



Cochrane Anaesthesia
Review Group's
“Tips for Authors”
*How to Write a Cochrane Review:
A Practical Guide*

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Introduction

Welcome to the Cochrane Anaesthesia Review Group's (CARG's) guide to writing a Cochrane review. We hope you will find the guide helpful. This guide is split into several parts.

- (1) A brief introduction to The Cochrane Collaboration.
- (2) How to register a review title.
- (3) Developing the protocol.
- (4) Developing your review.
- (5) Updating A Published Review.
- (6) Common errors which authors make which tend to make you unpopular with your editor!
- (7) The CARG editorial process.

A Brief Introduction to The Cochrane Collaboration and CARG

The Cochrane Collaboration is an international non-profit organization. It aims to help people make well-informed decisions about healthcare by producing and publishing systematic reviews of health care interventions.

The Collaboration is made up of five different entities or 'groups'.

- (1) Cochrane Review Groups
- (2) Cochrane Centres
- (3) Methods Groups
- (4) Networks or fields
- (5) The Consumer Network

CARG is a Collaborative Review Group (CRG). We prepare systematic intervention and diagnostic test accuracy reviews in:

- (i) Anaesthesia
- (ii) Intensive care medicine
- (iii) Perioperative medicine
- (iv) Prehospital medicine
- (v) Resuscitation
- (vi) Emergency medicine

This guide deals with intervention reviews. We will develop a separate guide for diagnostic test accuracy reviews.

There are 51 CRG's worldwide, each focusing on a particular area of health. CARG's editorial base is in Copenhagen, Denmark. Our scope is wide and overlaps with many other Cochrane Groups, for example: the Pregnancy and Childbirth Group and the Pain, Palliative Care and Supportive Care Group. We work closely with other CRGs.

We are supported by the Nordic Cochrane Centre (NCC), which is also based in Copenhagen.

Cochrane Centres provide training for authors. You will find details of all available training workshops at:

<http://www.cochrane.org/cochrane/workshop.htm>

Useful hint: Please be aware that you do need to have registered a title with Cochrane before you can attend a Cochrane training workshop.

The CARG editorial team:

- | | |
|--------------------------------------|-------------------------------------|
| (1) Co-ordinating Editors: | Ann Møller and Nathan Pace |
| (2) Managing Editor (ME): | Jane Cracknell |
| (3) Trials Search Co-ordinator: | Karen Hovhannisyan |
| (4) Editorial adviser and treasurer: | Tom Pedersen |
| (5) Secretary: | Annette van Hauen |
| (6) PhD students: | Arash Afshari and Georgina Imberger |
| (7) And 13 editors: | |

CARG Editors

- | | |
|----------------------------|-------------------------|
| Senior Statistical Editor: | Nathan Pace (USA) |
| Statistical Editor: | Marialena Trivella (UK) |
| Statistical Editor: | Cathal Walsh (IRE) |
| Feedback Editor: | John Carlisle (UK) |
| Consumer Editor: | Janet Wales (Australia) |

Content Editors: Mike Bennett (Australia); John Carlisle (UK); Harald Herkner (Austria); Stephan Kettner (Austria); Anna Lee (Hong Kong, China); Mark Neuman (USA); Nicola Petrucci (Italy); Andrew Smith (UK); Mathew Zacharias (New Zealand).

What do we do?

The Co-ordinating Editors (Co-Ed) have overall responsibility for CARG. The Co-Eds run the Group. They assure the quality of all publications and make the final decision as to whether a title is registered; a protocol or review is published. They work on a part-time, unpaid basis. They also:

- (1) Manage the development and growth of the Group.
- (2) Disseminate *The Cochrane Library* through the Group.
- (3) Provide information on group activities and performance.
- (4) Ensure the effectiveness and efficiency of the Group.
- (5) Represent the Group and The Cochrane Collaboration.
- (6) Help the Steering Group attain its objectives.

The Managing Editor (ME) is responsible for the smooth daily running and effectiveness of CARG. The ME is a full-time paid member of staff and:

- (1) Liaises with, and supports authors, editors and peer reviewers throughout the review process.
- (2) Recruits peer reviewers to comment on all CARG protocols and reviews.
- (3) Recruits consumers to comment on all CARG protocols and reviews
- (4) Liaises with the Cochrane Consumer Network.
- (5) Co-ordinates the production of a review from title registration, through the editorial process, to publication in *The Cochrane Library*.
- (6) Submits the approved monthly module (all approved reviews) to the publisher.
- (7) Helps promote the group.
- (8) Communicates with publishers.
- (9) Recruits new members.

The Trials Search Co-ordinator (TSC) is a part-time paid member of staff. The TSC is responsible for trial identification and manages the CRG's specialized register (database of trials). The TSC works closely with the ME and:

- (1) Submits the register for inclusion in *The Cochrane Library's* Controlled Trials Register.
- (2) Helps authors with searching.
- (3) Co-ordinates the handsearching process.
- (4) Maintains the members' directory.
- (5) Maintains the CARG website
- (6) Is responsible for the newsletter

The Secretary is a part-time paid member of staff and is responsible for:

- (1) Fundraising.
- (2) Secretarial support.

CARG Editors are part-time and unpaid.

Content Editors:

- (1) Comment on and approve new titles for registration.
- (2) Oversee and have overall editorial control of individual protocols and reviews.
- (3) Evaluate protocols and reviews within a set time frame.
- (4) Approve manuscripts for publication.
- (5) Liase closely with authors, ME, peer reviewers and other editors.

Statistical Editors:

Please note: Statistical Editors DO NOT provide individual statistical support for review teams. We expect each review team to find its own statistical advisor. This person should have experience of systematic reviews.

Statistical editors do:

- (1) Comment on and approve new titles.
- (2) Comment on the methods of every draft of every review (and the second draft of protocols).
- (3) Evaluate reviews within a set time frame.
- (4) Approve reviews for publication.
- (5) Liase closely with authors, ME and other editors.

The Feedback Editor is also a content editor. In addition to that role he:

- (1) Responds to post-publication criticism of reviews through liaison with the critic and author.
- (2) Submits the authors' response for publication in *The Cochrane Library*.

The Consumer Editor

- (1) Comments on and approves new titles
- (2) Comments on most protocols and reviews

A Peer reviewer is someone who assesses the quality of your review. Peer reviewers are often classified as either: "internal" that is they have knowledge of Cochrane methods, or "external" that is they have knowledge of the subject. Peer reviewers are voluntary. They comment on first drafts of protocols and reviews within a set time frame.

A Consumer is defined by The Cochrane Consumer Network as:

- an individual who has unique personal experiences that allow him or her to provide an effective healthcare user/receiver perspective to a systematic review question.
- an individual or a representative of a community health support organization or group and is generally without specialist medical knowledge.

The term consumer is used more broadly than for patients actively under treatment.

For a more detailed introduction to The Cochrane Collaboration

<http://www.cochrane.org/docs/newcomersguide.htm>

How to register a Cochrane review title

You first need to propose a title for a review. That title must be accepted and registered by a Cochrane Review Group (CRG). Once the title is registered, you can begin developing your protocol (the next stage of the review). When the protocol is published you can begin writing your review.

In brief the stages of a Cochrane Review are:

- (1) Title
- (2) Protocol
- (3) Review
- (4) Updated Review

How do I propose a title for review?

Cochrane reviews should not duplicate work already published in *The Cochrane Library*. You first need to search *The Cochrane Library* (www.thecochranelibrary.com) and the list of Cochrane titles (http://www.cochrane.org/reviews/en/index_list_all_titles.html) to check that the title you are interested in has not already been published, or registered, by another author.

Your title should conform to Cochrane standards: an intervention for a specific health problem. For example: "Drugs for preventing postoperative nausea and vomiting". Once you have undertaken initial checks to see whether your proposed title is free, send the ME (jane_cracknell@yahoo.com) more details on your proposed title so that she can do a more detailed search of the Cochrane Database. To do this she will need the following information:

- Your clinical question
- Objective of the review
- Interventions and specific comparisons to be made
- Your outcomes (primary and secondary). Please keep the number of your outcomes to a reasonable level (that is not too many) and make sure they are clinically important.
- Any randomized controlled trials that you are aware of in this area, which may fulfil your inclusion criteria. (Generally, only randomized or controlled clinical trials are suitable for inclusion in the review.)

Assuming the title is available you will be asked to complete a title form, please return that form to the ME along with a one page CV for each author (it should list their most important publications and a signed declaration of interest form. All forms can be obtained from jane_cracknell@yahoo.com

HINT!! Please be aware that CARG requires that each review team consists of a content specialist, methodologist and a statistician, and that at least one author should have prior experience of performing systematic reviews or meta- analysis.

Please also be aware because English is the common language within The Cochrane Collaboration, we require that at least one author be proficient in written English. This person should be responsible for writing the protocol and review. If no author is proficient in written English, then we may well help you find a co-author with appropriate language competence

HINT!! You will find it helpful to:

(1) Download The Cochrane Reviewers' Handbook and, read the Handbook *before* completing your title registration form. You will need to be familiar with the 'Handbook' when writing your protocol and review. **'The Handbook is a large document and it is not easy to print from the on-line version. Please contact the ME (jane_cracknell@yahoo.com) if you wish to be sent a pdf version**

<http://www.cochrane.org/resources/handbook/>

(2) Look at the Cochrane Glossary <http://www2.cochrane.org/resources/glossary.htm> (This is a useful aid to using the terminology of statistics and epidemiology correctly)

How to complete a title registration form

- (1) Keep your title short and to the point.
- (2) Avoid medical terms if possible, e.g. use "children" rather than "paediatric population".
- (3) Provide a brief description of the review topic of interest including:
 - a. The objectives of the review.
 - b. The clinical question you wish to address.
 - c. The intervention(s) to be studied.
 - d. The population.
 - e. The outcome measures.
- (4) Provide a brief description of which member of the team will take on which roles and responsibilities.
- (5) Answer all questions (including the statistical questions)

We do need to know who will provide your team with statistical support.

We consider a statistician to be someone who has by training/and or experience the numeric and analytical skills able to perform meta-analysis summary statistics and their interpretation. This person may be a statistician by degree or job title or someone who has experience publishing previous Cochrane reviews or perhaps something else.

