

Guide to the contents of a Cochrane Methodology protocol and review

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A.1 Introduction

Cochrane Methodology reviews are published in the *Cochrane Database of Systematic Review (CDSR)* alongside Cochrane reviews of the effects of healthcare interventions, diagnostic test accuracy and prognosis. They are produced by the Cochrane Methodology Review Group, based in Belfast, Northern Ireland, UK. Cochrane Methodology reviews have a similar structure to Cochrane Intervention reviews, but with some changes to their section headings, to reflect the fact that they cover studies assessing the methodology of research in health and social care, rather than the effects of the care itself. They are preceded by published protocols and produced with the same rigour and attention to detail as Cochrane reviews of health and social care. For example, evidence from methodology research is included or excluded on the basis of explicit criteria. Each review covers a specific and well-defined area of methodology and data from included studies might be combined statistically to increase the power of the findings. In such cases, the review may include graphs or tables presenting the data from each individual study, along with the overall average.

The preparation of a protocol and, subsequently, the review with the required format is facilitated by the use of Review Manager (RevMan) software, following the selection of the option for a Methodology Review. This document discusses the content of the entire review (or protocol) and outlines what should be included in each section. It should be used in conjunction with the current version of the *Cochrane Handbook for Systematic Reviews of Interventions*, which provides much fuller information on, for example, the style of writing to use for Cochrane reviews; the reporting of search strategies; the inclusion of data, analyses and summary of findings tables; and the format for citations.

This document is based on the following resources, adapted for Methodology reviews:

- Cochrane's Editorial and Publishing Policy Resource
- Cochrane Style Manual *Cochrane Handbook for Systematic Reviews of Interventions*
- Methodological Expectations for Cochrane Intervention Reviews

A.2 Title and review information (or protocol information)

A.2.1 Title

The title succinctly states the methodology reviewed and the problem for which the methodology is being assessed.

A.2.2 Authors

See the Cochrane Editorial and Publishing Policy Resource for 'Authorship and contributorship'.

A.2.3 Contact person

See the Cochrane Editorial and Publishing Policy Resource for ‘Cochrane Review author teams’ section in ‘Managing expectations: what does Cochrane expect of authors, and what can authors expect of Cochrane?’

A.2.4 Dates

See the Cochrane Editorial and Publishing Policy Resource for ‘Reporting search dates in Cochrane Reviews’.

A.2.5 What’s New and History

See the Cochrane Editorial and Publishing Policy Resource for ‘What’s New’ section of ‘Reporting search dates in Cochrane Reviews’.

A.3 Abstract

See the Abstract (R3-R18) MECIR Reporting Standards and Section III.3.1 of the Cochrane Handbook for Systematic Reviews of Interventions

All full reviews must include an abstract. The abstract should be brief but should seek to include all important content. Abstracts to Cochrane reviews are published in MEDLINE and are made freely available on the internet. It is therefore important that they can be read as stand-alone documents.

A.4 Plain language summary

See Section III.4 of the Cochrane Handbook for Systematic Reviews of Interventions

The plain language summary aims to summarize the review in a straightforward style. Plain language summaries are made freely available on the internet, so will often be read as stand-alone documents. Plain language summaries for Cochrane Methodology reviews have two main parts: a plain language title (a restatement of the review’s title using plain language terms) and a summary text.

A.5 Main text

The text of the review should be succinct and readable. It should be written so that someone who is not an expert in the area can understand it. The text of a Cochrane Methodology review contains fixed headings and sub-headings that are embedded in RevMan and appear in every review. Optional subheadings are also available, which can be activated added by the author. The following headings are followed by fixed subheadings and therefore have no free text immediately following them: ‘Methods’, ‘Criteria for including studies’, ‘Results’ and ‘Authors’ conclusions’.

Background [fixed, level 1 heading]

See the Background (R25-R25) MECIR Reporting Standards and Section III.3.2 of the Cochrane Handbook for Systematic Reviews of Interventions

Well-formulated review questions occur in the context of an already-formed body of knowledge. The background should address this context, help set the rationale for the review, and explain why the questions being asked are important. It should be concise (generally around one page when printed) and be understandable to the users of the methodology under investigation. All sources of information should be cited.

Description of the problem or issue [recommended, level 2 heading]

The review should begin with a brief description of the methodology being investigated and its significance. It may include information about how common the methodology is in evaluations of health and social care.

Description of the methods being investigated [recommended, level 2 heading]

A description of the methods being investigated should place it in the context of any standard, or alternative methods in common use.

