

Chapter 2: Preparing a Cochrane review

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Key Points

- The publication of protocols for Cochrane reviews in the *Cochrane Database of Systematic Reviews (CDSR)* prior to publication of the Cochrane review reduces the impact of authors’ biases, promotes transparency of methods and processes, reduces the potential for duplication, and allows peer review of the planned methods.
- Cochrane reviews, and protocols for reviews, are prepared in the Cochrane Collaboration’s Review Manager (RevMan) software and have a uniform format.
- An outline of a Cochrane Intervention review is provided in this chapter.
- Titles for Cochrane Intervention reviews are agreed by and registered with Cochrane Review Groups (CRGs), who then manage the editorial process of publishing protocols and reviews.
- Cochrane reviews are prepared by teams.
- There are guidelines for co-publication of Cochrane reviews in other journals.
- The Cochrane Collaboration has a code of conduct for avoiding potential financial conflicts of interest.

2.1 Rationale for protocols

Preparing a Cochrane review is complex and involves many judgements. In order to minimize the potential for bias in the review process, these judgements should be made in ways that do not depend on the findings of the studies included in the review. Review authors’ prior knowledge of the results of a potentially eligible study may, for example, influence the definition of a systematic review question, the subsequent criteria for study eligibility, the choice of intervention comparisons to analyse, or the outcomes to be reported in the review. Since Cochrane reviews are by their nature retrospective (one exception being prospective meta-analyses, as described in Chapter 19), it is important that the methods to be used should be established and documented in advance. Publication of a protocol for a review prior to knowledge of the available studies reduces the impact of review authors’ biases,

promotes transparency of methods and processes, reduces the potential for duplication, and allows peer review of the planned methods (Light 1984).

While the intention should be that a review will adhere to the published protocol, changes in a review protocol are sometimes necessary. This is similarly the case for a protocol for a randomized trial, which must sometimes be changed to adapt to unanticipated circumstances such as problems with participant recruitment, data collection or unexpected event rates. While every effort should be made to adhere to a predetermined protocol, this is not always possible or appropriate. It is important, however, that changes in the protocol should not be made on the basis of how they affect the outcome of the research study. *Post hoc* decisions made when the impact on the results of the research is known, such as excluding selected studies from a systematic review, are highly susceptible to bias and should be avoided.

Protocols for Cochrane reviews are published before the completed systematic review in the *Cochrane Database of Systematic Reviews (CDSR)*. Changes in the protocol should be documented and reported in the ‘Differences between protocol and review’ section of the completed review, and sensitivity analyses (see Chapter 9, Section 9.7) exploring the impact of deviations from the protocol should be undertaken when possible.

2.2 Format of a Cochrane review

2.2.1 Rationale for the format of a Cochrane review

All Cochrane reviews of interventions have the same format. Benefits of this uniform format include:

1. helping readers find the results of research quickly and to assess the validity, applicability and implications of those results;
2. guiding review authors to report their work explicitly and concisely, and minimizing the effort required to do this;
3. facilitating electronic publication and maintenance of reviews; and
4. enabling the development of derivative products (e.g. Overviews of reviews, see Chapter 22) and empirical research studies based on multiple systematic reviews.

The format is flexible enough to fit different types of reviews, including those making a single comparison, those making multiple comparisons and those prepared using individual patient data. Standard headings and tables embedded in RevMan guide review authors when preparing their report and make it easier for readers to identify information that is of particular interest to them. The headings within RevMan are listed in Sections 2.2.2 and 2.2.3. A detailed guide to the content that should follow each heading is provided in Chapter 4.

2.2.2 Outline of a protocol for a Cochrane review

Box 2.2.a lists the elements that define a complete protocol for a Cochrane review, and indicate how the protocol is likely to appear in the *CDSR* (which may not be the same as in RevMan). If any of the sections marked with an asterisk (*) are empty, the protocol will not be published until something has been added to the section, that is they are ‘mandatory fields’.