HINT!! Common errors authors make when completing their title forms

- Authors do not complete the statistical questions
- Authors list far too many outcomes
- The title does not relate to the outcomes or objectives

Important point

You need to remember that undertaking a Cochrane systematic review is a significant commitment. A Cochrane review needs to be updated every two years, or more frequently in response to criticism or new evidence.

What happens with the form?

Send your completed title registration form to CARG's ME, Jane Cracknell. Your completed title form will then be sent out to all CARG's editors for commenting on. The editors use the following criteria to decide whether a title should be registered

- Is the topic of clinical relevance – Is it a common clinical issue? Or is it rare but important? Would the systematic review results (if significant) change relevant aspects of clinical practice?
- Would the topic impact on the cost of healthcare – Is the topic is relevant to developing/ underdeveloped countries
- Resources to perform the review – Do the authors have statistical support, do they have English language support.
- Sufficient clinical research
- Is the topic controversial – Is it a question that needs resolution?

You will be sent the editors' comments within three weeks of submitting your completed form to the CARG editorial office, and asked to amend your title form on the strength of them. The revised form will then be sent to CARG's Co-ordinating editors for approval. Once Dr Møller or Prof Pace approve your title form it will then be circulated to the other Cochrane Groups to ensure it does not duplicate work already registered or published with *The Cochrane Library*.

Deadlines

You should be informed within three weeks whether the proposed title has been successfully registered. Once your title is successfully registered, you are able to start work on your protocol.

We expect to see a copy of your draft protocol within six months of your title is registered.

We expect to see a copy of your draft review within one year of your protocol being published.

Please note.

We reserve the right, with prior notice, to reallocate or deregister titles that have not progressed to a draft protocol within six months, and where we have not had contact from authors.

Furthermore, protocols that have not been converted to reviews within three years may be allocated to alternative authors with prior notice. Reviews that have not been maintained in the light of new evidence within three years may also be reallocated with prior notice.

Developing the Protocol

The protocol is the outline of the systematic review you are planning to conduct. The protocol acts as a template for your review. A systematic review is rather like a primary clinical research study. A well-written protocol will guide you through the review. The protocol sets out what you propose to do, how you intend to deal with expected findings and how you will deal with unexpected problems.

Writing a Cochrane protocol is like writing a protocol for a research proposal.

We expect to see a draft of your protocol within six months of title registration.

Once your title has been registered you can begin working on the protocol for the review. You will need to download the RevMan software and have access to the Archie (IMS) website to

complete your review. All are available at <http://www.cochrane.org> and <http://ims.cochrane.org/>.

Archie user account

Archie is the Cochrane Collaboration's central server, which interacts with RevMan 5.1. Archie stores all authors' contact details, and drafts of every review. The principal feature of Archie and RevMan 5.1 is version control and secure storage of work. This helps to prevent any confusion over which is primary and secondary versions, and prevent loss of data. When you wish to write the protocol, you will need to 'check out' the review from Archie (or simply download the latest version). This locks the review and prevents anyone else checking out the review (they can still view the draft you have checked out, and download a copy, but they will not be able to check out that version). Only you will be able to check in the review again. Checking in the review creates a draft that is viewable at any time, and becomes the latest draft available to review authors. This process is explained in the RevMan tutorial (found in RevMan under 'Help').

You will need to have access to the website Archie (IMS). We recommend that you set this up on your 'favourites'. We will initiate a 'User Account' for you all, and you will receive an email titled 'Registration' from the Information Management System with instructions on how to proceed. Having an Archie user account will enable you to view, share, archive and submit drafts of your review with your review team.

RevMan 5.1

You will need to download Review Manager (RevMan) 5.1 which is the software used for preparing and maintaining Cochrane reviews. This program is available at <http://ims.cochrane.org/revman>. All members of your team will also need to use RevMan 5 to work on this review. When you install RevMan 5.1, you need to insert your Archie username and password to establish a connection with Archie server (check Tools > Preferences> General and Connection tabs in RevMan 5.1). A Tutorial for new users is available from the RevMan 5.1 Help file. We strongly recommend that you work through this Tutorial before beginning work on your protocol. A complete User Guide is also available from the RevMan 5.1 Help file.

Things to do BEFORE you start writing the protocol

- (1) If possible, attend a Cochrane Review Workshop. To see a schedule of workshops in your area:
<http://www.cochrane.org/cochrane/workshop.htm>
 - (2) Download the *latest* version of Review Manager 5.1 (RevMan); the official Cochrane <http://ims.cochrane.org/revman>
 - (3) Download and Read the 'Handbook'. If you use the online version of the 'Handbook' you will need to 'click' on the 'book icon' ('contents' top left of screen) to see an index.) **The 'Handbook' is also included with Review Manager (RevMan 5.1) in the 'Help' menu.**
<http://www.cochrane.org/resources/handbook/index.htm>
 - (4) Look at the Cochrane Glossary <http://www2.cochrane.org/resources/glossary.htm> (This is a useful aid to using the terminology of statistics and epidemiology correctly)
 - (5) Read the Cochrane Style Basic Guide: This will provide you helpful hints on the Cochrane writing style. (We will send you a copy of the basic style guide when your title is registered) You can also download it from
<http://www.cochrane.org/style/home.htm>
 - (6) **Quick start for Authors & Top tips for Authors using RevMan 5.1 and Archie**
- The 'Quick start for Authors' document gives a brief overview of how to manage contact details

and use Archie in conjunction with RevMan 5 to produce a Cochrane review. Top tips for Authors using RevMan 5 and Archie' is a more detailed document, which is essential reading for all authors.

Both documents can be viewed at: <http://ims.cochrane.org/archie/documentation>

Resource material – CARG specific

You will be sent a

- Copy of recently published CARG protocol
- Checklist for submission of a protocol
- Template data extraction forms
- Template contribution of authors' section (to be inserted in the protocol)
- Higgins I-squared article (Quantifying heterogeneity in a meta-analysis)
- Tips for authors

HINT!! Please use this material – it will help you write your protocol

Writing the Protocol

1. Read the 'Handbook': Chapter 4. Guide to the format of a Cochrane review.
<http://www.cochrane-handbook.org/>
2. If possible please attend a Cochrane Developing a Protocol and Introduction to Analysis Workshop <http://www.cochrane.org/cochrane/workshop.htm>
3. Look at the Cochrane Glossary <http://www2.cochrane.org/resources/glossary.htm> (This is a useful aid to using the terminology of statistics and epidemiology correctly)
4. Read Tips for authors

Opening your review

All Cochrane reviews are stored in Archie, The Cochrane Collaboration's online database. When you have registered a review with a Cochrane Review Group, you will be given a user name and password for Archie. To work on your review, you will need to find your review online in Archie and check it out into RevMan using the **Check Out** button on the RevMan toolbar. Please do NOT create a new file in RevMan 5.1 but instead check the review out of RevMan.

The document you check out should already contain

1. Your correct review title. The title of your protocol should be exactly the same as the registered title, unless a change has been agreed with CARG.
2. A list of all authors associated with the review and their affiliations. Please check that the authors are listed in the correct order.
3. Inserted references for RevMan 5.1 and Higgins 2011 (the handbook). These references will be found in the additional reference section)
4. An inserted template of 'authors' contributions' for you to complete.

If the above do not appear in the review you are working in, then you have opened the wrong version. (If this is the case then please contact the ME jane_cracknell@yahoo.com for help)

Please be aware that CARG uses Oxford English Dictionary (OED) Spellings. Your review will be copy edited to reflect this (OED = randomized, analysed, paediatric, anaesthesia).

You will need to complete the following sections of your protocol

The Background (Read the Handbook Section 4.5 iii Background)

Well-formulated review questions occur in the context of an already-formed body of knowledge. Your background section should address this context, and help set the rationale your review. Your background section should 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 intervention under investigation. All sources of information should be cited.

Please use the recommended headings, which will be found in your RevMan file.

Description of the condition

This section should contain 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).

Description of the intervention

This section should contain a description of intervention or interventions being studied. You should make clear the role of the comparator intervention(s) in standard practice. For drugs, you should present basic information on clinical pharmacology where available. This information might include dose range, metabolism, selective effects, half-life, duration and any known interactions with other drugs. For more complex interventions, a description of the main components should be provided.

How the intervention might work

This section might describe the theoretical reasoning why the interventions under review may have an impact on potential recipients, for example, by relating a drug intervention to the biology of the condition. You may refer to a body of empirical evidence such as similar interventions having an impact or identical interventions having an impact on other populations. You may also refer to a body of literature that justifies the possibility of effectiveness.

Why it is important to do this review

In this section, you should clearly state the rationale for the review and should explain why the questions you are asking are important. You 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 your 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.

HINT!! Remember to keep your writing style simple

Your background should be concise and easy to understand. The background should provide enough detail to understand the review and no more (i.e. it should not be a detailed literature review of the topic). CARG recommends that your background section should be between 300 to 1000 words in length. The background should avoid unnecessary abbreviations, be readable, discuss important issues and avoid repetition. You should make sure the references are up to date

and relevant, are inserted in alphabetical order, separated by a semicolon and enclosed in soft brackets; you should back up all facts, figures and statements with references.

The Objectives (Read the Handbook Section 4.5 iii Objectives)

Your objectives section should begin with 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]”. This might be followed by a series of specific objectives relating to different participant groups, different comparisons of interventions or different outcome measures. It is not necessary for you to state specific hypotheses.

Methods (Read Handbook 4.5 iv)

The Methods section in your 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).

Criteria for considering studies for this review

This section has four parts (please see below). Your selection criteria section should make it clear which studies will be included in your review, and which will be excluded. The aim is to come up with very specific, reproducible guidelines for deciding whether a study addresses the objective of the review. Later, the quality of included studies will also be assessed. You should have biological rationale or empirical evidence for, inclusion and exclusion criteria and all subgroup analyses. Please define all the criteria you are using e.g. what does ‘critically ill’ mean, what does ‘intensive care’ mean, what does ‘food’ mean etc.

Review Manager version 5.1 has implemented two new tables. The risk of bias (ROB) table is a tool for assessing risk of bias in included studies; please see the Handbook, Section 8.5. The summary of findings (SOF) table is a tabular listing of important outcomes and quality of evidence (GRADE); please see the Handbook, Chapters 11 and 12. The Cochrane Anaesthesia Review Group now requires inclusion of ROB and SOF tables in a review.

