

Module 9: Assessing quality of studies

CAUTION!! This module is not up to date.

Authors MUST refer to ‘Chapter 8: Assessing risk of bias in included studies’ in the *Cochrane Handbook for Systematic Reviews of Interventions* for current information.

This module will discuss the stage in a review when, having found studies relevant to the question, we assess the quality of studies.

Learning objectives

- Understand what is meant by the ‘quality’ of a trial
- Be aware of empirical studies investigating the relative importance of different aspects of quality
- Be aware of problems in using quality scales to measure quality
- Be aware of ways to reduce bias in quality assessment
- Be aware of methods of incorporating quality in a meta-analysis, for instance use of a threshold or requirement of minimal characteristics, quality related sensitivity analyses, and weighting

Relevant section of the *Cochrane Handbook for Systematic Reviews of Interventions*

- Chapter 8: Assessing risk of bias in included studies

Where does this go in a Cochrane review?

- The Methods section of your protocol should describe how you plan to do this, and then you should describe how you did this in your complete review
- The section ‘Risk of bias in included studies’ should summarise the quality of all studies, but not describe the quality of individual studies in great detail, although any important flaws in individual studies should be noted here
- The ‘Characteristics of included studies’ table should include details of the methodological quality of individual studies.

Garbage in, garbage out

This is a phrase that you may have heard in relation to systematic reviews. What people are worried about is that a reviewer might be collecting together poor quality studies and then presenting the results as if they are high quality. This is a real concern – putting together a group of biased studies is likely to give a biased answer.

So, having selected which studies are included in your review, you need to look at the quality of them.

The topic of quality assessment is covered in depth in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions*, so you'll need your copy close to hand and may want to look at it now.

This module will cover the quality of randomised controlled trials, and not the quality of other study designs.



Activity: Write a list of all the aspects of quality you can think of

What do we mean by quality of trials?

Write a list of all the factors that come to mind when you think about the quality of a randomised trial.

You've probably come up with quite a long list. Some things on the list will be to do with the design of the study (blinding, sample size), and some to do with the way it was reported (the presentation of tables, who the authors are).

This long list in part explains why there have been many different approaches to measuring quality. So which bits are we interested in for this part of a Cochrane review?

Randomised trials, like systematic reviews, are trying to measure some 'truth' about an average effect of an intervention in a group of participants. When we talk about trial quality, we're usually talking about how well we think the study has measured this 'true' effect – this aspect of quality is also called *validity*.

But since no-one knows what the 'true' effect is, there's an element of guesswork and judgement in knowing which factors are most likely to affect how the study measures it. This is another reason for the many different approaches people have taken.

Measuring validity – measuring what?

The approach taken within the Cochrane Collaboration is first of all to think of factors which might lead to bias in studies. Then we take into account any studies that can tell us which of these are more important. Once we've decided which factors we're interested in, we collect information about them from the study reports.



Read Sections [8.9-8.14](#) of the *Cochrane Handbook for Systematic Reviews of Interventions* which explain the approach to selecting which aspects of validity to look at, and how to report what you do

Now read the first few sections of chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions*, for an explanation of the sources of bias and which seem to be more important.

In summary, empirical evidence suggests that

- Allocation concealment is very important in protecting against bias, so we should look for information on what was done about this and report what we find
- Blinding of the interventions and the outcome assessment may be important
- Loss to follow-up of study participants may be important

Allocation concealment is the minimum information on validity you should report

Some people choose to report information on all these, others choose to collect more items, and some use scales to get overall quality scores. These scores seem attractive in comparing studies with each other, but there are problems with them. Since we have no 'gold standard' to check them against, it is difficult to tell how well the scales measure quality. Some scales contain items that are not really to do with validity, and there are worries that adding things up to produce an overall score makes assumptions about the relative importance of different items. For these reasons, the use of quality scales is NOT recommended for Cochrane reviews.

