

# Appendix ii: critical appraisal tools

## Critical appraisal tool: meta-analyses and systematic reviews (adapted from material produced by the Centre for Evidence-Based Mental Health)

Title of paper: .....  
Author: .....  
Source: .....  
Date: .....

### A. ARE THE RESULTS VALID?

1. Is the question clearly focused?	Comments
<ul style="list-style-type: none"><li><input type="radio"/> What is being reviewed?</li><li><input type="radio"/> What is the population?</li><li><input type="radio"/> What is the exposure/intervention?</li><li><input type="radio"/> What are the outcomes?</li></ul>	

2. Is the search thorough? (Did the authors look for the appropriate sort of papers?)	Comments
<ul style="list-style-type: none"><li><input type="radio"/> What bibliographic databases were used?</li><li><input type="radio"/> What years were searched?</li><li><input type="radio"/> What languages were searched?</li><li><input type="radio"/> Was any hand-searching conducted or references in relevant articles obtained?</li><li><input type="radio"/> Are the inclusion criteria appropriate – refer to study design, participants, intervention, and outcomes of interest.</li><li><input type="radio"/> Is the inclusion process discussed?</li></ul>	

<p><b>3. Is the validity of included studies adequately assessed?</b></p>	<p><b>Comments</b></p>
<ul style="list-style-type: none"> <li>○ Reproducible, blind assessment?</li> <li>○ Method of random selection?</li> <li>○ Is the analysis on an intention to treat basis?</li> <li>○ Is missing information obtained from investigators?</li> <li>○ Is publication bias an issue?</li> <li>○ Has methodological quality been assessed?</li> </ul>	<div style="border: 1px solid black; height: 200px;"></div>

**B. DETAILS OF INDIVIDUAL STUDIES USED IN META-ANALYSIS OR SYSTEMATIC REVIEW**

<p><b>4. How many individual studies were included in the systematic review/meta-analysis?</b></p>	<p><b>Comments</b></p>
<ul style="list-style-type: none"> <li>○ What type of studies were included? e.g. randomised controlled trials, cohort studies, case-control studies, etc.</li> <li>○ What are the sample sizes for each study group?</li> <li>○ Were the patient characteristics, interventions, outcome measures and the efficacious and adverse results discussed/presented for each study? What were they?</li> </ul>	<div style="border: 1px solid black; height: 200px;"></div>

<p><b>5. In what countries were the treatment studies conducted?</b></p>	<p><b>Comments</b></p>
	<div style="border: 1px solid black; height: 35px;"></div>

<p><b>6. If medication was used, what were the dosages of medication used for each study?</b></p>	<p><b>Comments</b></p>
	<div style="border: 1px solid black; height: 35px;"></div>

7. What was the duration of treatment (give the range)?

Comments

8. Are the studies focused on boys or girls or both?

Comments

9. Were the children receiving concomitant medication/treatment?

Comments

### C. WHAT ARE THE RESULTS?

10. How big is the overall effect?

Comments

- On what scale is the effect measured? (odds ratio, number needed to treat?)

11. Are the results consistent from study to study?

Comments

- How sensitive are the results to changes in the way the review was done?

12. If the results of the review have been combined, was it reasonable to do so?

Comments

- Were the results similar from study to study?
- Are the results of the included studies clearly displayed?
- Are the results of the different studies similar?
- Are the reasons for any variations in results discussed?

**13. How precise are the results?**

**Comments**

- Does the lower confidence limit include clinically relevant effects?
- Does the upper confidence limit exclude clinically relevant effects?

**D. INTERPRETATION OF THE RESULTS - WILL THEY HELP IN MAKING DECISIONS ABOUT PATIENTS?**

**14. Do conclusions flow from evidence that is reviewed?**

**Comments**

**15. Are subgroup analyses interpreted cautiously?**

**Comments**

**16. Can the conclusions and data be generalised to other settings? (Is the number needed to treat stated or should it be calculated?)**

**Comments**

**17. Were all important outcomes considered?**

**Comments**

**18. Are the benefits worth the harms and the costs?**

**Comments**

**ADDITIONAL COMMENTS**

**Critical appraisal tool: randomised controlled trials  
(adapted from material produced by the Centre for  
Evidence-Based Mental Health)**

Title of paper: .....  
Author: .....  
Source: .....  
Date: .....

