review being assessed:

Intervention reviews:

Category	Target question (e.g. overview or guideline)	Review being assessed
Patients/Population(s):		
Intervention(s):		
Comparator(s):		
Outcome(s):		

For aetiology reviews:

Category	Target question (e.g. overview or guideline)	Review being assessed
Patients/Population(s):		
Exposure(s) and comparator(s):		
Outcome(s):		

For DTA reviews:

Category	Target question (e.g. overview or guideline)	Review being assessed
Patients):		
Index test(s):		
Reference standard:		
Target condition:		

For prognostic reviews:

Category	Target question (e.g. overview or guideline)	Review being assessed
Patients:	Hospitalized pregnant and postpartum women	
Outcome to be predicted:	Maternal mortality	
Intended use of model:	Clinical decision or risk adjustment	
Intended moment in time:	Anytime while hospital admission	

Does the question addressed by the review match the target question?

YES/NO/UNCLEAR

Phase 2: Identifying concerns with the review process

DOMAIN 1: STUDY ELIGIBILITY CRITERIA

Describe the study eligibility criteria, any restrictions on eligibility and whether there was evidence that objectives and eligibility criteria were pre-specified:

- | | |
|--|--|
| 1.1 Did the review adhere to pre-defined objectives and eligibility criteria? | <input type="radio"/> Y/ <input type="radio"/> PY/ <input type="radio"/> PN/ <input type="radio"/> N/ <input type="radio"/> NI |
| 1.2 Were the eligibility criteria appropriate for the review question? | <input type="radio"/> Y/ <input type="radio"/> PY/ <input type="radio"/> PN/ <input type="radio"/> N/ <input type="radio"/> NI |
| 1.3 Were eligibility criteria unambiguous? | <input type="radio"/> Y/ <input type="radio"/> PY/ <input type="radio"/> PN/ <input type="radio"/> N/ <input type="radio"/> NI |
| 1.4 Were all restrictions in eligibility criteria based on study characteristics appropriate (e.g. date, sample size, study quality, outcomes measured)? | <input type="radio"/> Y/ <input type="radio"/> PY/ <input type="radio"/> PN/ <input type="radio"/> N/ <input type="radio"/> NI |
| 1.5 Were any restrictions in eligibility criteria based on sources of information appropriate (e.g. publication status or format, language, availability of data)? | <input type="radio"/> Y/ <input type="radio"/> PY/ <input type="radio"/> PN/ <input type="radio"/> N/ <input type="radio"/> NI |

Concerns regarding specification of study eligibility criteria

LOW/HIGH/UNCLEAR

Rationale for concern:

DOMAIN 2: IDENTIFICATION AND SELECTION OF STUDIES

Describe methods of study identification and selection (e.g. number of reviewers involved):

- | | |
|--|--|
| 2.1 Did the search include an appropriate range of databases/electronic sources for published and unpublished reports? | <input type="radio"/> Y/ <input type="radio"/> PY/ <input type="radio"/> PN/ <input type="radio"/> N/ <input type="radio"/> NI |
| 2.2 Were methods additional to database searching used to identify relevant reports? | <input type="radio"/> Y/ <input type="radio"/> PY/ <input type="radio"/> PN/ <input type="radio"/> N/ <input type="radio"/> NI |
| 2.3 Were the terms and structure of the search strategy likely to retrieve as many eligible studies as possible? | <input type="radio"/> Y/ <input type="radio"/> PY/ <input type="radio"/> PN/ <input type="radio"/> N/ <input type="radio"/> NI |
| 2.4 Were restrictions based on date, publication format, or language appropriate? | <input type="radio"/> Y/ <input type="radio"/> PY/ <input type="radio"/> PN/ <input type="radio"/> N/ <input type="radio"/> NI |
| 2.5 Were efforts made to minimise error in selection of studies? | <input type="radio"/> Y/ <input type="radio"/> PY/ <input type="radio"/> PN/ <input type="radio"/> N/ <input type="radio"/> NI |

