

Risk of Bias Assessment

Systematic Review Training

Center for Knowledge Management

VANDERBILT  UNIVERSITY
MEDICAL CENTER



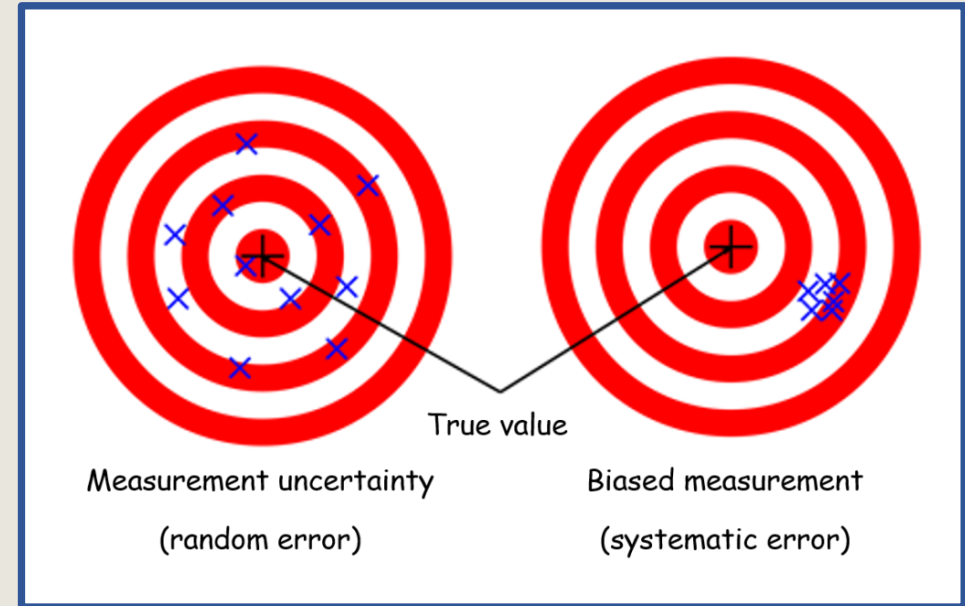
Objectives:

- ✓ *Describe factors that may impact study quality*
- ✓ *Discuss tools for assessing risk of bias*

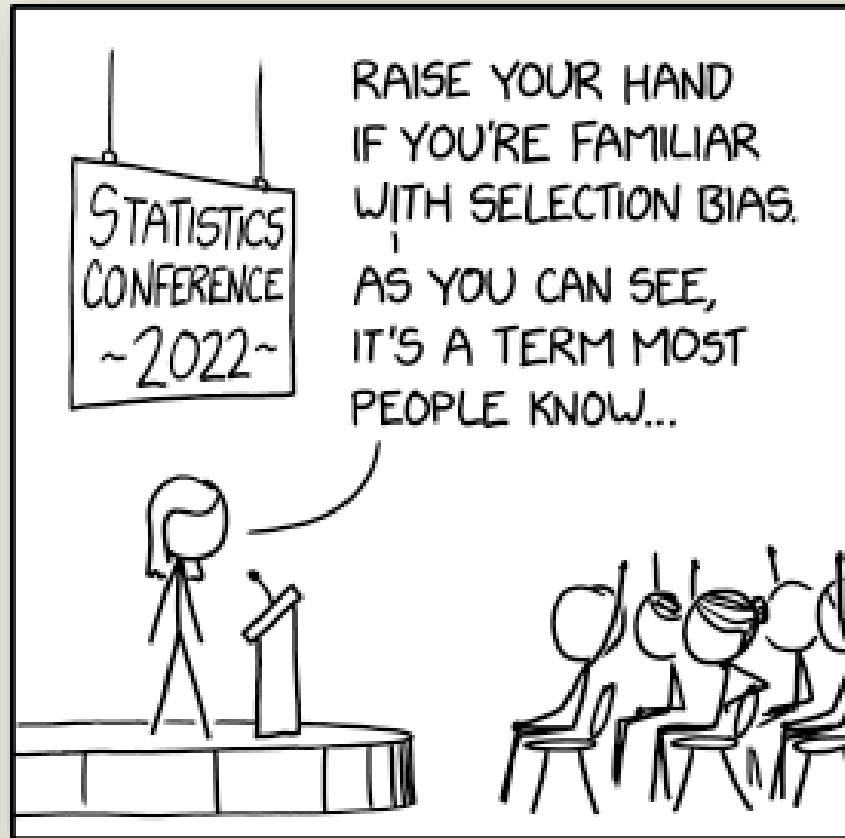
What is Bias?

