Critical Appraisal Worksheets

Randomised Controlled Trials

1. Validity

- Was the sample representative of the population where the treatment will be used?
- Was the sample large enough i.e. have adequate power?

Yes	No	Comments

2. Selection

- Was randomisation done properly and was the randomisation sequence concealed?

Yes	No	Comments

3. Confounding

- Were the two groups similar at baseline with respect to important confounders i.e. was randomisation successful?
- The differences may be just due to chance or non-random allocation. Think about how the differences may influence the results

Yes	No	Comments

4. Measurement

- Were the two groups treated equally?
- Was blinding carried out and was the trial open label, double blind or triple blind?
- How was blinding assessed?

(If subjects are not blind to their treatment, they may (unintentionally) give misleading answers to outcome questionnaires. Likewise, study personnel and clinicians may influence outcome if they are aware of treatment allocation. It is not enough to assume that initial blinding will be preserved. Subjects and clinicians alike can be de-blinded by adverse effects. One way to assess this is to ask all involved in the study to guess their allocation.

Yes	No	Comments

5. Attrition

- Were drop outs included in the final analysis and how was this done?

Yes	No	Comments

6. Results

- How large was the treatment effect? (NNT and ABI)
- How significant is the treatment effect (p value and CI)

Results

7. Applicability

- What would be the NNT for my patient?
- Are the benefits worth the harms and costs?
- What does my patient want?

Conclusion

Systematic Reviews and Meta analyses

1. Selection

- **Does the review address a focussed relevant question?**
- **Did the investigators attempt to minimise publication bias in its many forms?**
- **Were the inclusion and exclusion criteria made explicit?**
- A good systematic review should identify all relevant research literature, whether published or not. Look for the databases searched (Medline alone is insufficient), the contacts with researchers in the field and drug companies for unpublished data, and cross-checking references in reviews. Details of the search terms (headings and keywords) should be provided and should appear comprehensive. The decision to exclude studies should be based on specified criteria, and made by two authors blind to each other's decisions.

Yes	No	Comments

2. Quality assessment

- Were the studies weighted according to quality by independent people?
- Quality assessment according to PRISMA statement.
- Criteria include allocation concealment, randomisation , blinding and intention to treat analysis

Yes	No	Comments

3. Heterogeneity

- Were the results consistent from study to study
- Heterogeneity is when results differ significantly between studies. It may be due to differences in methods, study populations, etc., or to a statistical quirk. If heterogeneity is present, different statistical techniques should be used for the meta-analysis and the authors should attempt to explain its presence.

Yes	No	Comments

4. Results

- What are the measures of effect (OR, RR or WMD)?
- What does the pooled effect show?
- What are the confidence intervals?

Results

5. Applicability

- Can I make a inference of the NNT from the PEER from my population?
- Are the results applicable to my patient?
- Are the benefits worth the harms and costs?
- What is my patient preference?

Conclusion

Case Control Study

1. Selection

- Were cases clearly defined?
- Were controls representative of the population from which cases were selected?
- Were cases and controls similar in all aspects except for the outcome status?
- Can confounders be managed at this stage?

Yes	No	Comments

2. Measurement

- Was exposure clearly defined, specific and measurable?
- How was recall bias minimised?
- Were both cases and controls assessed for exposure status in the same way?
- Were the investigators assessing for exposure status blind to disease status?

Yes	No	Comments

3. Confounding

- Did the investigators identify potential confounders?
- How did they adjust for confounding?
- Confounding in case control studies is done by regression analysis

Yes	No	Comments

4. Results

- How large was the strength of association? (OR) = ad/bc
- How significant is the OR (p value and CI)
- What are the other factors that may explain the association?
- Are there any particular biases like Neyman's bias or Berkson's bias in play?
- Does the Study fulfil the Bradford hill criteria for Causation?

Results

5. Applicability

- Is my patient so different from those included in the study that its results don't apply?
- Perform risk benefit analysis

Conclusion

Cohort Studies

1. Selection

- Was cohort at risk of developing the outcome?
- Was exposure clear, specific and measurable?
- Were the exposed and unexposed groups similar in all respects except for exposure?

