Risk of Bias Assessment of Individual Studies

hlth301 teaching risk_of_bias

Evidence Based Practice has four components:

1. Frame an answerable question
2. Search literature
3. Critically Appraise the body of evidence
4. Actions based on collaboration and shared decision making with the client

Risk of Bias refers to the phenomenon where, systematic errors occur in the way a study is conducted. When these systematic errors occur, the results from the study, whether it is measurement of prevalence or incidence of a disease condition or whether it is association between exposure and outcome, cannot be relied upon. In evidence based health, you are expected to uncover if there are risks of bias in the studies that you critically appraise. As a matter of fact, critical appraisal process itself is about uncovering what are the risks or threats to bias

Such biases can occur in systematic reviews, meta analyses, and individual studies. We need to conduct risk of bias assessment because empirical investigations have shown studies with high risk of bias may lead to an exaggeration of treatment effects within trials when compared to studies with a low risk of bias

In critical appraisal of the literature of a single study, you look for internal validity issues. Internal validity is similar to shooting a target with darts. We want research to be both accurate or hit the bull's eye as well as the darts should be more or less around the bull's eye. How you get to the accuracy is what we are after

Three components of internal validity that the researchers must mitigate

- They must rule out the play of chance
  - They do this with proper sample size selection and power calculation
- They must eliminate all forms of bias
  - Selection Bias
  - Detectio Bias
  - Information or Measurement Bias
- They must control for known and unknown confounding variables
- Depending on the study designs, this is done in any of the five ways:
  - If the study design is an RCT, randomisation process takes care of known and unknown confounders
  - If the study design is NOT an RCT, then stratified analysis of the different levels of potential confounders are used to analyse the results
  - For case control studies, matching is used to control for confounding variables
  - For all study designs, multivariate analyses are used for control of confounding variables

Luijendijk (2020) has advised that we must consider three sources of bias (Luijendijk2020)

- Common cause of the intervention and outcome (Confounder)

  Outcome determines the intervention status (Happens in Case Control Studies)

  A third factor determines both the intervention and outcomes

- Intervention Status determines the outcome (Information Bias)
- Systematic error in the measurement of the intervention or outcome

Common effect of the intervention and outcome (Selection Bias)

Selection Bias

Drop out of participants

Intention to treat analysis important

Higgins (2024) in Cochrane Handbook lists five sources of bias in RCTs according to Higgins2024 source_of_bias

1. bias arising from the randomization process;
2. bias due to deviations from intended interventions;
3. bias due to missing outcome data;
4. bias in measurement of the outcome; and
5. bias in selection of the reported result.