How these methods might work [recommended, level 2 heading]

This section might describe the theoretical reasoning why the methods under review may have an impact in evaluations of health and social care. Authors may refer to a body of empirical evidence such as similar methods having an impact or identical methods having an impact in other settings. Authors may also refer to a body of literature that justifies the possible impact of the methods.

Why it is important to do this review [recommended, level 2 heading]

The background should clearly state the rationale for the review and should explain why the questions being asked are important. It might also mention why this review was undertaken and how it might relate to a wider review of a general problem. If this version of the review is an update of an earlier one, it is helpful to state this by writing, for example “This is an update of a Cochrane review first published in YEAR, and previously updated in YEAR”. This may be supplemented with a brief description of the main findings of the earlier versions, with a statement of any specific reasons there may be for updating the review.

Objectives [fixed, level 1 heading]

See Section III.3.2 of the Cochrane Handbook for Systematic Reviews of Interventions

This should begin with a precise statement of the primary objective of the review, ideally in a single sentence. This might be followed by a series of specific objectives relating to different types of health or social care evaluation or different settings.

Methods [fixed, level 1 heading]

See the Methods (R26) MECIR Reporting Standards and Section III.3.3 of the Cochrane Handbook for Systematic Reviews of Interventions

The Methods section in a protocol should be written in the future tense. Because Cochrane reviews are updated as new evidence accumulates, methods outlined in the protocol should generally be written as if a suitably large number of studies will be identified to allow the objectives to be met (even if it is known this is not the case at the time of writing).

The Methods section in a review should be written in the past tense and should describe what was done to obtain the *results and conclusions of the current review*. It should contain a reference to the previously published protocol for the review. Often a review is unable to implement all the methods outlined in the protocol, usually because there is insufficient evidence. In such circumstances, methods that were not implemented should be outlined in the section headed ‘Differences between protocol and review’ (see below), so that it serves as a protocol for future updates of the review.

Criteria for considering studies for this review [fixed, level 2 heading]

See the Criteria for considering studies for this review (R27-R32) MECIR Reporting Standards and Section III.3.3.1 of the Cochrane Handbook for Systematic Reviews of Interventions

Types of studies [fixed, level 3 heading]

Eligible study designs should be stated here, along with any thresholds for inclusion based on the conduct of the studies or their risk of bias. For example, ‘All randomized comparisons of different methods’ or ‘All cohorts of clinical trials with prospective registration of the trials’.

Types of data [fixed, level 3 heading]

The raw material for the methodology studies to be included in the review should be described here, including any restrictions on, for example, the characteristics of the raw material (such as limiting to randomised trials only). Examples of ‘Types of data’ in Cochrane Methodology reviews are “healthcare trials, including trials of clinical interventions and non-clinical interventions where the effects of the intervention on one or more health outcomes were measured” and “biomedical sciences research studies”. Subgroup analyses should not be listed here (see ‘Subgroup analysis and investigation of heterogeneity’ under ‘Methods’).##

Types of methods [fixed, level 3 heading]

The methods under investigation should be defined here, under separate subheadings if appropriate. It should be made clear which comparisons are of interest. An example of ‘Types of methods’ for a Cochrane Methodology review is “randomised trials with adequately versus inadequately concealed allocation”. Subgroup analyses should not be listed here (see ‘Subgroup analysis and investigation of heterogeneity’ under ‘Methods’).

Types of outcome measures [fixed, level 3 heading]

Outcome measures do not always form part of the criteria for including studies in a review and, if they do not, this should be made clear. However, all outcome measures of interest for the review should be

listed in this section, whether or not they form part of the inclusion criteria. Examples of 'Types of outcome measures' in Cochrane Methodology reviews are effects estimates for the comparison of different methods (e.g. relative risk reductions, odds ratios, standardised effect sizes) and proportion of studies reported as abstracts that are subsequently published in full and the time interval between presentation at meetings and subsequent publication.

Primary outcomes

[recommended, level 4 heading]

There should be as few primary outcomes as possible. It is normally expected that the review should be able to analyse these outcomes if eligible studies are identified, and that the conclusions of the review will be based in large part on the findings for these outcomes.

Secondary outcomes

[recommended, level 4 heading]

Other outcomes should be listed here. The total number of outcomes addressed should be kept as small as possible.

Search methods for identification of studies

[fixed, level 2 heading]

See the Search methods for identification of studies (R33-R38) MECIR Reporting Standards and Section III.3.3.2 of the Cochrane Handbook for Systematic Reviews of Interventions

The methods used to identify studies should be summarized and the following headings are recommended for structuring this section.

