Cochrane Methods

Cochrane Handbook of Systematic Reviews for Interventions

Version 5.2.0

What's new

Trusted evidence.
Informed decisions.
Better health.

What's new

Following the development and introduction of the Methodological Expectations for Cochrane Intervention Review (MECIR) standards we set out to produce a minor Cochrane Handbook update, Version 5.2, to include these standards. We planned a major update, Version 6, to follow. Due to limited editorial capacity, we are proceeding to Version 6 and have produced a limited number of chapters for Version 5.2. We summarise below what is new in these 5.2 chapters. The *new* chapters are 1, 8, 9, 10, 11, 12, and 21.

Where we refer to individual MECIR standards in the text, a symbol in the margin highlights the standard covered. Summary tables of all chapter relevant MECIR standards are at the end of each chapter. We have clarified terminology throughout these chapters where we refer to included 'studies' rather than 'trials'.

Chapter 1

- Various amendments for consistency with the comparable chapters in the Cochrane Handbook for Reviews of Diagnostic Test Accuracy.
- New Section 1.3 outlining the four kinds of Cochrane Reviews (intervention, diagnostic test accuracy, overviews and methodology).
- Old Section 1.4, 'Contributors to the Handbook' relocated to the Preface.
- Updated information on the Cochrane Library, including which databases are archived and no longer actively updated (Section 1.4).
- New Section 2.5 brings together updating information on Cochrane training, software and guidance on resources and funding. Information internal to Cochrane (such as the internal workings of Archie) has been removed.

Chapter 8

- Includes a description of the feature in RevMan 5.3 allowing 'Risk of bias' assessments to be presented visually on forest plots (Section 8.6).
- Addition of recent empirical evidence (including from the BRANDO study) of the impact of random sequence generation on effect estimates (Section 8.9.1), allocation concealment (Section 8.10.1), blinding of participants and personnel (Section 8.11.1), blinding of outcome assessors (Section 8.12.1) and selective outcome reporting (Section 8.14.1).
- Additional text added to emphasize the importance of assessing incomplete outcome data separately for different outcomes or time points (Section 8.13.2).
- New Section 8.16.1.6 on issues that have been raised in relation to risk of bias, but for which the Handbook is unable to provide definitive guidance at present, including the influence of funders, early stopping, and single-centre versus multi-centre studies.

Chapter 9

- New Section 9.1.2.1 on the importance of checking data before completing a synthesis, including checking the magnitude and direction of effect in the synthesis against the original study data. This

can avoid several possible problems, including errors in the published data, data collection, any calculations or manipulation of data, and data entry into RevMan.
- Additional emphasis on the importance of considering missing participant data and its impact on meta-analysis (Section 9.4.2).
- Additional emphasis on the uncertainty of estimating the I^2 statistic to quantify heterogeneity when the number of studies in a meta-analysis is small (Section 9.5.2).
- Clarification that it is It is a mistake to compare within-subgroup inferences such as P values to test for a significant difference between subgroups, and that a formal statistical test to compare subgroups should be used (Section 9.6.3.1).
- Change in terminology from 'baseline risk' to the preferred 'underlying risk' when discussing possible sources of heterogeneity (Section 9.6.7).

Chapter 10

- Provides updated evidence on the prevalence of reporting bias from studies of FDA data (Section 10.2.1), the peer review process (Section 10.2.1.2), industry documents made available after legal challenges (Section 10.2.1.3), and the publication of positive trials in prestigious journals (Section 10.2.2.2).
- Includes a recommendation to search systematically for unpublished trial data, including a brief discussion of sources (Section 10.3.2).
- Notes that the Clinicaltrials.gov trials register now requires preliminary results to be posted within one year of the study's completion (Section 10.3.3).
- Notes that the minimum number of trials required to generate a funnel plot with adequate power to detect asymmetry may be considerably higher than 10 in some circumstances. (Section 10.4.3.1).
- New Section 10.4.4.7 discusses regression methods for dealing with potential reporting biases.

Chapter 11

- Title changed from 'Presenting results and 'Summary of 'Findings' Tables' to 'Completing 'Summary of findings' tables and grading the confidence in or quality of the evidence'.
- Old introduction removed (Section 11.1)
- Old Section 11.2 'Reporting the results of the search', including PRISMA flow diagrams and the 'Characteristics of included studies' table, has been removed. This content will be incorporated into updated chapters on searching and reporting the review in Version 6 of the Handbook.
- Old Section 11.3 'Data and analyses', including the 'Data ans analyses' section of a review, forest plots and other data tables has been removed. This content will be incorporated into anew chapters on meta-analysis and reporting the review in Version 6 of the Handbook.
- Specifically lists the footnotes as an essential component of a SoF table (Section 11.1.3)
- Updated to refer to the new SoF software, GRADEpro GDT (Section 11.1.4)
- Table 11.2.e 'Judgements about indirectness by outcome' added, based on GRADEpro GDT, to assist authors in assessing the indirectness of the evidence in their review in relation to the question originally asked.
- Further guidance included about the use of the Optimal Information Size (OIS) in assessing the imprecision of a body of evidence (Section 11.2.2).
- New section 11.2 'Assessing the quality of a body of evidence', including guidance on GRADE, moved here from Chapter 12.

- New Section 11.3 Describing the assessment of the quality of a body of evidence using the GRADE framework, providing guidance on how to express justifications for downgrading or upgrading the quality of the body of evidence using the GRADE approach.

Chapter 12

- Greater clarity on terminology used e.g. generalisability and numbers needed to treat.
- Old section 12.2 'Assessing the quality of a body of evidence', including guidance on GRADE, moved to Chapter 11.
- Extended Section 12.6 on implications for research with an additional table 12.6a providing a structured approach to the interpretation of the quality of a body of evidence according to individual GRADE criteria.

Chapter 21

Please note this chapter will be replaced by and integrated into at least two new chapters in Version 6: Issues of Equity and Specific populations, and Complex Interventions.

- Greater clarity defining public health and health promotion interventions emphasizing population level rather than individual level intervention are of interest that operate within a broader context.
- Database table at 21.3 is updated
- Section 21.4 on assessment of study quality and risk of bias is updated.
- At section 21.7 additional frameworks are added to assist in determining sustainability.