Cochrane Handbook for Systematic Reviews of Interventions

What's new in Version 5.1.0 (March 2011)

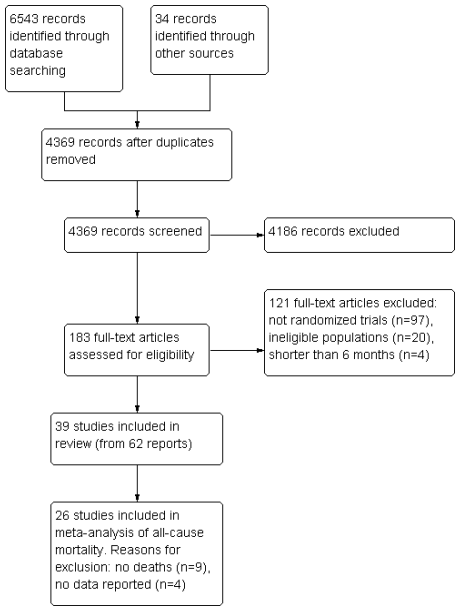
Main reason for update: to reflect changes introduced in RevMan 5.1.

Chapter 1	
1.1.3	The publication frequency of the CDSR has been updated (from quarterly to monthly).
Chapter 2	
2.3.6	Reference to the training web site and open learning modules has been updated.
Chapter 3	
Box 3.2.c and 3.2.5.4	Criterion 5 (Accumulation of changes) for creating a new citation version has been relaxed slightly.
Chapter 4	
4.5 (Methods)	A new section about planning a 'Summary of findings' table has been added.
4.5 (Results)	A reference PRISMA flow diagrams has been inserted under 'Results of the search'
4.5 (Discussion)	The section on 'Quality of the evidence' has been amended to refer to 'Summary of findings' tables and GRADE assessments.
4.7.2	Guidance on referring to 'Other published versions of this review' has been clarified. As a general rule, only new citation versions of publications in the *CDSR* should be listed (i.e. those that yield a new MEDLINE record).
Table 4.9.a and 4.9.1	Two new types of RevMan Figure have been added: RevMan study flow diagram (PRISMA template) and RevMan flow diagram.
Chapter 5	
5.4.1	Guidance about using outcomes as criteria for including studies has been clarified, including advice against using a lack of 'usable' data as a criterion.
Chapter 6	
6.6.1	Advice to document the search results has been added in anticipation of a PRISMA flow diagram.
6.6.2	Clarity has been added that the search methods should be presented in a protocol, even if the detailed (line by line) search strategy is not.
Chapter 8	**The Cochrane 'Risk of bias tool' has been modified for RevMan 5.1. The chapter has been modified in numerous places to reflect the modified tool. The changes are summarized in Table 8.5.b, replicated below. The main alterations are in sections 8.4, 8.5, 8.6, 8.8.3, 8.11, 8.12 [new] and 8.15.** The chapter's editors are now Higgins JPT, Altman DG and Sterne JAC.
Chapter 9	
9.6.3.1	A more general version of the test for differences between subgroups is now described, as it has been implemented in RevMan.
Chapter 10	
Figure 10.4.c	The figure has been corrected.
Chapter 11	
11.2	**A new section about PRISMA study flow diagrams has been introduced.**
11.5.3	The text of bullet point 5 has been modified slightly to clarify the purpose of GRADE.
11.5.4	A comment has been inserted to point out the context-specific help file in GRADEpro.

Study flow diagrams

(Section 11.2.1 in *Handbook* 5.1.0)

Study flow diagrams are used to illustrate the results of the search and the process of screening and selecting studies for inclusion in the review. A flow diagram using the PRISMA template may be created within RevMan 5.1, and RevMan also includes the facility to create a flow diagram with a flexible structure.



Changes to 'Risk of bias' tool

(Table 8.5.b in *Handbook* 5.1.0).

After an extensive evaluation of the 'Risk of bias' tool, modifications and improvements have been made and an updated version has been implemented in RevMan 5.1.

Modification	***Explanation***
Separation of blinding	In the earlier version, biases related to blinding of participants, personnel and outcome assessors were all assessed within a single domain (although they may have been assessed separately for different outcomes). In the revised tool, bias related to blinding of participants and personnel is now assessed separately from bias related to blinding of outcome assessment.
Nature of the judgement	The judgements are now expressed simply as 'Low risk', 'High risk' or 'Unclear risk' of bias. The questions have been removed, along with the responses 'Yes' indicating low risk of bias and 'No' indicating high risk of bias.
Minor rewording	The items have been renamed with the removal of question-based judgements: *Adequate sequence generation?* ⇒ *Random sequence generation* *Allocation concealment?* ⇒ *Allocation concealment* *Blinding?* ⇒ *Blinding of participants and personnel* *Blinding?* ⇒ *Blinding of outcome assessment* *Incomplete outcome data addressed?* ⇒ *Incomplete outcome data* *Free of selective outcome reporting?* ⇒ *Selective reporting* *Free of other bias?* ⇒ *Other bias*
Insertion of categories of bias	The revised tool clarifies the category of bias within which each domain falls: • selection bias (random sequence generation and allocation concealment); • performance bias (blinding of participants and personnel); • detection bias (blinding of outcome assessment); • attrition bias (incomplete outcome data); • reporting bias (selective reporting); and • other bias.
Reconsideration of eligible issues for 'other bias', including early stopping of a trial	The guidance for the 'other bias' domain has been edited to strengthen the guidance that additional items should be used only exceptionally, and that these items should relate to issues that may lead directly to bias. In particular, the mention of early stopping of a trial has been removed, because (i) simulation evidence suggests that inclusion of stopped early trials in meta-analyses will not lead to substantial bias, and (ii) exclusion of stopped early trials has the potential to bias meta-analyses towards the null (as well as leading to loss of precision).