Electronic searches

[recommended, level 3 heading]

The bibliographic databases searched, the dates and periods searched and any constraints, such as language should be stated. The full search strategies for each database should be listed in an appendix to the review.

Searching other resources

[recommended, level 3 heading]

Any grey literature sources, such as internal reports and conference proceedings that were searched should be listed. If journals are specifically handsearched for the review, these should be listed along with the publication years that were searched. People (e.g. researchers or topic specialists) and organizations who were contacted should be listed. List any other methods used, which may include, for example, the checking of reference lists (Horsley 2011), general searches of the internet and personal collections of articles. The following *optional* headings may be used, either in place of 'Searching other resources' (in which case they would be level 3 headings) or as subheadings (level 4).

Grey literature

Handsearching

Reference lists

Correspondence

Data collection and analysis [fixed, level 2 heading]

See the *Data collection and analysis (R39-R55) MECIR Reporting Standards and Section III.3.3.3 of the Cochrane Handbook for Systematic Reviews of Interventions*

This should describe the methods for data collection and analysis.

Selection of studies [recommended, level 3 heading]

The method used to apply the selection criteria. Whether they are applied independently by more than one author should be stated, along with how any disagreements are resolved.

Data extraction and management [recommended, level 3 heading]

The method used to extract or obtain data from published reports or from the original researchers (for example, using a data extraction/data collection form). Whether data are extracted independently by more than one author should be stated, along with how any disagreements are resolved. If relevant, methods for processing data in preparation for analysis should be described. If the original researchers were contacted for additional information on their studies (Young 2011), this should be stated.

Assessment of risk of bias in included studies [recommended, level 3 heading]

The method used to assess risk of bias of the methodology studies. Whether methods are applied independently by more than one author should be stated, along with how any disagreements are resolved. The tools used should be described or referenced, with an indication of how the results are incorporated into the interpretation of the results.

Measures of the effect of methods [recommended, level 3 heading]

The effect measures of choice should be stated. For example, odds ratio (OR), risk ratio (RR) or risk difference (RD) for dichotomous data; difference in means (MD) or standardized difference in means (SMD) for continuous data. The following *optional* headings may be used, either in place of ‘Measures of the effects of methods’ (in which case they would be level 3 headings) or as subheadings (level 4):

Dichotomous data

Continuous data

Time-to-event data

Unit of analysis issues [recommended, level 3 heading]

Special issues in the analysis of studies with designs such as cross-over or cluster should be described.

Dealing with missing data [recommended, level 3 heading]

Strategies for dealing with missing data should be described. This will principally include missing information for methodology studies (for example the loss of trials from cohorts of trials), and missing statistics (such as standard deviations or correlation coefficients).

Assessment of heterogeneity**[recommended, level 3 heading]**

Approaches to addressing design heterogeneity among the methodology studies should be described, along with how the authors will determine whether a meta-analysis is considered appropriate. Methods for identifying statistical heterogeneity should be stated (for example, visually, using a chisquared test or using I^2).

Assessment of reporting biases**[recommended, level 3 heading]**

How publication bias, and other reporting biases are addressed (for example, funnel plots, statistical tests, imputation). Authors should remember that asymmetric funnel plots are not necessarily caused by publication bias (and that publication bias does not necessarily cause asymmetry in a funnel plot).

Data synthesis**[recommended, level 3 heading]**

The choice of any meta-analysis method should be stated, including whether a fixed-effect or a random-effects model is used. If meta-analyses are not undertaken, systematic approaches to synthesizing the findings of multiple studies should be described.

Subgroup analysis and investigation of heterogeneity**[recommended, level 3 heading]**

All planned subgroup analyses or independent variables for meta-regression should be listed. Any other methods for investigating heterogeneity of results should be described.

Sensitivity analysis**[recommended, level 3 heading]**

This should describe analyses aimed at determining whether conclusions are robust to decisions made during the review process, such as inclusion or exclusion of particular studies from a meta-analysis, imputing missing data or choice of a method for analysis.

The following *optional* (level 3) heading for the Methods section may be helpful for describing when and how the review might be updated (Moher 2008):

Methods for future updates**Results****[fixed, level 1 heading]****Description of studies****[fixed, level 2 heading]**

See the Description of studies (R56-R72) MECIR Reporting Standards and Section III.3.4.1 of the Cochrane Handbook for Systematic Reviews of Interventions

Results of the search**[recommended, level 3 heading]**

The results sections should start with a summary of the results of the search (for example, how many references were retrieved by the electronic searches).

