

Summary assessments of the risk of bias^{1*}

8.7 Summary assessments of risk of bias

The Collaboration's recommended tool for assessing risk of bias in included studies involves the assessment and presentation of individual domains, such as allocation concealment and blinding. To draw conclusions about the overall risk of bias for an outcome it is necessary to summarize these. The use of scales (in which scores for multiple items are added up to produce a total) is discouraged for reasons outlined in Section [8.3.1](#).*

Nonetheless, any assessment of the overall risk of bias involves consideration of the relative importance of different domains. A review author will have to make judgements about which domains are most important in the current review. For example, for highly subjective outcomes such as pain, authors may decide that blinding of participants is critical. How such judgements are reached should be made explicit and they should be informed by:

- **Empirical evidence of bias:** Sections [8.5](#)* to [8.14](#)* summarize empirical evidence of the association between domains such as allocation concealment and blinding and estimated magnitudes of effect. However, the evidence base remains incomplete.
- **Likely direction of bias:** The available empirical evidence suggests that failure to meet most criteria, such as adequate allocation concealment, is associated with overestimates of effect. If the likely direction of bias for a domain is such that effects will be underestimated (biased towards the null), then, providing the review demonstrates an important effect of the intervention, such a domain may be of less concern.
- **Likely magnitude of bias:** The likely magnitude of bias associated with any domain may vary. For example, the magnitude of bias associated with inadequate blinding of participants is likely to be greater for more subjective outcomes. Some indication of the likely magnitude of bias may be provided by the empirical evidence base (see above), but this does not yet provide clear information on the particular scenarios in which biases may be large or small. It may, however, be possible to consider the likely magnitude of bias relative to the estimated magnitude of effect. For example, inadequate allocation sequence concealment and a small estimate of effect might substantially reduce one's confidence in the estimate, whereas minor inadequacies in how incomplete outcome data were addressed might not substantially reduce one's confidence in a large estimate of effect.

¹ From: Higgins JPT, Altman DG (editors). Chapter 8: Assessing risk of bias in included studies. In: Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.0.1 (updated September 2008). The Cochrane Collaboration, 2008. Available from <http://training.cochrane.org/handbook>

*References are to sections in the Cochrane Handbook.

Summary assessment of risk of bias might be considered at four levels:

- **Summarizing risk of bias for a study across outcomes:** Some domains affect the risk of bias across outcomes in a study: e.g. sequence generation and allocation sequence concealment. Other domains, such as blinding and incomplete outcome data, may have different risks of bias for different outcomes within a study. Thus, review authors should not assume that the risk of bias is the same for all outcomes in a study. Moreover, a summary assessment of the risk of bias across all outcomes for a study is generally of little interest.
- **Summarizing risk of bias for an outcome within a study (across domains):** This is the recommended level at which to summarize the risk of bias in a study, because some risks of bias may be different for different outcomes. A summary assessment of the risk of bias for an outcome should include all of the entries relevant to that outcome: i.e. both study-level entries, such as allocation sequence concealment, and outcome specific entries, such as blinding.
- **Summarizing risk of bias for an outcome across studies (e.g. for a meta-analysis):** These are the main summary assessments that will be made by review authors and incorporated into judgements about the 'quality of evidence' in 'Summary of findings' tables, as described in Chapter 11 (Section [11.5](#)).*
- **Summarizing risk of bias for a review as a whole (across studies and outcomes):** It may be tempting to summarize the overall risk of bias in a review, but this should be avoided for two reasons. First, this requires value judgements about which outcomes are critical to a decision and, therefore, should be included in this assessment. Frequently no data are available from the studies included in a review for some outcomes that may be critical, such as adverse effects, and the risk of bias is rarely the same across all of the outcomes that are critical to such an assessment. Second, judgements about which outcomes are critical to a decision may vary from setting to setting, both due to differences in values and due to differences in other factors, such as baseline risk. Thus, judgements about the overall risk of bias of evidence across studies and outcomes should be made in a specific context, for example in the context of clinical practice guidelines, and not in the context of systematic reviews that are intended to inform decisions across a variety of settings.

Review authors should make explicit judgements about the risk of bias for important outcomes both within and across studies. This requires identifying the most important domains ('key domains') that feed into these summary assessments. [Table 8.7.a](#) provides a possible approach to making summary assessments of the risk of bias for important outcomes within and across studies.

Table 8.7.a: Possible approach for *summary assessments* of the risk of bias for each important outcome (across domains) within and across studies

Risk of bias	Interpretation	Within a study	Across studies
Low risk of bias.	Plausible bias unlikely to seriously alter the results.	Low risk of bias for all key domains.	Most information is from studies at low risk of bias.
Unclear risk of bias.	Plausible bias that raises some doubt about the results.	Unclear risk of bias for one or more key domains.	Most information is from studies at low or unclear risk of bias.
High risk of bias.	Plausible bias that seriously weakens confidence in the results.	High risk of bias for one or more key domains.	The proportion of information from studies at high risk of bias is sufficient to affect the interpretation of results.