



Cochrane Upper Gastrointestinal and Pancreatic Diseases Group

Guidance for the completion of your Cochrane intervention **Review**

Revised June 2019

INTRODUCTION

This guide has been created by the UGPD group to assist authors with a review title registered with the UGPD group. As such, we have included guidance particular to our authors which may or may not be applicable in other Cochrane groups. The guidance is presented in the order in which you will encounter sections in RevMan, the software used to author reviews.

We have included details of the Methodological Expectations of Cochrane Intervention Reviews (MECIR) standards particular to each section in text boxes on the right hand side. The MECIR project aims to specify methodological conduct and reporting expectations for Cochrane Protocols, Reviews, and updates of reviews on the effects of interventions, and to ensure that these methodological expectations are supported and implemented across The Cochrane Collaboration. Standards which are mandatory are framed in red (such as the one on this page under “Authors”), while standards which are recommended are framed in blue (as on this page under “Title”). Conduct standards are noted by the letter “c” following the standard number, which reporting standards are noted by the letter “r”. Please ensure you address all mandatory standards in your review. Please see <https://methods.cochrane.org/mecir> for further details on the MECIR standards.

PRIOR TO STARTING YOUR REVIEW

Prior to starting your review, the following fields should have been completed when drafting your protocol. If they haven't been completed, or if revisions are necessary, please contact the UGPD group Managing Editor.

TITLE

The title should succinctly state the focus of the review. It should make clear the intervention(s) reviewed and the problem at which the intervention is directed. Someone reading the title on its own should be able to decide quickly whether the review addresses a question of interest. At its most basic, a title should take the structure ‘Intervention for condition’. Other structures are included in the Style Guidelines for Cochrane reviews (<http://www.liv.ac.uk/lstm/ehcap/CSR/home.html>). Specific outcomes should be mentioned only rarely within the title. If so, this should usually be done as a subtitle separated by a colon from the main title. Do not start your title with “A systematic review of the effectiveness of ...” – all Cochrane reviews are!

1r The review title should follow the standard template for a Cochrane title as detailed in Table 4.2.a of the Cochrane handbook.

AUTHORS

This should be a list of co-authors on the review. When deciding who should go in the byline for Cochrane reviews, it is important to distinguish individuals who have made a substantial contribution to the review (and who should be listed) and those who have made other contributions, which should be noted in the Acknowledgements section. Authorship should be based on substantial contributions to all of the following three steps, based on conception and design of study, or analysis and interpretation of data drafting the review or revising it critically for important intellectual content final approval of the version to be published. Brief contact details of co-authors may be published within the completed protocol or review, so authors should ensure that these fields are completed and up-to-date in RevMan. The fields that must be completed are the First name(s) and Last name, Organization and Country. If a co-author does not have a publishable address, but should still appear in the byline for the citation, then the Organization and Country should be those of the Review Group (for example, ‘Smith J. c/o Cochrane Pregnancy and Childbirth Group, UK’).

2r All authors and their affiliations should be listed as detailed in section 4.2.2 of the Cochrane handbook.

The format for the byline of the review is Last-name Initial(s), without prefix (such as Dr) or internal punctuation but with a comma between names (for example, ‘Jepson RG, Mihaljevic L, Craig JC’). The list of authors for citations can be the name of an individual, several individuals or a collaborative group (for example, ‘Early Breast Cancer Trialists’ Collaborative Group’). Ideally, the order of authors should relate to their relative contributions to the review. The person who contributed most should be listed first.

CONTACT AUTHOR

This should provide the contact details for the person to whom correspondence about the review should be addressed, and who has agreed to take responsibility for maintaining and developing the review. This usually is the person who takes responsibility for developing and organizing the review team, communicates with the editorial base, ensures that the review is prepared within agreed timescales, submits it to the editorial base, communicates feedback to co-authors and ensures that the updates are prepared.

The contact author need not be the first listed author, and the choice of contact author will not affect the citation for the review. If the contact author no longer wishes to be responsible for a published review and another member of the review team does not wish to take responsibility for it, then the Managing Editor (ME) should be listed as the contact author, and the former contact author listed as a co-author. The ME need not be listed as a co-author.

PROPERTIES

The properties about your review are accessible from within Archie. To access the properties, log in to Archie (archie.cochrane.org), and choose your review title. From the “file” menu, choose “properties”. Some of the items on the “general” and “advanced” tabs are described below.

REVMAN ID

A unique 18-digit number is assigned to each review and is used by Archie to match up versions of reviews under one title.

DOI

Digital object identifiers (DOIs) are assigned by the publisher of the Cochrane Library, and will be assigned to your review once published.

REVIEW NO

The UGPD group assigns a unique review number to each review title. We kindly ask that you do not edit this number as it is used for our internal tracking.

VERSION NO

One version of each review must be marked as the primary version and this is the one that should be submitted for publication in the CDSR.

STATUS

This specifies what stage the review is active, withdrawn or inactive. For reviews in development the status should be “active”.

STAGE

This specifies what stage the review is at: title, protocol or full review. Titles are only used internally, within Collaborative Review Groups, and are not included in the Cochrane Database of Systematic Reviews (CDSR). For reviews in development the stage should be “Review”.

REVIEW INFORMATION

AUTHORS

The order of the authors may be altered by expanding the “Review information” and “authors” sections in the left hand panel in RevMan. Click on the author name to be moved, highlighting it. Then using your secondary mouse button, choose “move up” or “move down” to reposition. Changes to the details of an author’s record can only be done by the author logging into Archie, or by the Cochrane Review Group.