Types of studies

You should state the eligible study designs here, along with any thresholds for inclusion based on the conduct of the studies or their risk of bias. For example, ‘We will include all randomized controlled comparisons’ or ‘we will include all randomized controlled trials with blind assessment of outcome’. Exclusion of particular types of randomized studies (for example, cross-over trials) should be justified.

Please also refer to

- Eligibility criteria for types of study designs are discussed in Handbook, Chapter 5 (Section 5.5).

Types of participants

You should briefly describe which types of people would be included (and excluded) in the studies. If the review has to be about one age group avoid rigid age limits but be explicit e.g. “we will include all studies that assessed children (using the authors’ definitions)”.

You should describe the diseases or conditions of interest here, including any restrictions such as diagnoses, age groups and settings.

You should not list subgroup analyses in this section.

See also

- Eligibility criteria for types of participants are discussed in Handbook, Chapter 5 (Section 5.2).

Types of interventions

An intervention is anything that is meant to change the course of events (e.g. surgery, a drug, a test, a treatment, counseling).

You should define experimental and comparator interventions here, under separate subheadings if appropriate. You should make clear which comparisons are of interest to you. You should state any restrictions on dose; frequency, intensity or duration should be stated.

You should not list subgroup analyses here.

See also

- Eligibility criteria for types of interventions are discussed in Handbook, Chapter 5 (Section 5.3).

Types of outcome measures

You should include the most important outcomes that need to be considered in order to make decisions about the particular intervention. You need to specify these outcomes in advance. The studies may not address particular outcomes: in which case, it is important for the authors to know that important topics have been overlooked.

NOTE: *If an outcome is an important key to understanding or assessing the impact of an intervention, this needs to be stated by you in the protocol. Coming up with theories about outcomes later does not have the same scientific strength.*

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

You should select a maximum of seven key important outcomes, including adverse effects, to be included in your 'Summary of findings' tables when the review is complete.

See also

- Types of outcomes are discussed in Handbook, Chapter 5 (Section 5.4).
- The importance of addressing patient-relevant outcomes is discussed further in Handbook, Chapter 11 (Section 11.5.2); see also an extended discussion of patient-reported outcomes in Handbook, Chapter 17.

Primary outcomes

The review's 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. 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 effects of the interventions on these outcomes.

Secondary outcomes

You should list your non-primary outcomes here. The total number of your outcomes should be kept as small as possible and they should be clinically important

You may find the following *optional* (level 4) headings helpful, as supplements or replacements for the headings above:

Main outcomes for 'Summary of findings' table

Timing of outcome assessment

Adverse outcomes

Economic data

Search methods for identification of studies

See also

- Search methods are discussed in detail in Handbook, Chapter 6 (Sections 6.3).

The following subheadings are recommended.

Electronic searches

The search section explains to the reader how, and where, you will look for studies that may be eligible for inclusion in your review. You should include: The Cochrane Library, MEDLINE, EMBASE and all other relevant databases and major trials registers for ongoing trials that you plan to search. The CRG's specialized register should be referenced. The date ranges of searches should be included (write the start year and then 'to date').

You should consult with the CARG Trials Search Co-ordinator (Karen Hovhannisyan karen.hovhannisyan@gmail.com), regarding the development of your search strategy. It would be helpful if you could indicate in the protocol's acknowledgement section which person helped you design and search your search strategies.

Please include your MEDLINE search terms in the protocol. Please place them in the protocol appendices and link them to the text: 'see Appendix 1'.

Please ensure that the inclusion criteria for the review, including the types of studies, are consistent with your search strategy.

Searching other resources

You should state whether you will search conference proceedings of important meetings and abstracts; and if efforts will be made to contact experts in order to identify unpublished research and trials still underway. Any speciality journals that have been hand searched should be identified and referenced. The name of the journal should, be entered in full. We strongly recommend also mentioning the databases of on-going trials such as <http://www.controlled-trials.com/> or <http://clinicaltrials.gov/> and others.

The search strategy must be reproducible. The search must not be limited by language or publication status.

Data collection and analysis

This section should describe the methods you will use for data collection and analysis. You should

provide details of the methods you will use to identify published and unpublished data to be included in your review. You need to explicitly state how many authors will extract data. We recommend that at least two persons should extract data independently. This is to assure objectivity. Quality assessment tends to be subjective, value-laden and surprisingly heterogeneous. You should state how you will identify the trials, which authors will retrieve the trials and how you will resolve disagreements.

You need to state which authors will check and enter those data into Review Manager (RevMan 5.1). Please be aware that transcription errors in entering data into the data extraction form are a common problem. You should explain, in this section, how you would deal with missing information or data inconsistencies.

You should state how you will grade the evidence and formulate a recommendation (see Chapter 12.2.1 of the Handbook).

Selection of studies

This section should describe both the steps of the review process and its standards and criteria used to apply the selection criteria. You should describe whether more than one author will apply these standards and criteria independently, and how you will resolve any disagreements

See also

- Study selection is discussed in Handbook, Chapter 7 (Section 7.2).

Data extraction and management

You should describe in this section the method you will use to extract or obtain data from published reports or from the original researchers (for example, using a data collection form). You should describe whether more than one author will independently extract data, along with how you will resolve any disagreements. If relevant, you should describe the methods processing data in preparation for analysis.

NOTE: We expect all authors to submit a copy of their data extraction form with their protocol.

WHY?

*A data extraction form provides a quick overview of each study and helps you complete your **Tables of “Characteristics of Included” “Excluded Studies” and “Risk of Bias”** at review stage. If you have lots of studies to go through you want to extract the data as efficiently as possible to avoid ever having to go back through the same paper twice.*

You will be sent sample forms when your title is successfully registered.

See also

- Data collection is discussed in Handbook, Chapter 7, including which data to collect (Section 7.3), sources of data (Section 7.4), data collection forms (Section 7.5) and extracting data from reports (Section 7.6)

Assessment of risk of bias in included studies

You should describe in this section the method you will use to assess risk of bias (or methodological quality). You should state whether the methods will be applied independently by more than one author, along with how you will resolve any disagreements. You should describe the tool(s) used or referenced, with an indication of how you will incorporate the results into the interpretation of the results. The judgements are expressed as ‘low risk’, ‘high risk’ or ‘unclear risk’ of bias.

See also

- The recommended tool for assessing risk of bias is described in Handbook, Chapter 8 (Section 8.5).

Measures of treatment effect

In this section you should state the effect measures of choice. For example, odds ratio (OR), risk ratio (RR) or risk difference (RD) for dichotomous data; weighted mean difference (WMD) or standardized mean difference (SMD) for continuous data. The following optional headings may be used, either in place of 'Measures of treatment effect' (in which case they would be level 3 headings) or as subheadings (level 4):

Dichotomous data

Continuous data

Time-to-event data

See also

- Types of data and effect measures are discussed in Handbook, Chapter 9 (Section 9.2).

Unit of analysis issues

In this section you should describe any special issues in the analysis of studies with non-standard designs, such as cross-over trials and cluster-randomized trials. Alternatively, you may use optional (level 3) headings specific to the types of studies, such as:

Cluster-randomized trials

Cross-over trials

Studies with multiple treatment groups

See also

- Unit of analysis issues are discussed in Handbook, Chapter 9 (Section 9.3).
- Some non-standard designs are discussed in detail in Handbook, Chapter 16, including cluster-randomized trials (Section 16.3), cross-over trials (Section 16.4), and studies with multiple intervention groups (Section 16.5). Non-randomized studies are discussed in Handbook, Chapter 13.

Dealing with missing data

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

See also

- Issues relevant to missing data are discussed in Handbook, Chapter 16 (Sections 16.1) and intention-to-treat issues (Section 16.2).

Assessment of heterogeneity

In this section you should describe any approaches to addressing clinical heterogeneity, along with how you will determine whether a meta-analysis is considered appropriate. You should state the methods you will use for identifying statistical heterogeneity (e.g. visually, using I^2 , using a chi-squared test).

See also

- Assessment of heterogeneity is discussed in Handbook, Chapter 9 (Section 9.5).

Assessment of reporting biases

In this section you should describe how publication bias and other reporting biases are addressed (for example, funnel plots, statistical tests, imputation). You 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).

Please be aware that you need at least 10 studies to create a funnel plot.

Useful reference

Egger M, Smith GD, Phillips AN. Meta-analysis: principles and procedures. *BMJ* 1997;315(7121):1533-7. [MEDLINE: 9432252]

See also

- Reporting biases are discussed in Handbook, Chapter 10.

Data synthesis

In this section you should state your choice of meta-analysis method, including whether you will use a fixed-effect or a random-effects model. If meta-analyses are not undertaken, then you should describe systematic approaches to synthesizing the findings of multiple studies.

See also

- Meta-analysis and data synthesis are discussed in Handbook, Chapter 9 (Section 9.4).

Subgroup analysis and investigation of heterogeneity

In this section you should list all planned subgroup analyses (or independent variables for meta-regression). Any other methods for investigating heterogeneity of effects should be described by you.

A subgroup analysis means looking for differences in particular groups of people.

See also

- Investigating heterogeneity is discussed in Handbook, Chapter 9 (Section 9.6).

Sensitivity analysis

In this section you 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.

A sensitivity analysis involves re-analysing the results having excluded particular studies, to see if they are skewing the results. Sensitivity analyses try to find out if there are reasons to explain heterogeneity in the results (differences in results from study to study).

See also

- Sensitivity analysis is discussed in Handbook, Chapter 9 (Section 9.7).

You may find the following further, *optional* (level 3) headings for the Methods section:

Economics issues

Methods for future updates

If you are seeking to cover economics aspects of interventions in a review you will need to consider economics issues from the earliest stages of developing a protocol.

See also

- Economics issues are discussed in Handbook, Chapter 15.
- Issues in updating reviews are discussed in Handbook, Chapter 3.

NOTE: You need to specify these analyses (subgroup and sensitivity) in advance to safeguard against developing theories afterwards. If there is a reason to speculate that the results might be different for particular subgroups, this reason should be specified in your protocol

Summary of findings

At the end of Sensitivity analysis section insert the following level 4 heading: **Summary of**

findings tables

You need to include Summary of Findings (SOF) tables in your review. You need to mention how you will construct the SOF table in your protocol.