**A. ARE THE RESULTS OF THIS TRIAL VALID?**

**1. Are you using the right research paper to answer your particular question?**      **Comments**

**2. Was the group of patients clearly defined?**      **Comments**

Consider:

- the population studied (age, gender, setting, country)
- comorbidity (note if any children were excluded from the study)
- classification used
- outcomes measured.

**3. Was the assignment of patients to treatments randomised?**      **Comments**

- Was the randomisation list concealed?

**4. Were all patients who entered the trial accounted for at its conclusion?**      **Comments**

**5. Were they analysed in the groups to which they were randomised?**      **Comments**

6. Were patients and clinicians kept 'blind' to which treatment was being received? **Comments**

7. Aside from the experimental treatment, were the groups treated equally? **Comments**

8. If a cross-over design was used, were attempts made to reduce the carry-over effects? **Comments**

- Did the authors acknowledge that this was a potential problem?
- Was an appropriate wash-out period used?

**B. WHAT ARE THE RESULTS?**

9. How large was the treatment effect? **Comments**

- See Guidance: calculating number needed to treat (page 193)

10. How precise is the estimate of treatment effect? **Comments**

- See Guidance: calculating confidence intervals (page 195)

**C. WHAT ARE THE IMPLICATIONS OF THIS PAPER FOR LOCAL PRACTICE?**

11. Are the results of this study generalisable to your patients? **Comments**

- Does your patient resemble those in the study?
- What are your patient's preferences?
- Are there alternative treatments available?

## Guidance for calculating: 'number needed to treat'

'Number needed to treat' (NNT) represents the number of patients you need to treat in order to prevent one negative outcome.

A worked example is included on the following page.

### 2.1 ESTABLISH THE CONTROL EVENT RATE

The control event rate (CER) is the proportion of patients in the study's control group experiencing the observed negative event.

Enter the CER for your study in the box:

CER =

### 2.2 ESTABLISH THE EXPERIMENTAL EVENT RATE

The experimental event rate (EER) is the proportion of patients in the study's experimental group (i.e. the group receiving the experimental treatment) experiencing the observed negative event.

Enter the EER for your study in the box:

EER =

### 2.3 CALCULATE THE ABSOLUTE RISK REDUCTION

The absolute risk reduction (ARR) is the absolute difference in the risk of an adverse outcome between the control group and the experimental group. It is calculated by deducting the EER from the CER.

Perform this calculation now:

ARR = (CER from above) - (EER from above) =

### 2.4 CALCULATE THE NUMBER NEEDED TO TREAT

The NNT is calculated by dividing the ARR into 1 and multiplying the result by 100. Perform this calculation now:

NNT = 1 / (ARR from above) x 100 =

## NNTs: worked example

### SAMPLE DATA

A population of 200 patients was divided into an experimental and a control group with 100 patients in each. The experimental group was given haloperidol in order to prevent recurrence of psychotic episodes. Ten patients in the experimental group experienced a psychotic episode during the period of the trial. Thirty-five patients in the control group experienced a psychotic episode during the period of the trial.

### 1. ESTABLISH THE CER

35 patients experienced the event out of a population of 100, therefore the CER will be 35%.

$$\text{CER} = 35\%$$

### 2. ESTABLISH THE EER?

10 patients experienced the event out of a population of 100, therefore the EER will be 10%.

$$\text{EER} = 10\%$$

### 3. CALCULATE THE ARR

In this example, the CER equals 35% and the EER equals 10%.

$$\text{ARR} = 35 \text{ (CER from above)} - 10 \text{ (EER from above)} = 25\%$$

### 4. CALCULATE THE NNT

In our sample data, the ARR equals 25%.

$$\text{NNT} = 1/25 \text{ (ARR from above)} \times 100 = 4$$

**Guidance for calculating: 'confidence intervals'**

The confidence interval (CI) gives the range within which we would expect the true value of a statistical measure to lie.

Most research studies use a CI of 95%; for example, an NNT of 10 with a 95% CI of 5 to 15 would give us 95% confidence that the true NNT value was between 5 and 15.