Included studies**[recommended, level 3 heading]**

It is essential that the number of included studies is clearly stated. This section should comprise a succinct summary of the information contained in the ‘Characteristics of included studies’ table. An explicit reference and link to this table should be included. Key characteristics of the included studies should be described, including the methods, data (e.g. type of clinical trial in a methodology study), comparisons and outcome measures in the included studies and any important differences among the studies. Authors should note any other characteristics of the studies that they regard as important for readers of the review to know. The following *optional* (level 4) subheadings may be helpful:

Design***Sample sizes******Setting******Methods******Outcomes*****Excluded studies****[recommended, level 3 heading]**

This should refer to the information contained in the ‘Characteristics of excluded studies’ table. An explicit reference and link to this table should be included. A succinct summary of why studies were excluded from the review should be provided.

The following *optional* (level 3) headings may be used in the ‘Description of studies’ section:

Ongoing studies***Studies awaiting classification******New studies found at this update*****Risk of bias in included studies****[fixed, level 2 heading]**

See the Risk of bias in included studies (R73-R75) MECIR Reporting Standards and Section III.3.4.2 of the Cochrane Handbook for Systematic Reviews of Interventions

This should summarize the general risk of bias in results of the included studies, its variability across studies and any important flaws in individual studies. The criteria that were used to assess the risk of bias should be described or referenced in the ‘Methods’ section of the review and not here. How each study was rated on each criterion should be reported in a ‘risk of bias’ table and not described in detail in the text, which should be a concise summary.

For large reviews, aspects of the risk of bias assessment may be summarized for the primary outcomes under the following headings, where these are relevant to the topic of the review and the types of methodology study that are eligible.

Allocation [recommended, level 3 heading]

A summary of how the methods being investigated were assigned in any comparative methodology studies in the review. Judgements concerning the risk of bias that arise from this assignment should be summarized here.

Blinding [recommended, level 3 heading]

A brief summary of who was blinded or masked during the conduct and analysis of the methodology studies should be reported here. Judgements concerning the risk of bias associated with blinding should be summarized here.

Follow up and exclusions [recommended, level 3 heading]

The completeness of data should be summarized briefly here for each of the main outcomes.

Selective reporting [recommended, level 3 heading]

Concerns over the selective availability of data should be summarized briefly here, including evidence of selective reporting of outcomes, subgroups or analyses.

Other potential sources of bias [recommended, level 3 heading]

Any other potential concerns should be summarized here.

Effects of methods [fixed, level 2 heading]

See the Effect of interventions (R76-R99) MECIR Reporting Standards and Section III.3.4.3 of the Cochrane Handbook for Systematic Reviews of Interventions

This should be a summary of the main findings on the effects of the methods studied in the review. The section should directly address the objectives of the review rather than list the findings of the included studies in turn. The results of individual studies, and any statistical summary of these, should be included in 'Data and analysis' tables. Outcomes should normally be addressed in the order in which they are listed under 'Types of outcome measures'. Subheadings are encouraged if they make understanding easier (for example, for each different data, comparison or outcome measure if a review addresses more than one). Any sensitivity analyses that were undertaken should be reported. Authors should avoid making inferences in this section.

Discussion [fixed, level 1 heading]

See the Discussion (R100-R101) MECIR Reporting Standards and Section III.3.5 of the Cochrane Handbook for Systematic Reviews of Interventions

A structured discussion can aid the consideration of the implications of the review (Docherty 1999).

Summary of main results [recommended, level 2 heading]

Summarize the main findings (without repeating the ‘Effects of methods’ section) and describe any outstanding uncertainties, balancing important benefits against important harms. Refer explicitly to any ‘Summary of findings’ tables if these are included in the review.

Overall completeness and applicability of evidence [recommended, level 2 heading]

Describe the relevance of the evidence to the review question. This should lead to an overall judgement of the external validity of the review. Are the studies identified sufficient to address all objectives of the review? Have all relevant types of data, methods and outcomes been investigated? Comments on how the results of the review fit into the context of current practice might be included here, although authors should bear in mind that current practice might vary internationally or in different settings.

Certainty of the evidence [recommended, level 2 heading]

Does the body of evidence identified allow a robust conclusion regarding the objectives of the review? Summarize the amount of evidence that has been included (numbers of studies), state key limitations in the quality of the studies, and reiterate the consistency or inconsistency of their results. This should lead to an overall judgement of the internal validity of the results of the review.