This should be a list of co-authors on the review. When deciding who should go in the byline for Cochrane reviews, it is important to distinguish individuals who have made a substantial contribution to the review (and who should be listed) and those who have made other contributions, which should be noted in the Acknowledgements section. Authorship should be based on substantial contributions to all of the following three steps, based on:

- conception and design of study, or analysis and interpretation of data
- drafting the review or revising it critically for important intellectual content
- final approval of the version to be published.

Brief contact details of co-authors may be published within the completed protocol or review, so authors should ensure that these fields are completed and up-to-date in RevMan. The fields that must be completed are the First name(s) and Last name of the co-author, Organization and Country. If a co-author does not have a publishable address, but should still appear in the byline for the citation, then the Organization and Country should be those of the Review Group (for example, ‘Smith J. c/o Cochrane Pregnancy and Childbirth Group, UK’).

DATES

Note that the date fields are not all published in the CDSR. They should all be completed by the author (reviewer) or Collaborative Review Group (CRG) in RevMan.

ASSESSED AS UP-TO-DATE

This is the date on which the review was last assessed. The date will often coincide with the date on which the authors submit the review for consideration to be published in the *Cochrane Database of Systematic Reviews (CDSR)*, however it should be within six months of the date of the literature search.

DATE OF SEARCH

This date is used to help determine whether a review has been updated, and to inform the date on which the review is assessed as being up to date. It will not be published in the *CDSR*.

‘Search’ here refers to the searches of all the databases searched for the review. If different databases were searched on different dates, the most recent date of the search for each database should be given within the text of the review and the earliest of the dates should be put in this field.

NEXT STAGE EXPECTED

This date should be completed for reviews so that users of the CDSR will know when they can expect the completed review to be updated. Normally this date is two years after the search date.

PROTOCOL FIRST PUBLISHED

This date will have automatically been included when the protocol was published in the Cochrane library.

REVIEW FIRST PUBLISHED

This date will automatically be included when the review is published in the Cochrane library.

LAST CITATION ISSUE

This date will automatically be included when the review is published in the Cochrane library.

WHAT'S NEW

This should describe the changes to the protocol or review since it was last published in the *CDSR*. At each update of a review, substantive or not, the 'What's new' field should contain the calendar date of the change and a description of what was changed. This might be, for example, a brief summary of how much new information has been added to the review (for example, number of studies, participants or extra analyses) and any important changes to the conclusions, results or methods of the review.

HISTORY

This section is used to detail changes to published reviews such as amendments, updates and changes to the authorship. Normally, this section will be empty for reviews being published for the first time.

MAIN TEXT

Cochrane reviews should be written so that they are easy to read and understand by someone with a basic sense of the topic who may not necessarily be an expert in the area. Some explanation of terms and concepts is likely to be helpful, and perhaps even essential. However, too much explanation can detract from the readability of a review. Simplicity and clarity are also vital to readability.

The readability of Cochrane reviews should be comparable to that of a well-written article in a general medical journal.

The text of a Cochrane review contains a number of fixed headings that are embedded in RevMan. Subheadings may be added by the author at any point. Certain specific headings are recommended for use by all authors, but are not mandatory and should be avoided if they make individual sections needlessly short. Wording for further subheadings that may or may not be relevant to a particular review is also provided.

The review should be written in the **past tense** (e.g. We searched Medline...), as it describes the steps you took to find your results.

ABSTRACT

All full reviews must include an abstract of less than 700 words and no more than 1000. It should be kept as brief as possible without sacrificing important content. Abstracts to Cochrane reviews are published on MEDLINE and made freely accessible on the internet, so will often be read as stand-alone documents. They should, therefore, summarise the key methods and content of the review and not contain any material that is not in the review. The content must be consistent with the text, data and conclusions of the review and not include references to any information outside the review. Links to other parts of the review (such as references, studies, additional tables and additional figures) may not be inserted in the abstract.

Abstracts should be made as readable as possible without compromising scientific integrity. They should primarily be targeted to healthcare decision makers (clinicians, consumers and policy makers) rather than just researchers. Terminology should be reasonably comprehensible to a general rather than a specialist healthcare audience. Abbreviations should be avoided, except where they are widely understood (for example, HIV). Where essential, other abbreviations should be spelt out (with the abbreviations in brackets) on first use. Names of drugs and interventions that can be understood internationally should be used wherever possible.

- 3r** Less than 700 words, and no more than 1000 words in length
- 4r** Summarize the rationale and context of the review
- 5r** Summarize the main objectives in a single concise sentence
- 6r** Summarize the search method
- 7r** Summarize the eligibility criteria
- 8r** Summarize the methods used
- 9r** Report the number of included studies and participants
- 11r** Comment on the findings of the bias assessments
- 12r** Report findings for all important outcomes, irrespective of the strength and direction of result, and of the availability of data
- 13r** Report findings for adverse effects
- 14r** Consistently report statistical analyses
- 16r** State key conclusions
- 17r** Ensure all findings in abstract also appear elsewhere in the review
- 18r** Ensure consistent reporting across the review

- 10r** Describe the study characteristics
- 15r** Ensure key findings are interpretable/expressed in an interpretable way

BACKGROUND

This should be one or two sentences to explain the context or elaborate on the purpose and rationale of the review.

OBJECTIVES

This should be a precise statement of the primary objective of the review, ideally in a single sentence. Where possible the style should be of the form 'To assess the effects of *[intervention or comparison]* for *[health problem]* for/in *[types of people, disease or problem and setting if specified]*'.