**3.1 THE FORMULA**

The formula for calculating a 95% Confidence Interval on an NNT is:

$$+/-1.96 \sqrt{\frac{CER \times (1 - CER)}{n \text{ of control patients}} + \frac{EER \times (1 - EER)}{n \text{ of experimental patients}}}$$

Please note: in the formula the CER and EER are expressed as fractions, rather than percentages. For example, a 25% CER is expressed as 0.25.

$$+/-1.96 \sqrt{\frac{\dots \times (1 - \dots)}{\dots} + \frac{\dots \times (1 - \dots)}{\dots}} = \dots$$

This will give you the percentage range within which the truly accurate NNT can be found. The smaller the percentage, the more confident you can be that the NNT is accurate.

**Clinical guidelines (adapted from material from the Centre for Evidence-Based Mental Health)**

Title of paper: .....  
Author: .....  
Source: .....  
Date: .....

**A. ARE THE RECOMMENDATIONS IN THIS GUIDELINE VALID?**

1. Were all important decision options and outcomes clearly specified?	Comments
2. Was the evidence relevant to each decision option identified, validated and combined in a sensible and explicit way?	
3. Are the relative preferences that key stakeholders attach to the outcomes of decisions (including benefits, risks and costs) identified and explicitly considered?	
4. Is the guideline resistant to clinically sensible variations in practice?	

**B. IS THIS GUIDELINE POTENTIALLY USEFUL?**

5. Does this guideline offer an opportunity for significant improvement in the quality of health care practice?	Comments
<ul style="list-style-type: none"><li>○ Is there a large variation in current practice?</li><li>○ Does the guideline contain new evidence (or old evidence not yet acted upon) that could have an important impact on management?</li><li>○ Would the guideline affect the management of so many people, or concern individuals at such high risk, or involve such high costs that even small changes in practice could have major impacts on health outcomes or resources?</li></ul>	

**C. SHOULD THIS GUIDELINE BE APPLIED IN YOUR PRACTICE?**

6. What barriers exist to its implementation?	Comments
<p><input type="radio"/> Can they be overcome?</p> <p><b>7. Can you collaborate with key colleagues to implement the guideline?</b></p> <p><b>8. Can you meet the variety of conditions that will determine the success or failure of implementing the guideline? For example:</b></p> <ul style="list-style-type: none"><li><input type="radio"/> Has the evidence been collated by a respected body (e.g. a rigorously developed clinical practice guideline from a Royal College)?</li><li><input type="radio"/> Are local opinion leaders already implementing the strategy?</li><li><input type="radio"/> Have you received consistent information from all relevant sources?</li><li><input type="radio"/> Has there been an opportunity for individual discussions about the strategy with a respected colleague/ authority?</li><li><input type="radio"/> Has a 'user-friendly' format for the guidelines been developed? (It may require local adaptation.)</li><li><input type="radio"/> Can you implement the guideline within a target group of clinicians (without the need for extensive outside collaboration)?</li><li><input type="radio"/> Does the guideline represent a conflict of interest with patient and community expectations, economic incentives, administrative incentives, etc.?</li></ul>	

**ADDITIONAL COMMENTS**

**Criteria for the evaluation of qualitative research papers  
(adapted from the British Sociological Association Medical  
Sociology Group Guidelines, 1996)**

**1. Are the methods of the research appropriate to the nature of the question being asked?**

**Comments**

- Does the research seek to understand processes or structures, or illuminate subjective experiences or meanings?
- Are the categories or groups being examined of a type that cannot be pre-selected, or the possible outcomes cannot be specified in advance?
- Could a quantitative approach have addressed the issue better?

**2. Is the connection to an existing body of knowledge or theory clear?**

**Comments**

- Is there adequate reference to the literature?
- Does the work cohere with, or critically address, existing theory?

**METHODS**

**3. Are there clear accounts of the criteria used for the selection of subjects for study, and of the data collection and analysis?**

**Comments**

**4. Is the selection of cases or participants theoretically justified?**

- The unit of research may be people, or events, institutions, samples of natural behaviour, conversations, written material, etc. In any case, while random sampling may not be appropriate, is it nevertheless clear what population the sample refers to?
- Is consideration given to whether the units chosen were unusual in some important way?