Concerns regarding methods used to identify and/or select studies

LOW/HIGH/UNCLEAR

Rationale for concern:

DOMAIN 3: DATA COLLECTION AND STUDY APPRAISAL

Describe methods of data collection, what data were extracted from studies or collected through other means, how risk of bias was assessed (e.g. number of reviewers involved) and the tool used to assess risk of bias:

- | | |
|--|--|
| 3.1 Were efforts made to minimise error in data collection? | <input type="radio"/> Y/ <input type="radio"/> PY/ <input type="radio"/> PN/ <input type="radio"/> N/ <input type="radio"/> NI |
| 3.2 Were sufficient study characteristics available for both review authors and readers to be able to interpret the results? | <input type="radio"/> Y/ <input type="radio"/> PY/ <input type="radio"/> PN/ <input type="radio"/> N/ <input type="radio"/> NI |
| 3.3 Were all relevant study results collected for use in the synthesis? | <input type="radio"/> Y/ <input type="radio"/> PY/ <input type="radio"/> PN/ <input type="radio"/> N/ <input type="radio"/> NI |
| 3.4 Was risk of bias (or methodological quality) formally assessed using appropriate criteria? | <input type="radio"/> Y/ <input type="radio"/> PY/ <input type="radio"/> PN/ <input type="radio"/> N/ <input type="radio"/> NI |
| 3.5 Were efforts made to minimise error in risk of bias assessment? | <input type="radio"/> Y/ <input type="radio"/> PY/ <input type="radio"/> PN/ <input type="radio"/> N/ <input type="radio"/> NI |

Concerns regarding methods used to collect data and appraise studies

LOW/HIGH/UNCLEAR

Rationale for concern:

DOMAIN 4: SYNTHESIS AND FINDINGS

Describe synthesis methods:

- | | |
|--|--------------|
| 4.1 Did the synthesis include all studies that it should? | Y/PY/PN/N/NI |
| 4.2 Were all pre-defined analyses reported or departures explained? | Y/PY/PN/N/NI |
| 4.3 Was the synthesis appropriate given the nature and similarity in the research questions, study designs and outcomes across included studies? | Y/PY/PN/N/NI |
| 4.4 Was between-study variation (heterogeneity) minimal or addressed in the synthesis? | Y/PY/PN/N/NI |
| 4.5 Were the findings robust, e.g. as demonstrated through funnel plot or sensitivity analyses? | Y/PY/PN/N/NI |
| 4.6 Were biases in primary studies minimal or addressed in the synthesis? | Y/PY/PN/N/NI |

Concerns regarding the synthesis and findings

LOW/HIGH/UNCLEAR

Rationale for concern:

Y=YES, PY=PROBABLY YES, PN=PROBABLY NO, N=NO, NI=NO INFORMATION

Phase 3: Judging risk of bias

Summarize the concerns identified during the Phase 2 assessment:

Domain	Concern	Rationale for concern
1. Concerns regarding specification of study eligibility criteria		
2. Concerns regarding methods used to identify and/or select studies		
3. Concerns regarding used to collect data and appraise studies		
4. Concerns regarding the synthesis and findings		

RISK OF BIAS IN THE REVIEW

Describe whether conclusions were supported by the evidence:

- | | |
|--|--------------|
| A. Did the interpretation of findings address all of the concerns identified in Domains 1 to 4? | Y/PY/PN/N/NI |
| B. Was the relevance of identified studies to the review's research question appropriately considered? | Y/PY/PN/N/NI |
| C. Did the reviewers avoid emphasizing results on the basis of their statistical significance? | Y/PY/PN/N/NI |

Risk of bias in the review

RISK: LOW/HIGH/UNCLEAR

Y=YES, PY=PROBABLY YES, PN=PROBABLY NO, N=NO, NI=NO INFORMATION