HINT!! You could write something like this “We will use the principles of the GRADE system (Guyatt 2008) to assess the quality of the body of evidence associated with specific outcomes **(THEN STATE THE OUTCOMES YOU INTEND TO INCLUDE IN YOUR SOF Table; remember no more than seven)** in our review and construct a Summary of Findings (SoF) table using the GRADE software. The GRADE approach appraises the quality of a body of evidence based on the extent to which one can be confident that an estimate of effect or association reflects the item being assessed. The quality of a body of evidence for considers within study risk of bias (methodologic quality), the directness of the evidence, heterogeneity of the data, precision of effect estimates and risk of publication bias.”

Useful Reference:

Guyatt GH, Oxman AD, Kunz R, Vist GE, Falck-Ytter Y, Schunemann HJ. What is "quality of evidence" and why is it important to clinicians. *BMJ* 2008;336:995-8. [MEDLINE: 18456631]

Acknowledgements

This section should be used to acknowledge any people or organizations that you wish to acknowledge, including people who are not listed among the authors. For example you should acknowledge your statistician if that person is not listed among the authors. Please do not just mention their names but also actually tell us why you are acknowledging them. For example: “We would like to thank Dr Platz for translating two German studies into English.” (Please check that the people you have acknowledged in this section are willing to be acknowledged in your review.)

Contribution of authors

We ask that all authors complete the contribution of authors’ template, which will be inserted in your draft protocol by the CARG editorial office.

Please note: it is the responsibility of all authors listed on the protocol to have seen, read and approved each version of the protocol.

Example of template

Conceiving the review:

Co-ordinating the review:

Undertaking manual searches:

Screening search results:

Organizing retrieval of papers:

Screening retrieved papers against inclusion criteria:

Appraising quality of papers:

Abstracting 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 Review Manager (RevMan 5.1):

RevMan statistical data:

Other statistical analysis not using RevMan:

Double entry of data: (data entered by person one; data entered by person two)

Interpretation of data:

Statistical inferences:

Writing the review:

Securing funding for the review:

Guarantor for the review (one author):

Person responsible for reading and checking review before submission:

Declaration of interest

Sponsorship of a Cochrane review by any commercial source or sources is prohibited.

You should report any conflict of interest that is capable of influencing your judgement. This would include personal, political, academic, and particularly, financial conflicts. Financial conflicts of interest include the receipt of any benefit in cash or kind, any hospitality, or any subsidy derived from any source with an interest in the results of the review. Any sponsorship or funding of the review needs to be declared. If there are no conflicts please write: "none known".

Please read The Collaboration's policy on sponsorship:

<http://www.cochrane.org/docs/commercialsponsorship.htm>

You will be asked to complete a declaration of interest form at title registration, protocol publication and review publication time.

References

Studies and references

All of your references must be consistent with the Cochrane Style Guide (www.cochrane.org/style/home.htm).

In particular, please check the following items:

- That your references IDs are in the correct format (first author or group abbreviation and year of publication, e.g. Smith 1983, UKPDS 1990).
- You have included each journal title in full, with no abbreviations. *However please be aware that JAMA and BMJ are the journals full titles.*
- You have included relevant MEDLINE identifiers (or other database IDs)
- You have checked how each reference is displayed, to remove unnecessary punctuation.
- You have listed up to six authors before using 'et al.'
- You have provided complete pagination (e.g. 354-7).
- You have included the date accessed in any references to web pages.
- You have grouped reference links in the text in alphabetical order, separated by semi-colons and surrounded by round brackets.
- You have cited all relevant Cochrane reviews in the area (particularly relevant CARG reviews).
- See Handbook, Section 4.7.2

Please read the RevMan 'help' guide for instructions on how to correctly complete reference fields.

Appendices

You should have a minimum of two appendices in your protocol

1. Your MEDLINE search terms
2. A copy of your data extraction form

Please ensure that all appendices are linked to your text.

You will be sent a copy of the protocol submission checklist when you register your title. Please make sure you have addressed each item on this list before submitting your protocol for editorial approval. This form should be emailed to Jane Cracknell at jane_cracknell@yahoo.com when your protocol has been submitted via RevMan. If the form is not received, or if any of the checks are not completed, your protocol may be returned to you. Please include an explanation for any incomplete checks in the Notes field at the end of the form.

You should make sure that you:

1. Have run a spell check (of all parts of the protocol including references, additional tables and appendices). The spell check facility will be found under 'tools'
2. Have run a validation check. The validation check will be found under 'file/reports/validate'
3. Have gone through the items on the protocol submission checklist. The checklist is designed to ensure that your protocol is completed and ready for editorial and peer review before it is submitted to the Cochrane Anaesthesia Review Group.

If you have done all the above then please check your protocol in, via RevMan, for the editorial process. Please make sure to send your checklist by email to the ME: jane_cracknell@yahoo.com

Please be aware that your manuscript may be screened by CrossCheck plagiarism software. If you really feel that an idea cannot be expressed in any other way than that described by another researcher then you must put the text in quotation marks and identify the source of the statement in a reference.

Your protocol will now enter the editorial process. This is explained fully in the section entitled "CARG Editorial process" Once your protocol is accepted for publication you can start writing your review.

Developing your review

Before proceeding with the review you should:

- (1) Identify all the relevant studies on your topic.
- (2) Contact authors and pharmaceutical companies for additional data.
- (3) If possible, attend a Cochrane Review Workshop.
- (4) Make sure you have read the latest version of the Handbook.

<http://www.cochrane.org/cochrane/workshop.htm>

<http://www.cochrane.org/cochrane/hbook.htm>

(If you use the online version of the 'Handbook' you will need to 'click' on the book icon ('contents' top left of screen) to see an index.) The 'Handbook' is also included with Review Manager (RevMan 5.1) in the 'Help' menu. You can also request that the ME send you a pdf copy of the Handbook. (Please be aware that it is a large zipped file consisting of separate pdf chapters.)

- (5) Look at the Cochrane Glossary <http://www2.cochrane.org/resources/glossary.htm> (This is a useful aid to using the terminology of statistics and epidemiology correctly)

You should run all your searches, check the eligibility and quality of your identified

studies, and extract the data using the procedure determined in your protocol.

Once your studies have been identified and the data abstracted, you should create a **Table of Included Studies** in Review Manager (RevMan 5.1) and a risk of bias table. You should also create a **Table of Excluded studies** giving the reasons for their exclusion and if possible a summary of findings table

If you determine that participants, interventions and outcomes are similar enough to warrant statistical comparisons, a **Table of Comparisons** must be set up prior to entering data in order to carry out the meta-analysis.

Please remember:

Your protocol will have been written in the active voice and *future* tense. Your review should be written in the active voice and in the *past* tense. This means you must change: “we will search” to “we searched”. You need to make this change throughout the review.

Please be aware that CARG uses Oxford English Dictionary (OED) Spellings. Your review will be copy edited to reflect this (OED = randomized, analysed, paediatric, anaesthesia)

Title

The title of your review should be exactly the same as that of the published protocol. **(Or, if changed, this has been discussed and agreed with CARG; and noted in the section marked ‘Differences between protocol and review’)**

Your completed review should include the following sections

Plain language summary

Read the ‘Handbook’: Chapter 11 (Section 11.9.1)

The plain language summary (PLS) is a brief summary of the results of your review, written in plain simple language for consumers and non-specialist readers. You should explain all technical terms and abbreviations. The aim of the PLS is to summarize your review in a straightforward style, so that the review can be understood by consumers of health care. Plain language summaries are made freely available on the Internet, so will often be read as stand-alone documents. Plain language summaries have two parts: a title and a body of text.

You should write the first draft of the plain language summary. This draft may, like the rest of the review, be subject to alteration; you should anticipate one or more iterations.

- *Your ‘Plain language summary’ should include information on the number of included studies, the risk of bias, and any possible adverse effects.*
- *You should summarize the most important outcomes for answering your review question, including those that were not statistically significant or for which no results were found.*
- *The results and conclusions in your ‘Plain language summary’ should be consistent with those in the ‘Abstract’ and the main text of the review.*
- *Your ‘Plain language summary’ should not include any additional information to that found in the review.*
- *There are should be no references in your ‘Plain language summary’.*

Abstract (See also Handbook, Chapter 11 (section 11.8))

Your abstract is a stand-alone document and should summarize the results of your review. Your abstract needs to be suitable for publication in PubMed and other abstracting services and should contain no references. The maximum length of abstracts will increase from 400 words to 1,000 words with immediate effect. Cochrane authors are encouraged to make their abstracts no longer than 700 words, and an alert in RevMan will appear when 700 words is exceeded.

Your abstract should be targeted primarily at healthcare decision makers (clinicians, informed consumers and policy makers) rather than just to researchers. You should use terminology, which should be reasonably comprehensible to a general, rather than a specialist, healthcare audience. You should avoid abbreviations, except where they are widely understood (for example, HIV). Where essential, you should spell out abbreviations (with the abbreviations in round brackets) on first use. You should use names of drugs and interventions that can be understood internationally wherever possible. You should not use trade names.

- *Your abstract should include information on the number of included studies, the risk of bias, and any possible adverse effects.*
- *Your abstract should summarize the most important outcomes for answering your review question, including those that were not statistically significant or for which no results were found.*
- *The results and conclusions in your abstract should be consistent with those in the main text of your review.*
- *Your abstract should not include any additional information to that found in the review.*

The content under each heading in the abstract should be as follows:

Background: This should be a one or two sentence to explain the context or elaborate on the purpose and rationale of your review. If this version of your review is an update of an earlier one, it is helpful if you include a sentence such as “This is an update of a Cochrane review first published in YEAR, and previously updated in YEAR”.

Objectives: This should be a precise statement of the primary objective of your review, ideally in a single sentence, matching the Objectives in the main text of your review. 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 your 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, ‘Databases X, Y and Z were searched’. You should not include your search terms. The order for listing other databases should be the Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE, other databases. You should provide the date range of the search for each database. You can cover searching of bibliographies for relevant citations in a generic phrase ‘reference lists of articles’. You should list any constraints based on language or publication status here. If you contacted individuals or organizations to locate studies this should be noted. It is preferable if you write ‘We contacted pharmaceutical companies’ rather than listing of all the pharmaceutical companies contacted.

If you specifically handsearched journals for your review, then this should be noted, but handsearching to help build the Specialized Register of the CRG should not be listed in your review.