SEARCH METHODS

This should list the sources and the dates of the last search, for each source, using the active form 'We searched...' or, if there is only one author, the passive form can be used, for example, 'Database X, Y, Z were searched'. Search terms should not be listed here. If the CRG's Specialised Register was used, this should be listed first in the form 'Cochrane X Group Specialised Register'. The order for listing other databases should be the Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE, other databases. The date range of the search for each database should be given. For the Cochrane Central Register of Controlled Trials this should be in the form 'Cochrane Central Register of Controlled Trials (*The Cochrane Library Issue 1, 2012*)'. For most other databases such as MEDLINE, it should be in the form 'MEDLINE (January 1966 to December 2012)'. Searching of bibliographies for relevant citations can be covered in a generic phrase 'reference lists of articles'. If there were any constraints based on language or publication status, these should be listed. If individuals or organisations were contacted to locate studies this should be noted and it is preferable to use 'We contacted pharmaceutical companies' rather than a listing of all the pharmaceutical companies contacted. If journals were specifically handsearched for the review, this should be noted but handsearching to help build the Specialised Register of the CRG should not be listed.

SELECTION CRITERIA

These should be given as '*[type of study]* of *[type of intervention or comparison]* in *[disease, problem or type of people]*'. Outcomes should only be listed here if the review was restricted to specific outcomes.

DATA COLLECTION AND ANALYSIS

This should be restricted to how data were extracted and assessed, and not include details of what data were extracted. This section should cover whether extraction and quality assessment of studies were done by more than one person. If the authors contacted investigators to obtain missing information, this should be noted here. What steps, if any, were taken to identify adverse effects should be noted.

RESULTS

This section should begin with the total number of trials and participants included in the review, and brief details pertinent to the interpretation of the results (for example, the quality of the studies overall or a comment on the comparability of the studies, if appropriate). It should address the primary objective and be restricted to the main qualitative and quantitative results (generally including not more than six key results). The outcomes included should be selected on the basis of that are most likely to help someone making a decision about whether or not to use a particular intervention. Adverse effects should be included if these are covered in the review. If necessary, the number of studies and participants contributing to the separate outcomes should be noted, along with concerns over quality of evidence specific to these outcomes. The results should be expressed in a narrative as well as quantitatively if the numerical results are not clear or intuitive (such as those from a standardised mean differences analysis). The summary statistics in the abstract should be the same as those selected as the defaults for the review, and should be presented in a standard way, such as 'odds ratio 2.31 (95% confidence interval 1.13 to 3.45)'. Ideally, risks of events (percentage) or averages (for continuous data) should be reported for both comparison groups. If overall results are not calculated in the review, a qualitative assessment or a description of the range and pattern of the results can be given. However, 'vote counts' in which the numbers of 'positive' and 'negative' studies are reported should be avoided.

AUTHORS' CONCLUSIONS

The primary purpose of the review should be to present information, rather than to offer advice. The Authors' conclusions should be succinct and drawn directly from the findings of the review so that they directly and obviously reflect the main results. Assumptions should not be made about practice circumstances, values, preferences, tradeoffs; and the giving of advice or recommendations should generally be avoided. Any important limitations of data and analyses should be noted. Important conclusions about the implications for research should be included if these are not obvious.

PLAIN LANGUAGE SUMMARY

PLAIN LANGUAGE TITLE

Reword the title of the review, using as little jargon as possible. Do not declare the results of the review in the title.

SUMMARY TEXT

The plain language summary summarizes the review in an easily understood style which would be understandable by consumers of healthcare. Plain language summaries are made freely accessible on the internet, so will often be read as stand-alone documents. Plain language summaries have two parts. The first part is a restatement of the review's title using plain language terms. This does not need to be declarative but does need to include participants, intervention and outcome when included in the title of the review. The heading should be no more than 256 characters in length, should be written in sentence case (i.e. with a capital at the beginning of the title and for names, but the remainder in lower case- see example plain language summary), but should not end with a full stop. The title of the plain language summary should, where the review title is easily understood, simply restate the review's title.

The second part or body of the summary should be no more than 400 words in length and should include: A statement about why the review is important: for example definition of and background to the health care problem, signs and symptoms, prevalence, description of the intervention and the rationale for its use. The main findings of the review: this could include numerical summaries when the review has reported results in numerical form, but these should be given

in general and easily understood forms. Results in the plain language summary should not be presented any differently from in the review (ie no new results should appear in the summary. Where possible an indication of the number of trials and participants on which the findings are based should be stated.

Provide a comment on any adverse effects. Include a brief comment on any limitations of the review (for example trials in very specific populations or poor methods of included trials).

At the end of the plain language summary authors may give web links (for example to other information or decision aids on CRG websites, providing that these comply with the Cochrane Collaboration policy on web links. There should not be graphs or pictures in the plain language summary. As with other components of a Cochrane review, plain language summaries should follow the format of the Cochrane Style Guide.

The first draft of the plain language summary should usually be written by the review authors and submitted with the review to the relevant CRG. This draft may be subject to alteration, and authors should anticipate one or more iterations. Many CRGs have plain language summary writing skills within their editorial team. Where this is not available, a central support service is available to assist CRGs in their writing and editing. This service is co-ordinated by the Cochrane Consumer Network (ccnet-contact@cochrane.de), but should be accessed through the CRG (i.e. review authors needing assistance with writing a plain language summary should contact their CRG). Further information on the process of finalizing plain language summaries is available in the Cochrane Manual.

BACKGROUND

Well-formulated review questions usually do not appear out of thin air. They occur in the context of an already formed body of knowledge. This context should be addressed in the background section of the review. This background helps set the rationale for the review, and should explain why the questions being asked are important. It should be presented in a fashion that is understandable to the users of the health care under investigation, and should be concise (generally around one page when printed).