Potential biases in the review process [recommended, level 2 heading]

State the strengths and limitations of the review with regard to preventing bias. These may be factors within, or outside, the control of the review authors. The discussion might include the likelihood that all relevant studies were identified, whether all relevant data could be obtained, or whether the methods used (for example, searching, study selection, data extraction, or analysis) could have introduced bias.

Agreements and disagreements with other studies or reviews [recommended, level 2 heading]

Comments on how the included studies fit into the context of other evidence might be included here, stating clearly whether the other evidence was systematically reviewed.

Authors' conclusions [fixed, level 1 heading]

See the Authors' conclusions (R102-R103) MECIR Reporting Standards and Section III.3.6 of the Cochrane Handbook for Systematic Reviews of Interventions

The primary purpose of the review should be to present information, rather than to offer advice. Conclusions of the authors of Cochrane Methodology reviews are divided into two sections:

Implications for systematic reviews and evaluations of health care [fixed, level 2 heading]

The implications for systematic reviews and other evaluations of health and social care should be as practical and unambiguous as possible. They should not go beyond the evidence that was reviewed and be justifiable by the data presented in the review. ‘No evidence of effect’ should not be confused with ‘evidence of no effect’.

Implications for methodological research

[fixed, level 2 heading]

This section of a Cochrane Methodology review may be used by people making decisions about future methodology research, and authors should try to write something that will be useful for this purpose. As with the ‘Implications for systematic reviews and evaluations of health care’, the content should be based on the available evidence and should avoid the use of information that was not included or discussed within the review. In preparing this section, authors should consider the different aspects of research, perhaps using types of study, data, methods and outcome as a framework. Implications for *how* research might be done and reported should be distinguished from *what* future research should be done. For example, the need for randomized trials rather than other types of study, for better descriptions of studies in the particular topic of the review, or for the routine collection of specific outcomes including the use of core outcome sets (Williamson 2017), should be distinguished from the need for comparisons of specific types of method, or for research in specific settings.

It is important that this section is as clear and explicit as possible. General statements that contain little or no specific information, such as “Future research should be better conducted” or “More research is needed” are of little use to people making decisions and should be avoided.

Acknowledgements

[fixed, level 1 heading]

See the Acknowledgments (R104) MECIR Reporting Standards.

This section should be used to acknowledge any people or organizations that the authors wish to acknowledge, including people who are not listed among the authors. This would include any previous authors of the Cochrane Methodology review or previous sources of support to the review, and might include the contributions of the editorial team of the Cochrane Methodology Review Group or the peer reviewers. Permission should be obtained from persons acknowledged.

Contributions of authors

[fixed, level 1 heading]

See the Contributions of authors (R105) MECIR Reporting Standards.

The contributions of the current co-authors should be described in this section. One author should be identified as the guarantor of the review. All authors should discuss and agree on their respective descriptions of contribution before the review is submitted for publication on the CDSR. When the review is updated, this section should be checked and revised as necessary to ensure that it is accurate and up to date.

The following potential contributions are adapted from Yank et al. (Yank 1999). This is a suggested scheme and the section should describe what people did, rather than attempt to identify which of these categories someone’s contribution falls within. Ideally, the authors should describe their contribution in their own words:

- Conceiving the review.
- Designing the review.
- Coordinating the review.

- Data collection for the review.
 - Designing search strategies.
 - Undertaking searches.
 - Screening search results.
 - Organizing retrieval of papers.
 - Screening retrieved papers against inclusion criteria.
 - Appraising quality of papers.
 - Extracting data from papers.
 - Writing to authors of papers for additional information.
 - Providing additional data about papers.
 - Obtaining and screening data on unpublished studies.
- Data management for the review.
 - Entering data into RevMan.
- Analysis of data.
- Interpretation of data.
 - Providing a methodological perspective.
 - Providing a clinical perspective.
 - Providing a policy perspective.
 - Providing a consumer perspective.
- Writing the review.
- Providing general advice on the review.
- Securing funding for the review.
- Performing previous work that was the foundation of the current review.

Declarations of interest

[fixed, level 1 heading]

See the Declarations of interest (R106) MECIR Reporting Standards.

Authors should report any present or past affiliations or other involvement in any organization or entity with an interest in the review that might lead to a real or perceived conflict of interest. Situations that might be perceived by others as being capable of influencing a review author's judgements include personal, political, academic and other possible conflicts, as well as financial conflicts. Authors must state if they have been involved in a study included in the review. If there are no known conflicts of interest, this should be stated explicitly, for example, by writing 'None known'.

Differences between protocol and review

[fixed, level 1 heading]

See the Differences between protocol and review (R107-R108) MECIR Reporting Standards.