COMMON ERROR: authors often forget to update the date ranges in the protocol (e.g MEDLINE 1966 to ‘date

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

Data collection and analysis: This should be restricted to how you extracted and assessed data, and should not include details of what data were extracted. This section should cover whether more than one person did data extraction and assessments of risk of bias. If you contacted investigators to obtain missing information, then this should be noted here. What steps, if any, you took to identify adverse effects should also be noted.

Main results: This section should begin with the total number of studies and participants included in your review, and brief details pertinent to the interpretation of the results (for example, the risk of bias in 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 you included should be selected on the basis of which are most likely to help someone making a decision about whether or not to use a particular intervention. You should include adverse effects 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 narratively as well as quantitatively if the numerical results are not clear or intuitive (such as those from a standardized 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 your review, a qualitative assessment or a description of the range and pattern of the results can be given. However, you should avoid 'vote counts' in which the numbers of 'positive' and 'negative' studies are reported.

Authors' conclusions: The primary purpose of your review should be to present information, rather than to offer advice or recommendations. 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 generally not be made about practice circumstances, values, preferences, tradeoffs; and the giving of advice or recommendations should generally be avoided. You should note any important limitations of data and analyses. You should include any important conclusions about the implications for research if these are not obvious.

Background

This section may need to be updated if several months have passed since the protocol was published, or if there have been many developments in the topic area. Please ensure that:

- *You have clarified technical and medical terms for non-specialists (terms could be explained by putting the lay term in brackets, e.g. hypoglycaemia (low blood sugar).*
- *You have supported all updated facts, figures and statements with references.*
- *Please note any changes in the '**Differences between protocol and review**' section.*

Objectives

*Your objectives remain the same as in your protocol or any changes are noted in the '**Differences between protocol and review**' section. They should be rewritten in the past tense.*

Criteria for considering studies for this review

Types of studies

Types of participants

Types of interventions

The criteria in this section should be the same as those in your published protocol, or any changes should be noted in the ‘Differences between protocol and review’ section.

Types of outcome measures

Again this section remains the same as in your protocol or any changes are noted in the ‘Differences between protocol and review’ section. Please ensure it is rewritten in the past tense. “We included...”

Search strategy for identification of studies

*This section should be the same as your published protocol except you now enter the precise dates you searched the databases. The search date should be within **six months** of the date the review is checked in for the editorial process. Please be aware that the date of search determines how up to date your review is.*

You should now include all the search terms for ALL the databases you searched. The search terms should be placed in your review’s appendices and linked to the text.

You should note any changes (e.g. databases you were unable to search) in the ‘Differences between protocol and review’ section.

Methods of the review

You need to follow your published protocol, describing what you did and how you did it in the past tense, making sure that any changes are noted in the ‘Differences between protocol and review’ section.

Please remember it is important that a minimum of two authors extract data and that, that data is double checked BEFORE insertion into RevMan.

Results

Description of studies

Results of the search

We recommend that the results sections should start with a summary of the results of the search. This should include the total number of hits you found from electronic databases; the number of potentially relevant studies you found from other sources; the number of records remaining after you removed duplicates; the number of papers you retrieved in full text; the number of papers you excluded at each stage with the reasons for their exclusion; and the final number of studies that you classified as included, ongoing and awaiting assessment.).

You should state whether you attempted to contact the authors of any included studies; how many were contacted and what responses you received.

We ask that all authors complete a searching flow diagram (sent to you at title registration and protocol publication stage), which shows the reader how many studies you found and how. This document can be sent into the CARG editorial office in word format. We will convert it to a png file and insert it in the review and link to the relevant part of the text.

See also

- Presentation of search findings is discussed in Chapter 6 (Section 6.6).

Included studies

It is essential that you clearly state the number of included studies. This section should comprise a succinct summary of the information contained in your 'Characteristics of included studies' table. You should include an explicit reference to this table. You should describe the key characteristics of the included studies, including the study participants, location (e.g. country), setting (if important), interventions, comparisons 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). You should provide important details of specific interventions used (for drugs, this might summarize preparation, route of administration, dose and frequency). You should note any other characteristics of the studies that you regard as important for readers of the review to know.

The following *optional* (level 4) subheadings may be helpful:

Design

Sample sizes

Setting

Participants

Interventions

Outcomes

See also

- The 'Characteristics of included studies' table is discussed in detail in Handbook, Chapter 4 (Section 4.6.1).

Excluded studies

This should refer to the information contained in your 'Characteristics of excluded studies' table. An explicit reference to this table should be included. A succinct summary of why you excluded studies from the review should be provided.

See also

- The 'Characteristics of excluded studies' table is discussed in detail in Handbook, Chapter 4 (Section 4.6.3).

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

This section should summarize the general risk of bias in results of your included studies, its variability across studies and any important flaws in individual studies. The criteria that you used to assess the 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 a 'Risk of bias' table and not described in detail in the text, which should be a concise summary.

You should generate risk of bias summary and graph. (To do this open review in RevMan, go to 'figures' in tree. Right click /add figure/choose risk of bias summary and graph/link to text)

See also

- Presentation of 'risk of bias' assessments is addressed in Chapter 8 (Section 8.6).

For large reviews, aspects of the assessment of risk of bias may be summarized for the primary outcomes under the following headings:

Allocation

A summary of how allocation sequences were generated and attempts to conceal allocation of intervention assignment should be summarized briefly here, along with any judgements concerning the risk of bias that may arise from the methods used.

Blinding

A brief summary of who was blinded or masked during the conduct and analysis of the studies should be reported here. Implications of blinding of outcome assessment may be different for different outcomes, so these may need to be addressed separately. Judgements concerning the risk of bias associated with blinding should be summarized.

Incomplete outcome data

The completeness of data should be summarized briefly here for each of the main outcomes. You should report any concerns of the review authors over exclusion of participants and excessive (or differential) drop-outs.

Selective reporting

You should briefly summarize any concerns over the selective availability of data, including evidence of selective reporting of outcomes, time-points, subgroups or analyses.

Other potential sources of bias

You should summarize any other potential concerns here.

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 your 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 your 'Data and analysis' tables. You should address your outcomes 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 participant group, comparison or outcome measure if a review addresses more than one). You should report any sensitivity analyses that were undertaken.

You 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.

- You should summarize the results in a structured way, for example organized by comparison and then outcome.

- You should report the outcomes in the same order as listed in the ‘**Types of outcome measures**’ section.
- You should report the available results for each comparison, outcome and subgroup described in your published protocol, including those for which no results were found and those that were not statistically significant.
- You should report the results using the statistics and methods described in your ‘**Methods**’ section.
- The numerical results reported should be the same as those displayed in your ‘**Data and analyses**’ section.
- You have included links to all figures, analyses or tables of results where the results are discussed. Please remember, figures should seldom be required, and should not be used to draw forest plots that could be drawn using RevMan. If you do decide to use figures then **please remember that linked figures will appear in the published pdf version of the review exactly where you place them. So think about the readability of the text and try to insert figures at the end of paragraphs, beginning/end of sections. Ideally you should include no more than six figures in your review. Please remember that your review must contain a search flow diagram figure and a risk of bias graph and summary – both of which are generated as figures.** Since additional tables are presented in the same way as Figures (ie positioned within the review text), this number applies to Figures and Additional tables combined. Only the most important tables should remain as 'Additional tables' and other additional tables should be moved to the Appendices and referenced with a hyperlink. (The ME is happy to help you move any additional tables to the appendices.)
- You have presented every result with a measure of uncertainty (e.g. 95% confidence interval).
- You have conducted sensitivity analyses as described in your protocol, if appropriate, and reported the results.
- You have investigated heterogeneity as described in your protocol, if appropriate, and reported the results.
- You have investigated reporting bias as described in your protocol, if appropriate, and reported the results.
- You have been careful not to confuse ‘no evidence of effect’ with ‘evidence of no effect’.
- You have clearly identified any post-hoc analyses that were not planned at the protocol stage.
- ***Please do not list all the studies of a comparison in the text. Listing all the studies of a comparison in the text is distracting for the reader and duplicates the information in ‘Table of Comparisons’. You should refer the reader to the appropriate table of data and analysis (see ‘table 01/01’)***

See also

- Presentation of results is addressed in Handbook, Chapter 11 (Section 11.7).
- Interpretation of numerical results is discussed in Handbook, Chapter 12 (Sections 12.4, 12.5 and 12.6).

Discussion

This section should include brief comments on any methodological limitations of the included studies and the issues that are important for decisions about practice or future research. A structured discussion can aid the consideration of the implications of the review.

See also

- Interpretation of results is discussed in Handbook, Chapter 12.

Summary of main results

In this section you should summarize the main findings (without repeating the 'Effects of interventions' section) and outstanding uncertainties, balancing important benefits against important harms. You should refer explicitly to any 'Summary of findings' tables.

Overall completeness and applicability of evidence

This section should describe the relevance of the evidence to the review question. This should lead to an overall judgement of the external validity of your review. Are the studies identified sufficient to address all of the objectives of your review? Have you investigated all relevant types of participants, interventions and outcomes? You could include comments on how the results of your review fit into the context of current practice, although you should bear in mind that current practice might vary internationally.

Quality of the evidence

Does the body of evidence identified allow a robust conclusion regarding the objective(s) of your review? You should summarize the amount of evidence that has been included (numbers of studies, numbers of participants), state key methodological limitations of the studies, and reiterate the consistency or inconsistency of their results in this section. This should lead to an overall judgement of the internal validity of the results of the review.

Potential biases in the review process

You should state the strengths and limitations of your review with regard to preventing bias. These may be factors within, or outside, your control. 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 collection, analysis) could have introduced bias.

Agreements and disagreements with other studies or reviews

You should include comments on how the included studies fit into the context of other evidence here, stating clearly whether the other evidence was systematically reviewed.

- You have briefly summarized the included studies and their results in plain language, including the risk of bias, areas of uncertainty and completeness of the available evidence.
- You have checked that this section does not include any new results i.e. not reported in the previous section.
- You have referred to your '**Summary of findings**' table(s) and included links, as appropriate.
- You have considered both the statistical significance and clinical significance of the results.
- You have considered the applicability and context of the results.

- You have discussed the strengths and limitations of your review.
- You have discussed your findings in the context of current knowledge, including the findings of other reviews in the area.

Authors' conclusions

The primary purpose of the review should be to present information, rather than to offer advice. Avoid platitudes such as "more research is needed". You should state exactly what research is needed and why. Opinions on how the review might be improved with additional data or resources can also be noted. Conclusions of the authors are divided into two sections:

Implications for systematic reviews and evaluations of health care

The implications for systematic reviews and other evaluations of health 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

This section of a Cochrane review might be used 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. 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, 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.