Yes	No	Comments

2. Attrition

- What efforts were made to limit loss to follow up?
- Was loss to follow up similar in both groups?

Yes	No	Comments

3. Measurement

- Was outcome clearly defined, specific and measurable?
- Were both groups assessed for outcome status in the same way?
- Were the investigators assessing for outcome status blind to exposure status?

Yes	No	Comments

4. Confounders

- Did the investigators identify potential confounders?
- How did they adjust for confounding?

Yes	No	Comments

5. Results

- How large was the strength of association?? (RR)
- How significant is the RR (p value and CI)
- What are the other factors that may explain the association?
- Does the study satisfy the Bradford hill criteria?

Results

6. Applicability

- Express risk in both absolute and relative terms
- For public health evaluations
- What is the Attributable risk (AR), Attributable risk fraction (ARF), Population attributable risk (PAR) and Population attributable risk fraction (PARF)?
- AR = EER –CER
- ARF = EER – CER / EER * 100
- PAR = PER (Event rate in total population) – CER
- PARF = PER - CER / PER * 100
- Does the study have public health implications?

Conclusion

Diagnostic Studies

1. Selection

- Was the test evaluated in a sufficiently large sample of people at risk of developing the disease?
- Was the sample representative of the population in which the test will be used in clinical practice?

Yes	No	Comments

2. Measurement

- Was the gold standard appropriate and valid?
- Was there an independent blind comparison to reference standard?
- Was the method in applying the test described in detail so that there were no differences in applying the test?
- Was the gold standard applied to all individuals irrespective of the results of the test?

Yes	No	Comments

3. Results

- What are the measures of effect?
- Sensitivity, Specificity, PPV, NPV, LR +ve , LR –ve

Results

4. Applicability

- In what setting should the test be used?
- Is the test a cost effective substitute for currently used diagnostic tests
- Is it easily available and easily performed?
- How will the PPV change (post test probability) if applied to my population

Conclusion

Economic Analysis

Appraise the Methodology based on type of study

Appraisal Points

Results

- Was the outcome measure(s) appropriate?
- Were direct and indirect costs included?
- Calculate the (Incremental Cost Effectiveness Ratio) ICER = Δ C / Δ E
  - Δ C = Cost of Intervention A – Cost of Intervention B
  - Δ E = Effect of Intervention A – Effect of Intervention B
- Calculate the **Incremental Net Benefit** = (Δ E ×λ) - Δ C, λ = Willingness to pay
- Was discounting used to calculate adjusted ICER if interventions were expected to produce benefits after a year?

Applicability

- How does this change my practice?
- Is the intervention cost effective?
- Can cost savings be achieved for the service through the adoption of this intervention?

Qualitative Analysis

Validity

- Does the paper address a clearly focused issue?
- Is the choice of qualitative methods appropriate?
- Was the author's position clearly stated? I.e. preconceptions, assumptions etc.

Yes	No	Comments

Selection

- Was sampling strategy clearly described?
- Did the authors attempt to seek out diverse views and describe the individuals sampled?

Yes	No	Comments

Data Collection

- Were the data collection methods described adequately?
- Did the authors attempt to collect data through different methods i.e triangulation?

Yes	No	Comments

Data Analysis

- Were the methods of data analysis described in detail
- Was there a clear audit trail of how interpretations were generated
- Were verbatim transcriptions included?
- Did different individuals analyse data or was analysis restricted to one individual?
- Was member checking part of data analysis?
- Were negative and discrepant results also taken into account?

Yes	No	Comments

Results

- Were sequences from the original data presented (eg quotations) and were these fairly selected?
- How much of the information collected is available for independent assessment?
- Are the explanations for the results plausible and coherent?
- Are the results of the study compared with those from other studies?

Yes	No	Comments

Applicability

- Can the results from the study be applied to my population?
- How is my patient different?
- Can this be used for further quality improvement?

Yes	No	Comments