- 19r** Summarize the condition or problem addressed
- 21r** Support statements with references
- 22r** State the main objective
- 24r** State if health economics evidence reviewed
- 25r** State if qualitative evidence reviewed

- 20r** Use the four standard headings (Description of the condition, etc...)
- 23r** State any secondary objectives as specific questions

DESCRIPTION OF THE CONDITION

The review should begin with a brief description of the condition being addressed and its significance. It may include information about the biology, diagnosis, prognosis and public health importance (including prevalence or incidence worldwide, if possible). All information should be backed with references. Information on linking the references into the text can be found in RevMan help and this should be done before submitting your review to the editorial base.

DESCRIPTION OF THE INTERVENTION

A description of the experimental intervention(s) should place it in the context of any standard or alternative interventions. It should be made clear what role the comparator intervention(s) have in standard practice.

HOW THE INTERVENTION MIGHT WORK

Systematic reviews gather evidence to assess whether the expected effect of an intervention does indeed occur. This section might describe the theoretical reasoning why the interventions under review might have an impact on potential recipients, for example, by relating a drug intervention to the biology of the condition.

Authors may refer to a body of empirical evidence such as similar interventions having an impact, or identical interventions having an impact on other populations. Authors may also refer to a body of literature that justifies the possibility of effectiveness. Although every review, just like every intervention, is based on a theory, this may not be

explicit or well explored. Controversy remains about whether or not theory makes a difference to intervention effectiveness, but as Oakley (1999) points out “the importance or unimportance of theory is unlikely to emerge unless review activity is structured to cross problem/outcome areas, and allow for the classification of interventions according to their theoretical base.”

WHY IT IS IMPORTANT TO DO THIS REVIEW

The background helps set 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.

OBJECTIVES

This should begin with a precise statement of the primary aim of the review, including the intervention(s) reviewed and the targeted problem. This might be followed by a series of specific objectives relating to different participant groups, different comparisons of interventions or different outcome measures.

METHODS

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 version of the review. Often a review is unable to implement all of the methods outlined in the protocol, usually because there is insufficient evidence. In such circumstances, it is recommended that the methods that were not implemented still be outlined in the review, so that it serves as a protocol for future updates of the review. Some CRGs have policies on this issue, and these should be available from the Review Group Co-ordinator. Examples include adding an additional subsection at the end of ‘Methods of the review’, or including the methods for future updates in an additional table.

26r Cite the protocol for the review

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

The criteria used to select studies for inclusion in the review must be clearly stated.

TYPES OF STUDIES

Eligible study designs should be stated here, along with any thresholds for inclusion based on the conduct or quality of the studies. For example, ‘All randomized controlled comparisons’ or ‘All randomized controlled trials with blind assessment of outcome’. Exclusion of particular types of randomized studies (for example, cross-over trials) should be justified.

27r State eligible study designs

28r Justify if studies are excluded due to publication status or language

TYPES OF PARTICIPANTS

The diseases or conditions of interest should be described here, including any restrictions on diagnoses, age groups and settings. Subgroup analyses should not be listed here.

29r State eligibility criteria for participants

TYPES OF INTERVENTIONS

Experimental and control interventions should be defined here, making it clear which comparisons are of interest. Restrictions on dose, frequency, intensity or duration should be stated. Subgroup analyses should not be listed here.

30r State eligibility criteria for interventions and comparators

TYPES OF OUTCOME MEASURES

Note that outcome measures do not always form part of the criteria for including studies in a review. If they do not, then this should be made clear. Outcome measures of interest should be listed in this section whether or not they form part of the inclusion criteria.

- 31r** If measurement of particular outcomes is used as an eligibility criterion, state and justify this
- 32r** State primary and secondary outcomes

Primary outcomes should normally reflect at least one potential benefit and at least one potential area of harm, and should be as few as possible. Secondary outcomes should include all other non-primary outcomes. Additional subheadings for; adverse outcomes, economic data, and timing of outcome assessment may be added if appropriate.

SEARCH STRATEGY FOR IDENTIFICATION OF STUDIES

The data sources used to identify studies should be summarised. The following headings are recommended. Further details of the contents of these sections are discussed in Section 5.2.2 Documenting a search strategy. Some CRGs have a standard paragraph they ask their authors to use which refers to the Group's generic searching activities as detailed in the editorial information for the CRG. Before starting to develop this section, authors should contact their CRG for guidance.

- 33r** List all sources searched
- 34r** Provide the date of the last search and which version/issue searched
- 35r** Justify any restrictions on time period covered by search
- 37c** Rerun or update searches for all relevant databases within 12 months before publication of the review/review update
- 36r** Describe search methods for identifying adverse effects, health economics or qualitative research
- 37r** Present the search strategy/strategies in an appendix

ELECTRONIC SEARCHES

The bibliographic databases to be searched, the dates and periods to be searched and any constraints, such as language should be stated. The full search strategies for each database should be in an appendix. If a CRG has developed a Specialized Register of studies and this is searched for the review, a standard description of this register can be referred to but information should be included on when and how the Specialized Register was most recently searched for the current version of the review and the search terms used should be listed.

Authors are welcome to use the following text for this section, adding additional resources when appropriate:

We conducted a comprehensive literature search to identify all published and unpublished randomized controlled trials. No restrictions were placed on the language of publication when searching the electronic databases, [or reviewing reference lists in identified studies]. We searched the following electronic databases to identify potential studies:

Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library) (Appendix 1);
MEDLINE 1966 to date (Appendix 2);
EMBASE 1980 to date (Appendix 3); and
LILACS 1982 to date (Appendix 4).