It is sometimes necessary to use different methods from those originally described in the protocol. This could be because:

- methods for dealing with a particular issue had not been specified in the protocol;
- methods in the protocol could not be applied (for example, due to insufficient data or a lack of information required to implement the methods); or
- methods are changed because a preferable alternative is discovered.

Some changes of methods from protocol to review are acceptable but must be fully described in this section. The section provides a summary of the main changes in methods for the review over time. It should be used for the following:

- Point out any methods that were determined subsequent to the most recent published protocol (e.g. adding or changing outcomes, adding ‘Risk of bias’ or ‘Summary of findings’ tables).
- Summarize methods from the protocol that could not be implemented in the current review (e.g. because no studies fell in a particular pre-defined subgroup).
- Explain any changes in methods from the protocol to the review, state when they were made and provide the rationale for the changes. Such changes should not be driven by findings related to the methodology being studied in the review. Discuss the potential effect on the review’s conclusions of any changes in methods and consider sensitivity analyses to assess this.

Published notes

[fixed, level 1 heading]

Published notes will appear in the review in the *CDSR*. They may include editorial notes and comments from the Cochrane Methodology Review Group, for example where issues highlighted by editors or peer reviewers are believed worthy of publication alongside the review. The author or source of these comments should be specified (e.g. from an editor or a peer reviewer).

Published notes must be completed for all withdrawn protocols and reviews, giving the reason for withdrawal. These published notes, along with basic citation information and sources of support will be the only part of the review that is published as part of the withdrawn protocol or review in the *CDSR*.

A.6 Tables

See the Cochrane Style Manual for ‘Tables’.

A.6.1 Characteristics of included studies

The ‘Characteristics of included studies’ table has five entries for each study: Methods, Data, Comparisons, Outcomes and Notes. Up to three further entries may be specified for items not conveniently covered by these categories, (e.g. to provide information on length of follow-up, funding source, or indications of study quality that are unlikely to lead directly to a risk of bias).

Codes or abbreviations may be used in the table to enable clear and succinct presentation of multiple pieces of information within an entry. As with other tables in the review, footnotes should be used to explain any codes or abbreviations used, and these will be published in the *CDSR*.

A.6.2 Risk of bias

A ‘Risk of bias’ table is an optional, although strongly recommended, extension of the ‘Characteristics of included studies’ table. The ‘Risk of bias’ table includes a set of standard headings and those that are not relevant for the methodology studies in the review can be removed and authors can add further items as necessary. For each item, the table provides a description of what was reported to have happened in the study and a subjective judgement regarding protection from bias (‘Yes’ for a low risk of bias, ‘No’ for a high risk of bias; ‘Unclear’ otherwise).

A.6.3 Characteristics of excluded studies

Studies meeting the inclusion criteria, or appearing to meet the inclusion criteria, that were excluded should be listed and the reason for exclusion should be given (for example, inappropriate comparator intervention). This should be kept brief, and a single reason for exclusion is usually sufficient.

A.6.4 Characteristics of studies awaiting classification

The ‘Characteristics of studies awaiting classification’ table has the same structure as the ‘Characteristics of included studies’ table. It should be used for two categories of study:

- Studies about which an inclusion or exclusion decision cannot be made because insufficient information is currently available. All reasonable attempts to obtain information must be made before studies are left in this section when the review is published, but the review should not be delayed excessively waiting for this information, especially if the inclusion or exclusion of the study is unlikely to have an impact on the review’s conclusions. When information is not available for a table entry, the text ‘Not known’ should be inserted.
- Studies that have been identified but are awaiting full consideration when the review is updated. In particular, studies that have the potential to impact on the review’s conclusions, or studies that receive wide publicity, may warrant a mention in the review in the period between updates. An amended review may therefore be produced with such studies summarized in this table. The full update, with such studies fully incorporated, should be completed as soon as possible. When information is not available for a table entry, the text ‘Not yet assessed’ or ‘Not known’ should be inserted, as appropriate.

A.6.5 Characteristics of ongoing studies

The ‘Characteristics of ongoing studies’ table has eight entries for each study: Study name, Methods, Data, Comparisons, Outcomes, Starting date, Contact information and Notes. The contents of these entries should be comparable to those in the table of ‘Characteristics of included studies’.