**5. Does the sensitivity of the methods match the needs of the research questions?**

- Does the method accept the implications of an approach that respects the perceptions of those studied?
- To what extent are any definitions or agendas taken for granted, rather than being critically examined or left open?
- Are the limitations of any structured interview method considered?

**6. Has the relationship between field-workers and subjects been considered, and is there evidence that the research was presented and explained to its subjects?**

- If more than one worker was involved, has comparability been considered?
- Is there evidence about how the subjects perceived the research?
- Is there evidence about how any group processes were conducted?

**7. Was the data collection and record-keeping systematic?**

- Were careful records kept?
- Is the evidence available for independent examination?
- Were full records or transcripts of conversations used if appropriate?

**Comments**



8. Is reference made to accepted procedures for analysis?	Comments
<ul style="list-style-type: none"> <li>○ Is it clear how the analysis was done? (Detailed repetition of how to perform standard procedures ought not to be expected.)</li> <li>○ Has its reliability been considered, ideally by independent repetition?</li> </ul>	
<p><b>9. How systematic is the analysis?</b></p> <ul style="list-style-type: none"> <li>○ What steps were taken to guard against selectivity in the use of data?</li> <li>○ In research with individuals, is it clear that there has not been selection of some cases and ignoring of less interesting ones? In group research, are all categories of opinion taken into account?</li> </ul>	
<p><b>10. Is there adequate discussion of how themes, concepts and categories were derived from the data?</b></p> <ul style="list-style-type: none"> <li>○ It is sometimes inevitable that externally given or predetermined descriptive categories are used, but have they been examined for their real meaning or any possible ambiguities?</li> </ul>	
<p><b>11. Is there adequate discussion of the evidence both for and against the researcher's arguments?</b></p> <ul style="list-style-type: none"> <li>○ Are negative data given?</li> <li>○ Has there been any search for cases that might refute the conclusions?</li> </ul>	
<p><b>12. Have measures been taken to test the validity of the findings?</b></p> <ul style="list-style-type: none"> <li>○ Have methods such as feeding them back to the respondents, triangulation, or procedures such as grounded theory been used?</li> </ul>	

**13. Have any steps been taken to see whether the analysis would be comprehensible to the participants, if this is possible and relevant?**

- Has the meaning of their accounts been explored with respondents?
- Have apparent anomalies and contradictions been discussed with them, rather than assumptions been made?

Comments

**PRESENTATION**

**14. Is the research clearly contextualised?**

- Has all the relevant information about the setting and subjects been supplied?
- Are the variables being studied integrated in their social context, rather than abstracted and decontextualised?

**15. Are the data presented systematically?**

- Are quotations, fieldnotes, etc. identified in a way that enables the reader to judge the range of evidence used?

**16. Is a clear distinction made between the data and their interpretation?**

- Do the conclusions follow from the data?

**17. Is sufficient of the original evidence presented to satisfy the reader of the relationship between the evidence and the conclusions?**

- Although the presentation of discursive data is always going to require more space than numerical data, is the paper as concise as possible?

Comments

<p><b>18. Is the author's own position clearly stated?</b></p>	<p>Comments</p>
<ul style="list-style-type: none"> <li>○ Is the researcher's perspective described?</li> <li>○ Has the researcher examined his or her own role, possible bias and influence on the research?</li> </ul>	
<p><b>19. Are the results credible and appropriate?</b></p>	
<ul style="list-style-type: none"> <li>○ Do they address the research question(s)?</li> </ul>	
<ul style="list-style-type: none"> <li>○ Are they plausible and coherent?</li> <li>○ Are they important, either theoretically or practically, or trivial?</li> </ul>	

**ETHICS**

<p><b>20. Have ethical issues been adequately considered?</b></p>	<p>Comments</p>
<ul style="list-style-type: none"> <li>○ Has the issue of confidentiality been adequately dealt with?</li> <li>○ Have the consequences of the research – including establishing relationships with the subjects, raising expectations, changing behaviour, etc. – been considered?</li> </ul>	

**REFERENCE**

British Sociological Association Medical Sociology Group (1996) *British Sociological Association Medical Sociology Group Guidelines. Criteria for Evaluation of Qualitative Research Papers*. London: Medical Sociology Group of the British Sociological Association.