- You have summarized your findings clearly.
- You have avoided giving advice and limited your conclusions to those that can be supported by the findings of the review.
- If recommending additional research, you have included specific recommendations for how the research should be conducted (e.g. study designs, outcome measurements) as well as what research should be conducted (e.g. different populations, interventions).

See also

- **Guidance on formulating conclusions is provided in Handbook, Chapter 12 (Section 12.7).**

Acknowledgements

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. Please do not just mention their names but also actually tell us why you are acknowledging them. For example: "We would like to thank Dr Platz for translating two German studies into English." (Please check that the people you have acknowledged are prepared to be acknowledged in your review.) This would include any previous authors of the Cochrane review or previous sources of support to the review.

Contributions of authors

You should update the template provided in your protocol to reflect the contributions of the current co-authors. Any changes in authorship between protocol and review should be noted in the section “Differences between published protocol and 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.

Please note: it is the responsibility of all authors listed on the review to have seen, read and approved each version of the review.

Declarations of interest

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 (in the declaration of interest section) if they have been involved in a study included in the review.**

See also

- **A summary of the Collaboration’s policy on conflicts of interest appears in Handbook, Chapter 2 (Section 2.6).**

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 judgements 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 known conflicts of interest, this should be stated explicitly, for example, by writing ‘None known’.

Differences between protocol and review

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 on the effects of the methods under investigation. Consider the potential effect

on the review's conclusions of any changes in methods, and consider sensitivity analyses to assess this

Please ensure

- You have reported any changes to the authors of the review since the protocol was published.
- You have reported any differences in the methods used between the protocol and the review, including anything that was changed, added or removed from the proposed methods.
- You have given a rationale for any differences between the protocol and the review, and the rationale is not driven by the findings of the review.

Tables

Characteristics of included studies

This table should be completed if you have 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, for example, 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. Footnotes should be used to explain any codes or abbreviations used (these will be published in the *CDSR*).

Please ensure:

- The same categories of information are presented in the same order for each included study.
- In the '**Methods**' section, you have described the study design (including whether or not the study was randomized), a clear indication if the study differs from a standard parallel group design (e.g. cross-over or cluster-randomized) and duration of the study including start and end dates, if available.
- In the '**Participants**' section, you have stated the number of participants, and described their context, health status, age, and sex. Sufficient information is provided to allow users of the review to determine the applicability of the study to their population, and to allow exploration of differences across studies.
- In the '**Intervention**' section, you have described each intervention group in the study in sufficient detail for each intervention to be replicated in practice (if possible), including dose and frequency, components, mode of administration and duration of each intervention.
- In the '**Outcomes**' section, you have listed either (i) the outcomes from the study that are considered in the review, or (ii) all outcomes measured or reported in the study. For each outcome, you have described the time points measured as well as the tools, units and definitions used to measure the outcome.
- The table does not include study results.
- The table does not include information that should be included in the risk of bias assessment.
- You have included any available information on the funding of the study.
- You have included explanations of any abbreviations in footnotes.
- If you have used footnotes, references in the text are in superscript text (e.g. ¹).

Risk of bias

CARG requires all authors complete a 'Risk of bias' table. It is an extension of the 'Characteristics of included studies' table. The standard 'Risk of bias' table includes an assessment for allocation concealment and the authors can add further items. 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: 'low risk of bias', 'high risk of bias' and 'Unclear risk of bias').

Please ensure

- You have read Chapter 8 of the Handbook and completed the tables in accordance with this guidance.
- You have included rows in the table to assess sequence generation, allocation sequence concealment, blinding, incomplete outcome data, selective outcome reporting and other issues
- You have given a judgement of 'low risk of bias'; 'high risk of bias', or 'Unclear' to indicate that you do not have enough information available to reach a judgement.
- In each judgement, you have taken into consideration the evidence of bias, the likely direction of bias and the likely magnitude of bias, and your judgements are consistent with Table 8.5.c of the Handbook.
- You have provided detailed, clearly identified quotes from the study text and additional comments, where necessary, to support each judgement.
- In the '**Random sequence generation**' row, you have described how the sequence was generated to allocate participants into intervention groups, and whether it was random, quasi-random or non-random.
- In the '**Allocation concealment**' row, you have described whether the assignment of participants to intervention groups was concealed throughout the recruitment and allocation processes (before the interventions began).
- In the '**Blinding**' row, you have described who was blinded or masked during the conduct and analysis of the trial, including an assessment of the success of blinding.
- You have considered the possible impact of blinding for each outcome reported in the review and created additional rows in the table for outcomes at different levels of risk, if appropriate.
- In the '**Incomplete outcome data**' row, you have described the completeness of the data reported, including withdrawals, exclusions, imputation of missing data and an 'as treated' analysis.
- You have included an assessment of the possible impact of the incomplete data based on the proportion of missing outcomes (dichotomous), the plausible effect size (continuous), the balance of missing data between intervention groups and the reasons for incompleteness
- You have considered the impact of incomplete outcome data for each outcome and time point reported in the review, and created additional rows in the table for outcomes or time points at different levels of risk, if appropriate.
- In the '**Selective reporting**' row, you have considered whether the study protocol is available, and if you have any evidence of outcomes added, not reported, reported incompletely, or reported using measures, methods or subsets of data that were not pre-specified.
- In the '**Other bias**' row, you have described any other concerns about the study (e.g. baseline imbalance, early stopping).
- You have not included in the table concerns that do not have direct implications for bias (e.g. sample size, ethical approval).
- You have included explanations of any abbreviations in footnotes.
- If you have used footnotes, references in the text are in superscript text (e.g. ¹).

Characteristics of excluded studies

Certain studies that may appear to meet the eligibility criteria, but which 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 Cochrane review includes a list of excluded studies, detailing any studies that a reader might plausibly expect to see among the included studies. This covers all studies that may on the surface appear to meet the eligibility criteria but on further inspection do not, and also those that do not meet all of the criteria but are well known and likely to be thought relevant by some readers. By listing such studies as excluded and giving the primary reason for exclusion, the review authors can show that consideration has been given to these studies.

Please remember that the list of excluded studies should be as brief as possible. ***It should not list all of the reports that were identified by a comprehensive search.*** We do understand that you may want to make your search as transparent as possible – one way to do this is to provide brief details (i.e. 5 studies excluded – editorials) in the search flow diagram. If you want to provide more detail then you can always provide it in an appendix.

Please ensure

- You have listed the studies identified by your search that may have at first appeared to meet the eligibility criteria but on further inspection do not; or that are well known and likely to be thought relevant by some readers.
- You have briefly stated the specific reason why each study was excluded from the review.
- You have not included further information about the studies (e.g. location or results).
- If you have used footnotes, references in the text are in superscript text (e.g. ¹).

See also

Selection of which studies to list as excluded is discussed in Handbook, Chapter 7 (Section 7.2.5).

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:

1. Studies about which an inclusion or exclusion decision cannot be made because sufficient information is not currently available. All reasonable attempts to obtain information must be made before studies are left here on publication of the review, 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.
2. Studies that have been identified but are awaiting an update to the review. In particular, it is appropriate to mention studies that have the potential to impact on the review's conclusions, or studies that receive wide publicity, 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

Please ensure

- You have provided as much information as possible, similar to that provided in the '**Characteristics of included studies**' table.

- In any blank cells, you have stated 'Not yet assessed' or 'Not known', as appropriate.
- You have included explanations of any abbreviations in footnotes.
- If you have used footnotes, references in the text are in superscript text (e.g. ¹).

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'. Footnotes should be used to explain any abbreviations used in the table (these will be published in the *CDSR*).

Please ensure:

- You have provided as much information as possible, similar to that provided in the '**Characteristics of included studies**' table.
- In any blank cells, you have stated 'Not yet assessed' or 'Not known', as appropriate.
- You have included explanations of any abbreviations in footnotes.
- If you have used footnotes, references in the text are in superscript text (e.g. ¹).

Summary of findings

CARG requires that all authors complete a 'Summary of findings' table. It is a strongly recommended means of presenting findings for the most important outcomes, 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 people receiving experimental and control interventions; 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.

Please ensure:

- You have included a '**Summary of findings**' table for each comparison in your review.
- You have read Chapter 11 and Chapter 12 of the Handbook and completed the tables in accordance with this guidance.
- You have briefly described the population, setting and intervention in the studies relevant to each comparison.
- You have selected the seven most important outcomes to be reported in each table, including those outcomes for which good data were not found in the review.
- Adverse effects (or a specific adverse effect) are listed as one of the outcomes in each table.
- You have named each outcome in plain language, and clearly described any tools, units and definitions used to measure the outcomes, including the direction and upper and lower limits of any numerical scales.
- You have selected an assumed risk for each outcome based on either the control group risk(s) in your included studies or an external source (e.g. a well-conducted epidemiological study) and have included a footnote explaining the source selected.
- You have checked that all results appear correctly and are consistent with the results presented in your 'Data and analyses' and the 'Results' section of the review
- You have completed a GRADE assessment for each outcome and included footnotes stating the reasons for your judgements.

- You have included comments explaining any additional information required by the reader, including explanations for any outcomes for which results cannot be displayed in the standard format.
- You have included explanations of any abbreviations in footnotes.
- If you have used footnotes, references in the text are in superscript text (e.g. ¹).

You can generate a summary of findings table from within RevMan or by downloading GRADEpro software

The link to the GRADEpro software will be found via <http://ims.cochrane.org/revman/gradeopro>

This web page (<http://ims.cochrane.org/revman/gradeopro>) contains

- Download and technical information
- Information and resources (about Gradepro; relevant chapters in the Handbook etc) Support (answers to frequently asked questions and training information).

Here are the links to the available trainings and webinars

(<http://www.ims.cochrane.org/revman/gradeopro/resources> and <http://ccnc.cochrane.org/webinars>)

See also

- A full specification and discussion of ‘Summary of findings’ tables is provided in Handbook, Chapter 11 (Section 11.5);

The GRADE system is overviewed in Handbook, Chapter 12 (Section 12.2).