“a systematic error, or deviation from the truth, in results”

(Cochrane Handbook, 2022)



<https://eikosim.com/en/technical-articles/measurement-errors-and-digital-image-correlation/>



[https://www.explainxkcd.com/wiki/index.php/2618: Selection Bias](https://www.explainxkcd.com/wiki/index.php/2618:_Selection_Bias)

Terminology

- Risk of bias- assessment of bias in individual studies

Examples of risk of bias tools

Study Design	Risk of Bias Tool
Diagnostic accuracy study	Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2)
Randomized Controlled Trial	Version 2 of the Cochrane risk-of-bias tool for randomized trials (RoB2)
Case-Control Study	Newcastle-Ottawa Quality Assessment

QUADAS-2

Domains (risk of bias arising from...):

1. Patient selection
2. Index test
3. Reference standard
4. Flow and timing

QUADAS-2

Domains (risk of bias arising from...):

1. Patient selection
2. Index test
3. Reference standard
4. Flow and timing

Signaling questions (yes, no, unclear):

1. Was a consecutive or random sample of patients enrolled?
2. Was a case-control design avoided?
3. Did the study avoid inappropriate exclusions?

Could the selection of patients have introduced bias? (high, low, unclear)

QUADAS-2 Template (Patient Selection Domain)

<u>Citation:</u>			
SR Citation #:			
	<u>Signalling Question</u>	Comment	Rating
1a. Risk of Bias	Describe methods of patient selection.		N/A
	Notes on patient flow		N/A
	Was a consecutive or random sample of patients enrolled? (1a.1) <i>(Yes / No / Unclear)</i>		
	Was a case-control design avoided? (1a.2) <i>(Yes / No / Unclear)</i>		
	Did the study avoid inappropriate exclusions? (1a.3) <i>(Yes / No / Unclear)</i>		
	Could the selection of patients have introduced bias? (1a.4) <i>(Low / High / Unclear)</i> <i>Note: If all responses to the signaling questions are "Yes", select "Low"; if all responses to signaling questions are "No", select "High". All other options, select "Unclear"</i>		

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)

Domains (risk of bias arising from...):

1. Randomization process
2. Deviations from the intended interventions
3. Missing outcome data
4. Measurement of the outcome
5. Selection of the reported result

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)

Domains (risk of bias arising from...):

1. Randomization process
2. Deviations from the intended interventions
3. Missing outcome data
4. Measurement of the outcome
5. Selection of the reported result

Signaling questions (yes, probably yes, probably no, no, no information):

1. Was the allocation sequence random?
2. Was the allocation sequence concealed until participants were enrolled and assigned to interventions?
3. Did baseline differences between intervention groups suggest a problem with the randomization process?

Risk-of-bias judgement? (low, high, some concerns)

AHRQ recommendations for selecting a risk of bias tool:

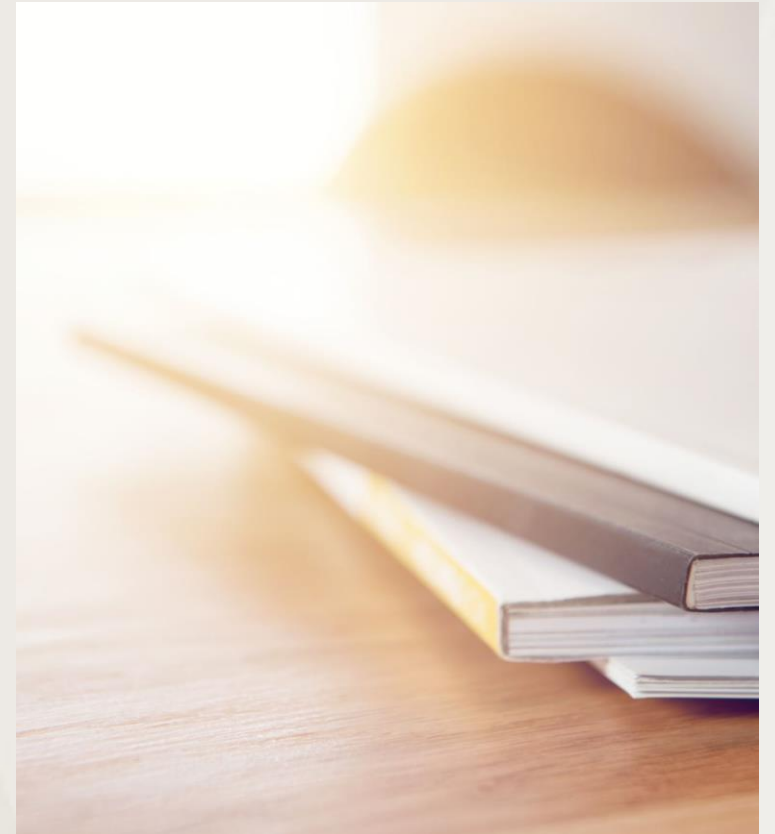
Use tools designed for use in a systematic review that:

- “have demonstrated acceptable validity and reliability, or show transparency in how assessments are made by providing explicit support for each assessment;
- specifically address items related to risk of bias (internal validity), and preferably are based on empirical evidence of bias;
- where available, are specific to the study designs being evaluated; and
- avoid the presentation of risk-of-bias assessment as a composite score, that is, an overall numeric rating of study risk of bias across items, for example 11 from 15 items.”

May be necessary to use more than one tool if studies included in the systematic review use different study designs.

Recap

- Describe factors that may impact study quality
- Describe common tools for assessing risk of bias in included studies



Presented by
Center for Knowledge Management

VANDERBILT  UNIVERSITY
MEDICAL CENTER