SEARCHING OTHER SOURCES

List grey literature sources, such as reports and conference proceedings to be searched. If journals are to be hand searched for the review, this should be noted but hand searching done by the authors to help build the Specialized Register of the CRG should not be listed. List people (for example, trialists, experts) and/or organizations will be contacted. List any other sources, which may include, for example, reference lists, the World Wide Web or personal collections of articles. The following optional headings may be used as subheadings: Grey literature, Handsearching, Reference lists, and Correspondence.

- 38r** Report the search terms used to search resources other than bibliographic databases and the dates of the searches

DATA COLLECTION AND ANALYSIS

This should describe the methods you plan to use for data collection and analysis and should again be written in the future tense.

SELECTION OF STUDIES

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 will be resolved.

- 39r** State how inclusion decisions were made
- 40c** Include studies irrespective of whether measured outcome data are reported in a 'usable' way
- 41c** Document the selection process in sufficient detail to complete a PRISMA flow chart and a table of 'Characteristics of excluded studies'
- 42c** Collate multiple reports of the same study so that each study rather than each report is the unit of interest in the review

DATA EXTRACTION AND MANAGEMENT

The method used to extract or obtain data from published reports or from the trialists (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 will be resolved. If relevant, methods for processing data in preparation for analysis should be described.

- 40r** State how data were extracted, and how disagreements and translations were handled
- 42r** List the types of information sought from reports of included studies
- 43r** Explain any transformations of reported data
- 50c** If a study is included with more than two intervention arms, include in the review only intervention and control groups that meet the eligibility criteria.

- 41r** Describe attempts to obtain or clarify data

ASSESSMENT OF METHODOLOGICAL QUALITY OF INCLUDED STUDIES

The method used to assess methodological quality. Whether methods are applied independently by more than one author should be stated, along with how any disagreements will be resolved. The tool(s) used should be described or referenced, with an indication of how the results are incorporated into the interpretation of the results.

- 45r** State the tool(s) used to assess risk of bias, how it was used and the criteria used to assign studies
- 54c** Justify judgments of risk of bias in the Risk of Bias tables
- 61c** Use the Cochrane tool as the primary assessment of bias

MEASURES OF TREATMENT EFFECT

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. Alternatively, optional headings specific to the type of data may be used, such as: Dichotomous data, Continuous data, and Time-to-event data.

- 46r** State the effect measures used (e.g. RR, mean difference)

UNIT OF ANALYSIS ISSUES

Special issues in the analysis of studies with non-standard designs, such as cross-over trials, cluster randomized trials and non-randomized studies, should be addressed (see The Cochrane Reviewers Handbook Section 8.3. Study designs and identifying the unit of analysis). Alternatively, optional (level 2) headings specific to the types of studies may be used, such as: Studies with multiple treatment groups, Cross-over trials, Cluster randomized trials.

- 47r** Describe any methods used to address clustering, matching etc, if other than individually randomized, parallel-group randomized trials are included
- 48r** If multi-arm studies are included, explain how they are addressed and incorporated into syntheses

DEALING WITH MISSING DATA

Strategies for dealing with missing data should be described. This will principally include missing participants due to drop-out (whether an intention-to-treat analysis will be conducted), and missing statistics (such as standard deviations or correlation coefficients).

44r Explain how missing outcome data were handled

ASSESSMENT OF HETEROGENEITY

Approaches to addressing clinical heterogeneity 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 Chi² test, or using I² statistic). See the Cochrane Reviewers Handbook Section 8.7 on Heterogeneity.

49r Describe the methods used to identify the presence of heterogeneity between the studies in the review

ASSESSMENT OF REPORTING BIASES

This section should include a description of 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). See the Cochrane Reviewers Handbook Section 8.11.1 on Publication bias and funnel plots.

50r Describe any methods used for assessing the risk of reporting biases such as publication bias

DATA SYNTHESIS (META-ANALYSIS)

The choice of 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.

51r Describe methods for combining results across studies. Reference the software, commands and settings used when not using RevMan
53r Describe how studies with high or variable risk of bias are addressed in the synthesis
49r Describe the methods used to identify heterogeneity between studies
62c If combining studies with different scales, ensure higher scores for continuous outcomes have the same meaning
67c If multi-arm studies are included, analyze multiple intervention groups in an appropriate way that avoids double-counting or omission of participants
71c Consider the impact on the analysis of clustering, matching or other

SUBGROUP ANALYSIS AND INVESTIGATION OF HETEROGENEITY

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

52r If subgroup analysis was performed, state the potential effect modifiers with rationale and whether each was defined *a priori* or *post hoc*

SENSITIVITY ANALYSIS

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

54r State the basis for any sensitivity analyses performed

RESULTS

Text should be placed in the three subheadings for this section (Description of Studies, Risk of Bias in Included Studies, and Effects of Interventions). The exception to this is if a review does not contain any eligible studies. In this case, the Results section should provide a description of the flow of studies and any brief comments about reasons for exclusion of studies.

56r If a review identifies no eligible studies, restrict the Results section to a description of the flow of studies and any brief comments about reasons for exclusion of studies

DESCRIPTION OF STUDIES

The three subheadings for this section (Results of the search, Included studies, Excluded studies) should be activated and completed.

RESULTS OF THE SEARCH

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).