A.6.6 Summary of findings tables

A ‘Summary of findings’ table is an optional means of presenting findings for the most important outcomes for a Cochrane Methodology review, whether or not evidence is available for them. A ‘Summary of findings’ table includes, where appropriate, a summary of the amount of evidence; typical absolute risks for the different methods; estimates of relative effect (e.g. risk ratio or odds ratio); a

depiction of the quality of the body of evidence; comments; and footnotes. The assessment of the quality of the body of evidence should follow the GRADE framework, which combines considerations of risk of bias, directness, heterogeneity, precision and publication bias.

A.6.7 Additional tables

Additional tables may be used for information that cannot be conveniently placed in the text or in fixed tables. Examples include:

- Information to support the background for the review.
- Summaries of study characteristics (such as detailed descriptions of the methods being investigated or outcomes).
- Results that do not fit into ‘Data and analysis’ tables, for example skewed data reporting a median and range.

A.7 Studies and references

See the Cochrane Style Manual for ‘References’.

A.7.1 References to studies

Studies are organized under four fixed headings:

Included studies

Studies that meet the inclusion criteria and are included in the review.

Excluded studies

Studies that do not meet the inclusion criteria and are excluded from the review.

Studies awaiting classification

Relevant studies that have been identified but cannot be assessed for inclusion until additional data or information are obtained.

Ongoing studies

Studies that are ongoing and meet (or appear to meet) the inclusion criteria.

Each of these headings can include multiple studies (or no studies). A study is identified by a ‘Study ID’ (usually comprising the last name of first author and the year of the primary reference for the study). A year can be explicitly associated with each study (usually the year of completion, or the publication year of the primary reference). In addition, each study should be assigned a category of ‘Data source’ from the following.

- Published data only.
- Published and unpublished data.
- Unpublished data only.
- Published data only (unpublished sought but not used).

Each study can have multiple references. Each reference may include identifiers such as a PubMed ID or a DOI. One reference for each study should be awarded the status of ‘Primary reference’. Authors should check all references for accuracy (Wager 2008).

A.7.2 Other references

References other than those to studies are divided among the following two categories. Authors should check all references for accuracy (Wager 2008).

Additional references

Other references cited in the text should be listed here. If a report of a study is cited in the text for some reason other than referring to the study (for example, because of some background or methodological information in the reference), it should be listed here as well as under the relevant study.

Other published versions of this review

References to other published versions of the review in a journal, textbook or the *CDSR* or elsewhere should be listed here.

Note: RevMan also includes a ‘Classification pending’ category to facilitate organization of references while preparing a review. All references should be moved out of this category before a review is marked for submission to the *CDSR*, since any references remaining in this category will not be published.

A.8 Data and analyses

Results of studies included in a review are organized in a hierarchy: studies are nested within (optional) subgroups, which are nested within outcomes, which are nested within comparisons.

RevMan automatically generates forest plots illustrating data, effect estimates and results of meta-analyses (where selected) from the data entered into the ‘Data and analyses’ structure. Authors are able to control whether, and how, meta-analyses are performed.

Note: The ‘Data and analyses’ should be considered as supplementary information because they may not appear in some formats of the published review. Key forest plots (containing data for each study) may be selected to be *always* included with the full text of the review by selecting them as figures (see Section A.9). The full published Cochrane Methodology review in the *CDSR* will, however, contain all of the ‘Data and analyses’ section as a series of forest plots or tables.

Authors should avoid listing comparisons or outcomes for which there are no data (i.e. avoid having forest plots with no studies). Instead, authors should note in the text of the review that no data are available for the comparisons. If a ‘Summary of findings’ table is included for the review, the main outcomes for the review should be included irrespective of whether data are available from the included studies or a forest plot has been included for them.

Comparison

The comparisons should correspond to the questions or hypotheses under ‘Objectives’.

Outcome

Five types of outcome data are possible: dichotomous data, continuous data, ‘O – E’ and ‘V’ statistics, generic inverse variance (estimate and standard error) and other data (text only).

Subgroup

Subgroups may relate to subsets of studies (e.g. studies done before and after the publication of the CONSORT statement) or to a sub-division of the outcome (e.g. short-term, medium-term, long-term).

Study data

Data for each study must be entered in a particular format specific to the type of outcome data (e.g. a sample size, mean and standard deviation for each group for continuous data).

A.9 Figures

See the Cochrane Style Manual for ‘Figures’ and Section III.S1 of the Cochrane Handbook for Systematic Reviews of Interventions.

Various types of figures may be included in a review. These figures will always be presented with the full-text publication of the review. Each figure must have a Caption providing a brief description (or explanation) of the figure and must be referred to (with a link) in the review text.