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; and
- Summaries of study characteristics (such as detailed descriptions of interventions or outcomes);
- **The CARG editors adopted a policy at their editorial meeting in June 2009 that an orphan study — a data and analysis with only one included study — should not be entered in a data and analysis table. Rather, the outcome could be placed in an additional table. An orphan study entered as a subgroup single included study would still be appropriate when associated with the other subgroups of the data and analysis table**

Please ensure

- Each table has a brief and informative heading.
- You have included explanations of any abbreviations in footnotes.
- If you have used footnotes, references in the text are in superscript text (e.g. ¹).
- You have included links to each table from the appropriate part of the main text.

See also:

- Additional tables are discussed in Handbook, Chapter 11 (Section 11.6).

References

Please ensure

- You have checked that a link has been created wherever a reference appears in the text of the review.
- You have included each journal title in full, with no abbreviations.
- You have checked how each reference is displayed in order to remove unnecessary punctuation.
- You have listed up to six authors before using 'et al'.
- You have written the page numbers correctly (e.g. 354-7).
- You have included the date accessed in any references to web pages.
- You have grouped reference links in the text in alphabetical order, surrounded by round brackets and separated by semi-colons.

References to studies

Studies are organized under four fixed headings. 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), as can identifiers such as an International Standard Randomised Controlled Trial Number (ISRCTN). In addition, each study should be assigned a category of 'Data source' from among 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 be given identifiers such as a MEDLINE ID or a DOI. One reference for each study should be awarded the status of 'Primary reference'.

Authors should check all references for accuracy.

Included studies

This section contains studies that meet the eligibility criteria and are included in the review.

Excluded studies

This section contains studies that do not meet the eligibility 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

This section contains studies that are ongoing and meet (or appear to meet) the eligibility criteria.

Please ensure

- Study IDs are in the correct format (first author or group abbreviation and year of study or year of publication, e.g. Smith 1983, UKPDS 1990).
- You have grouped all the references relevant to each study under a single Study ID.
- If there are two or more references listed under a Study ID, you have nominated one as the primary reference.
- You have noted whether data for each study include published, unpublished or both sources, and whether unpublished data were sought.

Other references

References other than those to studies are divided between the following two categories.

Note that 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.

Additional references

Other references cited in the text should be listed here, including those cited in the Background and Methods sections. 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. Please inform the ME if you have published, or intend to publish your review elsewhere. We may need to seek the approval of your previous publisher before being able to publish your review in *The Cochrane Library*.

The 'Data and analyses' section of a review

The 'Data and analyses' section of a Cochrane review is a detailed resource of results. It includes outcome data (numeric or text), forest plots and meta-analysis results. The root of the 'Data and analyses' resource is a table of comparisons, outcomes and (optionally) subgroups for which data are available. Analyses listed in this table comprise either a table of results ('other data' tables) or, more usually, a table of data accompanied by a forest plot. The 'Data and analyses' tables are included in the full publication of a Cochrane review. However, some formats of a published review may omit the forest plots and 'other data' tables (along with appendices), and so they should generally be considered as supplementary material, and key results should be included in the text of the review under 'Results'. The published review will always include a summary table of all analyses (including numbers of studies and meta-analysis results for each subgroup under each outcome for each comparison). The review should include the most important forest plots from the 'Data and analyses' resource as figures and these should be referenced in the 'Results' section (see Section 11.4.2).

The CARG editors adopted a policy at their editorial meeting in June 2009 that an orphan study — a data and analysis with only one included study — should not be entered in a data and analysis table. Rather, the outcome could be placed in an additional table. An orphan study entered, as a subgroup single included study would still be appropriate when associated with the other subgroups of the data and analysis table.

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. The author is 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 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. have forest plots with no studies). Instead, authors should note in the text of the review that no data are available for the comparisons. The main outcomes in a review should be included in a 'Summary of findings' table irrespective of whether data are available from the included studies.

Comparison

The comparisons should correspond to the questions 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 (for example, studies done before and after the publication of the CONSORT statement) or to a sub-division of the outcome (for example, 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).

Please ensure

- Comparison names are consistent with the names used in the '**Objectives**', '**Types of Interventions**' and '**Effects of interventions**' sections
- You have organized the outcomes in the same order as listed in the '**Types of outcome measures**' and the '**Effects of interventions**' sections.
- Outcome names are consistent with the names used in the '**Types of outcome measures**' and the '**Effects of interventions**' sections.
- Outcome names include brief information on the tools, units, definitions and time points for each outcome, if appropriate.
- You have changed the **Group labels** on the forest plots from 'Experimental' and 'Control' to the actual intervention groups used in the comparison.
- You have changed the **Graph labels** on the forest plots from 'Favours experimental' and 'Favours control' to the actual intervention groups used in the comparison.
- You have checked that the **Graph labels** indicate the correct direction of effect (for negative outcomes, the left side favours the experimental group; for positive outcomes, the left side favours the control group).

- You have set the scale of each forest plot so the point estimates and confidence intervals can be seen clearly and, if possible, so that the plots are consistent between outcomes on similar scales.
- You are not displaying meta-analysis totals for outcomes or subgroups with only one included study.
- You are not displaying meta-analysis totals to combine more than one measurement from the same individuals in the same study.
- The statistical options used in the forest plots are correct and consistent with the 'Methods' section, including the statistical method (e.g. Peto or inverse variance), analysis model (e.g. fixed or random effects) and effect measure (e.g. risk ratio or odds ratio).
- If you are combining results from studies that measured the same outcome on different scales, you have used standardized mean difference.
- You are not combining end point and change from baseline data using standardized mean difference
- You have checked any outlying or unexpected results for data entry and transcription errors.

See also

- Different types of data, statistical analyses and meta-analyses are discussed in Handbook, Chapter 9.

Additional Figures

Required: Searching flow diagram figure

All CARG reviews should contain a searching figure. This figure will be linked to the 'Description of studies section'

Required: Risk of bias graph and summary

If your review contains Risk of bias tables then it should also contain risk of bias graph and summary. These figures can be generated in RevMan and should be linked to the text.

Use with caution: Additional figures should not be used to draw forest plots that could be drawn using RevMan. (***A common error is to duplicate information in the additional figures that is already available in the data and analysis section. These forest plots are published in the review.***)

Where possible, figures should be produced using statistical software packages that produce appropriate publication-quality graphics, such as Stata, SAS, SPSS, S-Plus or specialized meta-analysis software. General-purpose spreadsheet programs may not provide suitable flexibility nor produce output of adequate quality.

Please be aware that additional figures will appear in the published version, exactly where you place them. Think about the readability of your text and try to place any additional figures at the end of paragraphs or at beginning of sections.

Please remember that you need to seek permission from the relevant publisher and author to reproduce or modify another author's figures/graphs/tables in your work

Please ensure

- If appropriate, you have selected the most important forest plots from your analysis and added them as figures to be linked to from the text of the review.
- You have permission to reproduce any figures from external sources that you have included in your review.
- Each figure has a brief caption describing the purpose of the figure, and acknowledging its source.
- All figures used are scaled so that a reader can see the complete picture within the RevMan window.
- All figures are of a sufficient resolution and quality for publication.

Sources of support for the review

Authors should acknowledge 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). Each source, its country of origin and what it supported should be provided.

Please ensure

- You have listed all sources of funding and in-kind support, including internal sources (e.g. the home institution of any author) and external sources (e.g. grant funding).

Appendices

1. We require that you provide all search terms for all databases searched in the appendices and link those appendices to the text
2. We require that you insert a copy of your data extraction form and link to the text. Please ensure
 - The title of each appendix is clear and informative.
 - You have included in an Appendix the complete set of search terms used for each electronic database.

Language and style

Please ensure

- You have removed all highlighting, notes and tracked changes from the review.
- You have changed any text that was written in the future tense for your protocol to the past tense in the review.
- The text is clearly written and all technical and medical terms are explained for non-expert readers.
- All text uses the active voice.
- Where possible, you have used the default headings and subheadings in RevMan.
- You have used the appropriate 'Heading styles' for all headings and subheadings.
- Spelling is consistent throughout the review and uses OED spelling (e.g. randomized, anaesthesia, paediatric, analysis).
- You have explained all acronyms and abbreviations.
- You have written numbers up to and including nine as words, and numbers 10 or higher as numerals (with the exception of those at the start of a sentence and numbers appearing in tables or figures).
- You have checked that all pairs of brackets and quotation marks are complete.
- You have included a space before and after each unit of measurement or mathematical symbol (e.g. 5 ml, P = 0.03).

Before submitting your review, please check it against the CARG review checklist. This checklist is designed to ensure that your review is completed and ready for editorial and peer review before you submit it to the Cochrane Anaesthesia Review Group (CARG). Please make sure you have addressed each item on this list in order to help the editorial approval process. The completed form should be emailed to Jane Cracknell at jane_cracknell@yahoo.com when your review has been submitted via RevMan. If Jane does not receive the form, or if any of the checks are not completed, your review may be returned to you. Please include an explanation for any incomplete checks in the Notes field at the end of the form.

Please make sure:

- You have run a spell check (of all parts of the review including references, tables and appendices). The spell check facility will be found under 'tools').
- You have run a validation check. The validation check will be found under 'file/reports/validate'
- You have gone through the items on the review submission checklist
- You have cited all relevant Cochrane reviews in the area (particularly relevant CARG reviews).

If you have done all the above then please check your review in, via RevMan, for the editorial process. Please make sure to send your checklist and searching flow figure by email to the ME:

jane_cracknell@yahoo.com

Please be aware that your manuscript may be screened by CrossCheck plagiarism software.

Your review will now enter the editorial process. This process is explained fully in Handbook, section seven.

Your review will now enter the editorial process

Updating A Published Review

Read the Handbook: Maintaining reviews: updates, amendments and feedback

Systematic reviews that are not maintained may become out of date or misleading. The Cochrane Collaboration policy is that Cochrane Intervention reviews should either be updated within two years or include a commentary to explain why this is not the case. Cochrane reviews may need to be updated earlier in response to criticism or new evidence. Reviews that are not updated will ultimately either be removed from the Library or offered to another author

Any change to a Cochrane review is either an update or an amendment. Updates involve a search for new studies; any other change is an amendment.

Criteria for new citations for updated reviews

All updated reviews should have their searches reran (within six months of submission of an updated review). However if the search is rerun but the studies just placed in the section 'awaiting assessment' then the review is classified as 'amended' rather than 'updated'.

If the searches are rerun and the results incorporated into the review then this classifies the review as an updated review.