55r Provide information on the flow of studies from the number(s) of references identified in the search, ideally using the PRISMA figure

INCLUDED STUDIES

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. Key characteristics of the included studies should be described, including the number of study participants, interventions and outcome measures in the included studies and any important differences among the studies. The sex and age range of participants should be stated here except where their nature is obvious (for example, if all the participants are pregnant). Authors should note any other characteristics of the studies that they regard as important for readers of the review to know. The following *optional* subheadings may be helpful:

- *Design*
- *Sample sizes*
- *Setting*
- *Participants*
- *Interventions*
- *Outcomes*

12c Include studies irrespective of their publication status, unless explicitly justified

13c Justify any changes to eligibility criteria or outcomes studied

61r Provide a brief narrative summary of any included studies

71r List all reports of each included study under the relevant study ID

EXCLUDED STUDIES

This should refer to the information contained in the 'Characteristics of Excluded Studies' tables, providing a succinct summary of why studies were excluded from the review.

The following *optional* (level 2) headings may be used:

- *Ongoing studies*
- *Studies awaiting assessment*
- *New studies found at this update*

57r List key excluded studies and justify their exclusion

59r Provide details of any identified studies that have not been completed

58r List the characteristics of studies that have been identified as potentially eligible but have not been incorporated into the review

RISK OF BIAS IN INCLUDED STUDIES

This should summarize the general quality of the included studies, its variability across studies and any important flaws in individual studies. The criteria that were used to assess the

73r Summarize the risk of bias across domains for each key outcome

74r Summarize the risks of bias among the included studies

risk of bias should be described or referenced under ‘Methods’ and not here. How each study was rated on each criterion should be reported in an additional table and not described in detail in the text, which should be a concise summary. For large reviews, aspects of the quality assessment may be summarized for the primary outcomes under the following headings.

ALLOCATION (SELECTION BIAS)

Attempts to conceal allocation of intervention assignment and methods for generation of the sequence of allocations should be summarized here, along with any judgments concerning the risk of bias that may arise from the methods used.

BLINDING (PERFORMANCE BIAS AND DETECTION BIAS)

A summary of who was blinded during the conduct and analysis of the trial should be reported here. Blinding of outcome assessment should be summarized for each main outcome. Judgments concerning the risk of bias associated with blinding should be summarized.

INCOMPLETE OUTCOME DATA (ATTRITION BIAS)

The completeness of data should be summarized here for each of the main outcomes. Concerns over exclusion of participants and excessive (or differential) drop-out should be reported.

90r Discuss the implications of missing outcome data from individual participants (due to losses to follow up or exclusions from analysis)

SELECTIVE REPORTING (REPORTING BIAS)

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

89r Comment on the potential impact of studies that apparently measured outcomes but did not contribute data

OTHER POTENTIAL SOURCES OF BIAS

Any other potential concerns should be summarized here.

91r Discuss the possibility and implications of skewed data when analyzing continuous outcomes

EFFECTS OF INTERVENTIONS

This should be a summary of the main findings on the effects of the interventions 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 tables. Subheadings are encouraged if they make reading easier (for example, for each different participant group, comparison or outcome measure if a review addresses more than one). Any sensitivity analyses that were undertaken should be reported.

Simple summaries such as numbers of events, means and standard deviations should be presented for each treatment group when available. This is achieved primarily by using the 'Data and analyses' section of the review, for dichotomous and continuous outcomes. For other outcomes, these should typically be presented in tables of 'Other data'. When data for each separate intervention group are available for outcomes analyzed as 'Generic inverse variance' data, these might be presented in Additional tables.

Authors should avoid making inferences in this section. A common mistake to avoid (both in describing the results and in drawing conclusions) is the confusion of 'no evidence of an effect' with 'evidence of no effect'. When there is inconclusive evidence, it is wrong to claim that it shows that an intervention has 'no effect' or is 'no different' from the control intervention. In this situation, it is safer to report the data, with a confidence interval, as being compatible with either a reduction or an increase in the outcome.

77r State how many studies and how many participants contributed data to results for each outcome
79r Describe any *post hoc* decisions that might give rise to accusations of selective outcome reporting
81r Report synthesis results for all pre-specified outcomes. Indicate whether data were not available for outcomes of interest, including whether harms were identified
82r Accompany all effect size estimate with a measure of statistical uncertainty (e.g. confidence interval of 90%, 95% etc)
86r Ensure that all statistical results presented are consistent between the text and the 'Data and analyses' tables
87r State whether findings indicate a clear direction of benefit
88r Ensure that findings are interpretable (e.g. assumed and corresponding risks, NNTs, group means, SMD)
98r Justify any measures of the quality of the body of evidence for each outcome

76r Ensure that simple summary data for each intervention group, as well as estimates of effect size (comparing the intervention groups), are available for each study for each outcome
78r State the source of data (e.g. trials register, published literature, etc.)
83r If reporting P values, provide *exact* P values
93r If presenting multiple sensitivity analyses or different ways of subgrouping the same studies, present these in summary form (e.g. a single Table or Figure) and not in multiple forest plots
96r Present the results of any assessment of the potential impact of reporting biases on the review's findings

DISCUSSION

A structured discussion can aid the systematic consideration of the implications of the review.

100r Discuss limitations of the review at study and outcome level (e.g. regarding risk of bias), and at review-level (e.g. incomplete identification of studies, reporting bias)

99r Include the standard headings when writing the Discussion

SUMMARY OF MAIN RESULTS

Summarize the main findings and outstanding uncertainties, balancing important benefits against important harms.

OVERALL COMPLETENESS AND APPLICABILITY OF EVIDENCE

Are the studies identified sufficient to address all of the objectives of the review? Have all relevant types of participants, interventions and outcomes been investigated? Describe the relevance of the evidence to the review question. This should lead to an overall judgment of the external validity of the review. 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.