Practical issues, minimising mistakes and bias

As with eligibility decisions, you'll want to record the information you collect on quality somewhere. Most people record it on their data collection form (we will cover this when we return to Module 7) and put it into the table of 'Characteristics of included studies' under the 'Methods' field in RevMan later.

The issues in minimising mistakes and bias while assessing study quality are the same as when we considered these in selecting studies, and you should report how you intend to assess quality, and how you did it:

- How many reviewers will do this?
- What are their backgrounds (for example, are they authors on any of the trials)?
- Will you try and blind the reviewers to details of the papers, such as journals or authors?
- Will you formally assess the reliability of the process



Reading: section [8.8](#) of the *Cochrane Handbook for Systematic Reviews of Interventions* explains what to do with this information on validity

Using information about validity in your review

So what should you do with this information you collected?

There are four approaches

- As a threshold for inclusion of studies
- As a possible explanation for differences in results between studies
- In sensitivity analyses
- As weights in statistical analyses

These are discussed in detail in section 8.8 of the *Cochrane Handbook for Systematic Reviews of Interventions*, which you should now read.

Everyone uses some sort of threshold for inclusion of studies, and this was set when we chose the selection criteria for the review. Sensitivity analyses are commonly undertaken in reviews to see the effect of aspects of quality. Because of the problems in deciding the weight to allocate to different aspects of quality, this is rarely done in Cochrane reviews. As a minimum, you should discuss the range of quality found in your included studies, and whether you think this may have any influence on the results of these studies, and any meta-analysis you performed. We will return to this topic in a later module, when we look at the investigation of heterogeneity.

Finally, check with your review group whether they have a policy on how to incorporate study quality in reviews.



*Activity:
Complete the following activity of assessment of a randomised controlled trial and check how you did against the answers that follow.*

Read the trial about a nursing intervention for treating heart failure. You will find the report of the trial at:

<http://www.bmj.com/cgi/content/full/323/7315/715?maxtoshow=>

Appraise this article as you plan to for your review. Ensure you extract information about allocation concealment, blinding and loss to follow up.

Test yourself by comparing your answers to the suggested responses on the next page.

TO BE REVISED

Randomisation and allocation concealment.

Assignment to groups was determined by central off-site randomisation and so could not be influenced by the investigators, nurses or participants. Allocation concealment was therefore adequate.

Blinding

This trial is an example of a complex, procedural intervention where complete blinding is not possible. Attempts to blind participants may be made either by designing an appropriate placebo or partially concealing (within ethical boundaries) the purpose of trial from participants. Neither was done in this trial. Obviously, in a procedural trial it is not possible to blind the health care workers (unlike a drug trial when an identical placebo will blind the carer as well as the participant). Outcome assessment (determining rates of death and rates and cause of admission) was blind to treatment allocation. A potential problem with outcome assessment is the use of hospital and health department records to determine death and readmission, with the possibility of records missed. A more appropriate method of assessing outcome would have been for the investigators to formally follow-up participants at given time points.

Here is a good time to make note of a common problem in assessing the adequacy of blinding within randomised controlled trials. Often you will see a trial, and indeed validity scale, referring to the trial being “single blind”, “double blind” and “triple blind”. The problem with this phrasing is that, while single blind obviously refers to only one party being masked from the intervention, double blind two parties etc, it does not make it clear who it is without the knowledge. A triple blinded trial is usually referring to intervention being masked from participants, care providers and outcome assessors, but what of double blind? Some people interpret this as participants and care providers, others as participants and outcome assessors. And what of single blind? As you can see, a much better way of describing blinding within the methods of a trial, and in any scale you chose to use to assess its validity, is to specify which party or parties were unaware of the intervention.

Loss to follow up

165 patients were randomised and 156 completed the trial. A description is provided of those who failed to complete (see Figure 1). From Table 3, we can see intention-to-treat was used as the column heading, showing 81 participants in usual care and 84 in intervention group. This value is the number randomised.

Now return to Module 7 and incorporate what you have learned into your data extraction form.