A.9.1 RevMan plots and graphs

Forest plots and funnel plots from among those in the ‘Data and analyses’ may be selected as figures that will always be included in the full text of the review in the CDSR. Pictorial representations of judgments on risk of bias can also be generated within RevMan and included as figures.

A.9.2 Other figures

Graphs and other images that are not generated by RevMan can also be included as figures, as well as a completed PRISMA flow diagram to show the progress of studies through the review (Moher 2009).

These figures should not be used for content that can be generated in other ways within RevMan, for example as forest plots or as additional tables.

Authors are responsible for obtaining permission for images included in the review and for following guidance to ensure the images are fit for publication. If permission to publish a copyrighted figure is granted, the final phrase of the figure caption must be: "Copyright © [Year] [Name of copyright holder, or other required wording]: reproduced with permission.".

A.10 Sources of support to the review

See the Sources of support (R109) MECIR Reporting Standards.

Authors should acknowledge grants or other funding that supported the review, and other forms of support, such as support from their university or institution in the form of a salary. Sources of support are divided into 'internal' (provided by the institutions at which the review was produced) and 'external' (provided by other institutions or funding agencies). Each source, its country of origin and what it supported should be provided.

A.11 Feedback

Each piece of Feedback incorporated into a review is identified by a short title and the date. Summary, Reply and Contributors are subheadings in this section. The summary should be prepared by the Feedback editor or the Coordinating editor for the Cochrane Methodology Review Group in consultation, if necessary, with the person submitting the comment. The authors of the review should prepare a reply. The names of the people who contributed to the process of responding to the feedback should be given under 'Contributors'.

A.12 Appendices

Appendices provide a place for supplementary information, such as:

- detailed search strategies (appendices are the recommended place to put these);
- lengthy details of non-standard statistical methods;
- data extraction forms; and
- details of outcomes (e.g. measurement scales).

Appendices may not appear in some formats of the published review.

See also the Cochrane Editorial and Publishing Policy Resource for 'Supplemental data and files'.

A.13 Document information

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A.14 References

Clarke 2008

Clarke M, Oxman AD, Paulsen E, Higgins JPT, Green S (editors). Appendix A: Guide to the contents of a Cochrane Methodology protocol and review. In: Higgins JPT, Green S (editors), *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.0.1 (updated September 2008). The Cochrane Collaboration, 2008.

Docherty 1999

Docherty M, Smith R. The case for structuring the discussion of scientific papers. *BMJ* 1999; 318: 1224-5.

Flanagin 1998

Flanagin A, Carey LA, Fontanarosa PB, Phillips SG, Pace BP, Lundberg GD, Rennie D. Prevalence of articles with honorary authors and ghost authors in peer-reviewed medical journals. *JAMA* 1998; 280: 222-4.

Horsley 2011

Horsley T, Dingwall O, Sampson M. Checking reference lists to find additional studies for systematic reviews. *Cochrane Database of Systematic Reviews* 2011; (8): MR000026. DOI: 10.1002/14651858.MR000026.pub2.

Moher 2008

Moher D, Tsertsvadze A, Tricco A, Eccles M, Grimshaw J, Sampson M, Barrowman N. When and how to update systematic reviews *Cochrane Database of Systematic Reviews* 2008; (1): MR000023. DOI: 10.1002/14651858.MR000023.pub3.

Moher 2009

Moher D, Liberati A, Tetzlaff J, Altman DG; PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *Annals of Internal Medicine* 2009; 151: 264-9.

Rennie 1997

Rennie D, Yank V, Emanuel L. When authorship fails. A proposal to make contributors accountable. *JAMA* 1997; 278: 579-85.

Rennie 1998

Rennie D, Yank V. If authors became contributors, everyone would gain, especially the reader. *American Journal of Public Health* 1998; 88: 828-30.

Wager 2008

Wager E, Middleton P. Technical editing of research reports in biomedical journals. *Cochrane Database of Systematic Reviews* 2008; (4): MR000002. DOI: 10.1002/14651858.MR000002.pub3.

Williamson 2017

Williamson PR, Altman DG, Bagley H, Barnes KL, Blazeby JM, Brookes ST, et al. The COMET Handbook: version 1.0. *Trials* 2017; 18(suppl 3): 280.

Yank 1999

Yank V, Rennie D. Disclosure of researcher contributions: a study of original research articles in *The Lancet*. *Annals of Internal Medicine* 1999; 130: 661-70.

Young 2011

Young T, Hopewell S. Methods for obtaining unpublished data. *Cochrane Database of Systematic Reviews* 2011; (11): MR000027. DOI: 10.1002/14651858.MR000027.pub2.