QUALITY OF THE EVIDENCE

Do the studies identified allow a robust conclusion regarding the objective(s) that they address? Summarize the amount of evidence that has been included (numbers of studies, numbers of participants), review the general methodological quality of the studies, and reiterate the consistency of their results. This should lead to an overall judgment of the internal validity of the results of the review.

POTENTIAL BIASES IN THE REVIEW PROCESS

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 whether all relevant studies were identified, whether all relevant data could be obtained, or whether the methods used (for example, searching, study selection, data extraction, analysis) could have introduced bias.

AGREEMENTS AND DISAGREEMENTS WITH OTHER STUDIES OR REVIEWS

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

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

IMPLICATIONS FOR PRACTICE

The implications for practice 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'

101r Provide a general interpretation of the evidence so that it can inform healthcare or policy decisions. Avoid making recommendations for practice

IMPLICATIONS FOR RESEARCH

This section of Cochrane reviews is used increasingly often by people making decisions about future research, and authors should try to write something that will be useful for this purpose. As with the 'Implications for Practice', 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.

102r If recommending further research, structure the implications for research to address the nature of evidence required, including population, intervention comparison, outcome, and type of study

In preparing this section, authors should consider the different aspects of research, perhaps using types of study, participant, intervention 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, should be distinguished from the lack of a continuing need for a comparison with placebo if there is an effective and appropriate active treatment, or for the need for comparisons of specific named interventions, or for research in specific types of people.

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

This section should be used to acknowledge any individuals or organizations who are not listed among the authors. This would include any previous authors of the Cochrane review and might include the peer referees, contributions of the editorial team of the CRG, non-author contributions to searching, data collection, study appraisal or statistical analysis, and the role of any funders. Permission should be obtained from persons acknowledged.

103r Acknowledge the contribution of people not listed as authors of the review

CONTRIBUTIONS OF AUTHORS

The names and contribution of the present co-authors should be described in this section. One author, usually the contact 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.

104r Describe the contributions of each author

The following potential contributions have been adapted from Yank 1999. This section should describe what people did, rather than attempt to identify which of these categories someone’s contribution falls within. Ideally, the contributors should describe their contribution in their own words:

1. Conceiving the review
2. Designing the review
3. Coordinating the review
4. Data collection for the review
 - a. Designing search strategies
 - b. Undertaking searches
 - c. Screening search results
 - d. Organising retrieval of papers
 - e. Screening retrieved papers against inclusion criteria
 - f. Appraising quality of papers
 - g. Extracting data from papers
 - h. Writing to authors of papers for additional information
 - i. Providing additional data about papers
 - j. Obtaining and screening data on unpublished studies
5. Data management for the review
 - a. Entering data into RevMan
6. Analysis of data
7. Interpretation of data
 - a. Providing a methodological perspective
 - b. Providing a clinical perspective
 - c. Providing a policy perspective
 - d. Providing a consumer perspective
8. Writing the review
9. Providing general advice on the review
10. Securing funding for the review
11. Performing previous work that was the foundation of the current study

DECLARATIONS OF INTEREST

Authors should report any conflict of interest that might be perceived by others as being capable of influencing their judgments, including 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. Details of the Collaboration’s policy on conflicts of interest appear in The Cochrane Reviewers Handbook 2.6 Conflict of interest and commercial sponsorship.

105r Report any present or recent affiliations or other involvement in any organization or entity with an interest in the review’s findings that might lead to real or perceived conflict of interest. Include the dates of involvement

Financial conflicts of interest cause the most concern, and should be avoided, but must be reported if there are any. Any secondary interest (such as personal conflicts) that might unduly influence judgments made in a review (concerning, for example, the inclusion or exclusion of studies, assessments of the validity of included studies or the interpretation of results) should be reported. If there are no conflicts of interest, this should be stated explicitly, for example, by writing ‘None known’.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

This section should detail any differences in methods or scope between the protocol and review, and may be left blank if there are none.

106r Explain and justify any changes from the protocol (including any post hoc decisions about eligibility criteria or the addition of subgroup analyses)

107r Document aspects of the protocol that were not implemented (e.g. because no studies were found) here rather than in the Methods Section

PUBLISHED NOTES

These will be published in the CDSR. They may include: editorial notes and comments from the CRG, for example where issues highlighted by editors or referees are believed worthy of publication alongside the review; a summary of previous changes to the review. Changes since the previous published version must be stated under ‘What’s new’.

The published notes must be completed for all withdrawn publications to give the reason for withdrawal. Only the cover sheet and published notes are published for withdrawn protocols and reviews.

TABLES

Additional tables may be included if required. They should be referenced in the text by clicking “Insert link” from your secondary mouse button within the RevMan file.

83r Link to each table from the review text

84r Restrict the number of tables to a small number to convey key findings without affecting the readability of the review text

CHARACTERISTICS OF STUDIES

A table in each section will be populated from the references included in the respective sections. Each table should be completed for the studies that appear within it.

- Characteristics of included studies
- Characteristics of excluded studies: a simple statement of why the study was excluded should be included. E.g. “Prospective non-randomized trial”.
- Characteristics of studies awaiting classification
- Characteristics of ongoing studies

60r Complete table using a uniform format across all studies

62r Include the study design

63r Include information about the study population, such that a user could assess the applicability of the review’s findings to their own setting

64r Include the sample size for each included study

65r Include information about the study intervention, such that a user could assess the applicability of the review’s findings to their own setting

66r Include information about how the outcomes were measured

68r Include details of funding source, if available

69r Include details of any declarations of interest among the researchers

72r Assess the risks of bias, providing supports, for each study

67r Include the dates the study was conducted

70r If a study is included with more than two intervention arms, restrict comments on any irrelevant arms to a brief comment

SUMMARY OF FINDINGS TABLES

Cochrane reviews should include 'Summary of Findings' tables. These are designed to summarize the key results of a specific question within a Cochrane review, and allow guidance to be issued on the basis of this. To assist with this process, special software has been developed, known as GRADEpro.