A new citation is classified as a change in the conclusions, a change in the conclusions (correcting of serious error)

Reasons for giving a review a new citation (conclusions not changed)

- New authorship (not just reordering of old authors)
- Accumulation of changes (e.g. updating background, references plus inclusion of SOF ROB tables)
- Correction of serious error in citation (Erratum)

Examples of changes that do not automatically indicate a new citation version

- Changes in order of authors
- Just updating background
- Change in methodology

The benefit to you, as an author, of updating your review is that a new citation in Cochrane means another citation in MEDLINE. (Minor updates: updating searches but finding no new studies, do not justify another citation in MEDLINE. But they do mean you do not have to update your review for another two years!)

What will we do to help?

We will help you by rerunning your search strategies and sending you the results.

What do you need to do?

If you are submitting an update to an already published review, you should go through all the sections in the review and check whether they need updating.

Don't forget to provide an updated searching figures, make sure all numbers (of included/excluded studies are updated, as are the number of participants.

Don't forget to update your references so that you cite the most up to date evidence.

In addition you must address these additional criteria:

Please check:

- You have entered the date on which you are submitting the draft in the 'Assessed as Up-to-date' field in the 'Dates' section.
- If you have updated the search, you have updated the 'Date of Search' field in the 'Dates' section.
- You have updated the date 'Next Stage Expected' field in the 'Dates' section
- You have checked with CARG whether this is a new citation version of the review (see criteria below).
- Remember: if you have updated the search, the event is listed as an 'Update'; if not, the event is listed as an Amendment'.

- If you have updated the search, every source listed in the original review has been updated and the new date range listed in the 'Methods' section, or an explanation given why not.
 - You have updated the text of the review to include any new subheadings available in RevMan.
 - You have updated your background so that the references etc are up to date (and all statements are referenced).
 - You have updated the methods of the review to reflect the latest guidance available in the Handbook, and noted these changes in the 'Differences between protocol and review' section.
 - You have edited the 'Abstract' to reflect the update or amendment. (For example insert in the Background of the abstract "This is an update of a Cochrane review first published in YEAR, and previously updated in YEAR".
 - You have edited the 'Plain language summary' to reflect the update or amendment.
 - If this is a new citation version, you have included a reference to the previous citation version of the review under 'Other published versions of this review'.
 - If you received any feedback on your review via *The Cochrane Library*, you have included the comments received and your response in the 'Feedback' section.
 - Finally please complete the 'what's new section'. This section will be published in the updated review in The Cochrane Database of Systematic Reviews and informs the reader as to why they should want to read your updated review.
1. Tell the reader when you reran your searches to: "We reran our search from XXXX to XXXX"
 2. Tell the reader how many new included studies you found and provide links to those references: "We identified two new RCTs XXXX; XXXX)". Provide information on the number of patients involved in those studies "involving a total of 530 patients". Of these, eight trials included patients with chronic obstructive pulmonary disease and four trials included mixed populations.
 3. Tell the reader how many new studies were excluded "We excluded three additional trials (XXXX; XXXX, XXXX) and if any studies are awaiting assessment or ongoing.
 4. Make sure to check whether any studies previously classified as ongoing or awaiting assessment can be moved to the excluded or included section. "One study (XXX) previously classified as awaiting assessment has now been translated and excluded
 5. We have updated our previous review (provide a link to the previous version) to include 12 RCTs
 6. Inform the readers if the team of authors have changed "We invited one new reviewer (XXXX) to participate in the update to the previously published meta-analysis XXXX). We

invited one new reviewer (XXXX) to participate in the update to the previously published meta-analysis XXXXX).

7. Inform the reader whether the conclusions have changed “Minor changes were made to the review text and formatting but no changes were made to either the content of discussion or conclusions”

Before checking your updated review in for the editorial process please check it against the review checklist. This checklist is designed to ensure that your review is completed and ready for editorial and peer review before you submit it to the Cochrane Anaesthesia Review Group (CARG). Please make sure you have addressed each item on this list in order to help the editorial approval process. The completed form should be emailed to Jane Cracknell at jane_cracknell@yahoo.com when your review has been submitted via RevMan. If Jane does not receive the form, or if any of the checks are not completed, your review may be returned to you. Please include an explanation for any incomplete checks in the Notes field at the end of the form.

Common errors which authors make which tend to make you unpopular with your editor!

1. If the protocol is thorough the chances of the review producing results that misrepresent the evidence will be minimized. Therefore the most likely sources of error are either that the authors do not follow their protocol (acts of omission or commission) or that the protocol was inadequate.
2. There will always be errors of style in the first draft of a review. You will find errors on the Cover sheet and in the Tables as well as in the main text of the review (or protocol).
3. The Background is usually too long. The sentences are usually too long. The words are usually too long.
4. There are usually too many outcomes and proposed subgroup analyses.
5. The authors fail to proof read the tabular text. The format of some of the references will be incorrect.

The CARG editorial process

The editorial process is similar for both protocol and review, any differences will be marked with: ** and explained. For ease both documents will be referred to as ‘reviews’ in this part of the booklet.

CARG operates an open editorial process. All members of the editorial team (content editor, statistical editor, peer reviewers and consumers) are identified, as are the authors. All comments will be directly returned to the author of the review unblinded.

All CARG reviews are sent out to a content editor, and a statistical editor** (** statistical editors only comment on the second draft of a protocol); a minimum of two peer reviewers and CARG’s consumer panel. Please be aware that it can take the editorial office two weeks or more to allocate a suitable editorial team.

The peer reviewers, consumer panel and statistical editor are asked to return their comments to the ME within 28 days of receiving the review. Their comments are then sent to your content editor. The content editor will (from the editorial evaluations) outline a plan of action for you to follow. The content editor is allowed a further 28 days to make a plan of action for you to follow.

You will be sent that plan plus the individual, unblinded, comments of all the members of the editorial team hopefully within 12 to 14 weeks.

Please be aware that although we try to give an idea of deadlines for returning comments, sometimes-other events (such as large number of reviews in editorial process, holidays, difficulty finding peers) intervene and deadlines get put back.

We ask that authors respond to their editors' comments within three months of receipt. You are asked to revise your review on the strength of your editors' comments. You should submit your revised review, along with a detailed covering letter describing the changes made. This covering letter should answer all comments made by the editor. Your covering letter should clearly outline any changes you have made to your review. The letter should clarify how you have responded to the editors' comments (or your reasons for not implementing the suggested changes).

It is important that you detail in your covering letter how and where in the text you dealt with your editors' comments. Please do not simply write: "done" but actually copy and paste the amended passage from your final review. If you have not made any of the recommended changes please outline (in that letter) why you chose not to. This will help your editors evaluate the changes and consequently speed up the editorial process. Please make all changes in the text in Review Manager (RevMan 5.1). Your editors need to be able to track the changes you have made. The CARG editorial office will generate a pdf file showing tracked changes for your editors. The more information you supply your editors with, the quicker the editorial process will be.

Please note that your revised review will **not** be forwarded onto the content and statistical editors unless the review is accompanied by a covering letter.

The peer reviewers and consumer representatives will not see your revised review again. Peer reviewers and consumers are only asked to comment on the first draft of protocols, reviews and updated reviews. They will be sent a full copy of all unblinded editorial comments for their interest. They will also be sent a pdf copy of your published review as a way of thanking them for their help. You will 'work' with the statistical and content editors until they approve your review. This can take several drafts. Once your editors have approved your review, the review will be sent to the Co-ordinating editors for final publication approval. Please be aware they may request further changes, and that you need to respond to their comments. Once the Co-ordinator Editor has approved your review for final publication the review will be internally and externally copyedited to conform to Cochrane style. You will be sent the copyedited version to check and approve prior to its inclusion in the next available edition of *The Cochrane Library*. (As with all journals, Cochrane has its own 'style', the final review must follow the style guidelines.)

You will be asked to complete and return declaration of interest forms. Once that form is signed and the authors have indicated that they approve the copyedited version, the review will be marked for publication.

Electronic Licence for publication

On 25 February 2011, The Cochrane Collaboration introduced electronic Licence for Publication forms for reviews. This means that authors no longer have to either sign a paper copy of the form or sign it electronically and fax, post or email it to the Managing Editor (ME). Instead, when the ME marks a new citation version of a protocol or review for publication, Archie will

automatically send each author an email with a link, which will take the author to the Archie login page and then on to the Licence for Publication web form. The email will also have, as an attachment, a PDF of the proof of the review. Once the author has accessed the web form, s/he will be asked to accept the licence, type her/his name, and click a button. The author will also be able to read the final version of the review from within the form.

The review will not be released to Wiley and included in the Anaesthesia Group's next module submission (to be published protocols and reviews) unless all authors have completed and submitted their forms. If an author does not accept his/her Licence for Publication form by the module deadline, the new citation version will automatically be transferred to the next module submission and will only be accepted for publication once the author has accepted the Licence for publication form.

To help Managing Editors easily identify a missing Licence for Publication form, which will consequently stop the review being accepted for publication, we have introduced three new warning systems within three different locations in Archie: the 'to be published' icon in the Reviews folder under Resources will be coloured red and will only turn blue once all forms have been submitted to confirm that the review will be included in the next module submission; as a warning in the Publication Report; and on the (new) Licence for Publication Forms Report

Access to electronic Licence for Publication forms is dependent upon authors having Archie user accounts. In most cases, we will have arranged Archie user accounts for authors as part of the title registration process. However, if not all the authors on the review team have an Archie account, then please contact the ME and we will initiate registration on a case-to-case basis whenever we think it is appropriate for the individual author rather than trying to initiate multiple Archie accounts.

Of interest to member of the American Medical Association (AMA)

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Cochrane corner in Anesthesia and Analgesia (A&A)

CARG has a dual publication arrangement with the journal Anesthesia and Analgesia (A&A). All authors of published CARG review will be contacted by the CARG editorial office and asked whether they wish to submit their abstracts to (A&A) for consideration. Some CARG reviews will be published by A&A as full reviews; others may be published as abstracts in the Cochrane Corner in that paper journal. It is up to A&A to decide whether the full review or abstract is published. (All Cochrane reviews must still follow A&A's style guidelines and go through that journal's editorial process.)

Please be aware that authors do not have to submit their abstracts to A&A, they are entitled to seek publication in a journal of their choice. (Each individual republication is of course subject to Cochrane Library approval.)

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Reference

Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.