98r use footnotes to explain any downgrading or upgrading according to the GRADE system

97r Include a “Summary of Findings” table

Present a ‘Summary of Findings’ table according to recommendations described in Chapter 11 of the Cochrane Handbook (version 5 or later). Specifically: include results for one clearly defined population group (with few exceptions); indicate the intervention and the comparison intervention; include seven or fewer patient-important outcomes; describe the outcomes (e.g. scale, scores, follow-up); indicate the number of participants and studies for each outcome; present at least one baseline risk for each dichotomous outcome (e.g. study population or median/medium risk) and baseline scores for continuous outcomes (if appropriate); summarize the intervention effect (if appropriate); and include a measure of the quality of the body of evidence for each outcome. Detailed information regarding Summary of Findings tables and GRADE can be accessed through the GRADE Working Group (<https://gradepro.org/>).

ADDITIONAL TABLES

Additional tables which are not able to be recorded elsewhere in the review may be included. These may be copied and pasted from word processors and should follow formatting laid out in the Cochrane Style Guide (<https://community.cochrane.org/style-manual>).

Please note that in order for the additional table to display correctly, the first column should not include hyperlinks, to study references or other sections of the review.

STUDIES AND REFERENCES

The reference ID should be in the format “Surname Year” and the citation should follow the formats listed in the Cochrane Style Guide (<https://community.cochrane.org/style-manual>).

Often there are several papers which report the results of a study. In RevMan it is possible to include more than one citation under a reference ID. If more than one citation is included under a reference ID Authors should mark which citation is the primary reference by ticking the box labeled “This is the primary reference for the study” when entering details regarding the citation.

References should be referenced in the text by clicking “Insert link” from your secondary mouse button within the RevMan file.

References may be copied and pasted or dragged and dropped between sections within “studies and references”.

DATA AND ANALYSES

This section will contain only data and analyses. No additional text is required.

Analyses should be sequentially numbered. If analyses are reordered or removed, the outcomes may be renumbered by choosing the group of outcomes, clicking the secondary mouse button and choosing “renumber outcomes”.

Appropriate use of the hierarchy ensures consistency of structure across reviews. It is confusing for the user if outcomes are listed against the heading ‘Comparison’ and interventions listed against the heading ‘Outcome or subgroup’.

By default, RevMan currently uses ‘Experimental’ and ‘Control’ as labels in forest plots. It is helpful to replace these with more specific intervention names, and essential if the ordering is swapped (or for head-to-head comparisons). Directions of effect should be used as consistently as possible within a review.

75r Ensure appropriate use of the hierarchy of Comparisons / Outcomes / Subgroups / Study data

94r Label the directions of effect and the intervention groups in forest plots with the interventions being compared

80r Order comparisons and outcomes specified in the protocol, distinguishing between primary and secondary outcomes

92r Present data from multiple studies in forest plots wherever possible

FIGURES

RevMan has several standard figures available for inclusion: a risk of bias graph and summary, and a PRISMA flow diagram.

Please note that it is not necessary to include forest plots as figures as, by default, all forest plots will appear at the end of a review. Two exceptions to this are when 1) there is a strong need for a forest plot to appear within the text of the review or 2) if a sensitivity analysis has been conducted and the results are to be shown graphically.

Additional figures may be included if required, but should be kept to a limit of seven in total. They should be referenced in the text by clicking “Insert link” from your secondary mouse button within the RevMan file.

83r Link to each figure

84r Restrict the number of Figures to a small number to convey key findings without affecting the readability of the review text

SOURCES OF SUPPORT

Authors should give details of grants 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).

108r List sources of funding for the review and the role of the funder

FEEDBACK

This section may include feedback on the review once published and should be left blank.

APPENDICES

An appendix should be created for each search strategy (e.g. titled “CENTRAL search strategy”)

SUBMITTING YOUR REVIEW

Before submitting your review for editorial consideration and publication, please use the following tools.

SPELLING

Please check the spelling throughout the review. A spell check function is available in RevMan, under the “tools” menu, listed as “Check Spelling”.

VALIDATION

Running a validation report in RevMan will list if there are any errors or warnings in the review to be addressed. The report may be accessed by the “File” menu, “Reports”, “Validation report”. Please correct all errors. Reviews with errors are unable to be published. Please contact the UGPD group if you have any difficulty in resolving errors or warnings.

HOW TO SUBMIT

You submit (“check in”) the review online using Archie and /or RevMan. When checking in, after typing a Version Description, click “next”, so that you are shown the tick box option for “Submit for editorial approval”. Check this box. Once you have checked in a review and ticked this box, the editorial office will be notified and the review will be inaccessible by authors until approved for publication or unlocked by the editorial office.

WHAT TO SUBMIT

After submitting your review for editorial consideration through RevMan/Archie, we ask that you also submit copies of your data extraction and papers of included studies to the UGPD group. These are used to confirm data extraction and will be kept on file, should they be required for reference when the review is updated.

GETTING HELP

If you have any questions on preparing your review that are not answered by this document, the User Guide (found in the “Help” section of RevMan), the Revman website (<https://community.cochrane.org/help/tools-and-software/revman-5>) and Archie or by the Cochrane Handbook (<https://training.cochrane.org/handbook>) please contact the editorial base at <mailto:yyuan@mcmaster.ca>.