Box 2.2.a: Sections of a protocol for a Cochrane review

Title*

Protocol information:

Authors*

<p>Contact person*</p> <p>Dates</p> <p>What's new</p> <p>History</p> <p>The protocol:</p> <p>Background*</p> <p>Objectives*</p> <p>Methods:</p> <p> Criteria for selecting studies for this review:</p> <p> Types of studies*</p> <p> Types of participants*</p> <p> Types of interventions*</p> <p> Types of outcome measures*</p> <p> Search methods for identification of studies*</p> <p> Data collection and analysis*</p> <p>Acknowledgements</p> <p>References:</p> <p> Other references:</p> <p> Additional references</p> <p> Other published versions of this review</p> <p>Tables and figures:</p> <p> Additional tables</p> <p> Figures</p> <p>Supplementary information:</p> <p> Appendices</p> <p> Feedback:</p> <p> Title</p> <p> Summary</p> <p> Reply</p> <p> Contributors</p> <p>About the article:</p> <p> Contributions of authors</p> <p> Declarations of interest*</p> <p> Sources of support:</p> <p> Internal sources</p> <p> External sources</p> <p> Published notes</p>

2.2.3 Detailed outline of a Cochrane review

Box 2.2.b lists the elements that define a complete Cochrane review, and indicate how the review is likely to appear in the *CDSR* (which may not be the same as in RevMan). If any of the sections marked with an asterisk (*) are empty, the review will not be published until something has been added to the section, that is they are 'mandatory fields'.

Box 2.2.b: Sections of a Cochrane review

<p>Title*</p> <p>Review information:</p> <p> Authors*</p> <p> Contact person*</p> <p> Dates*</p> <p> What's new</p> <p> History</p> <p>Abstract:</p> <p> Background*</p> <p> Objectives*</p> <p> Search methods*</p> <p> Data collection and analysis*</p>
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Results*
Authors' conclusions*

Plain language summary:

Plain language title*
Summary text*

The review:

Background*

Objectives*

Methods:

Criteria for selecting studies for this review:

Types of studies*

Types of participants*

Types of interventions*

Types of outcome measures*

Search methods for identification of studies*

Data collection and analysis*

Results:

Description of studies*

Risk of bias in included studies*

Effects of interventions*

Discussion*

Authors' conclusions:

Implication for practice*

Implication for research*

Acknowledgements

References:

References to studies:

Included studies

Excluded studies

Studies awaiting classification

Ongoing studies

Other references:

Additional references

Other published versions of this review

Tables and figures:

Characteristics of studies:

Characteristics of included studies (*includes 'Risk of bias' tables*)

Characteristics of excluded studies

Characteristics of studies awaiting assessment

Characteristics of ongoing studies

'Summary of findings' tables

Additional tables

Figures

Supplementary information:

Data and analyses

Appendices

Feedback:

Title

Summary

Reply

Contributors

About the article:

Contributions of authors

Declarations of interest*

Differences between protocol and review

Sources of support:

Internal sources

External sources

Published notes

2.3 Logistics of doing a review

2.3.1 Motivation for undertaking a review

A number of factors may motivate authors to undertake a systematic review. For example, reviews can be conducted in an effort to resolve conflicting evidence, to address questions where clinical practice is uncertain, to explore variations in practice, to confirm the appropriateness of current practice or to highlight a need for future research. The overarching aim of Cochrane reviews should be to summarize and help people to understand the evidence. They should help people make practical decisions about health care. This aim has important implications for deciding whether or not to undertake a Cochrane review, how to formulate the question that a review will address, how to develop eligibility criteria to guide study inclusion based on the review question, how to develop the protocol and how to present the results of the review.

2.3.2 Planning the topic and scope of a review

Some important points to consider when planning a review and developing a protocol are as follows.

- Review questions should address the choices (practical options) people face when deciding about health care.
- Reviews should address outcomes that are meaningful to people making decisions about health care.
- Review authors should describe how they will address adverse effects as well as beneficial effects.
- The methods used in a review should be selected to optimize the likelihood that the results will provide the best current evidence upon which to base decisions, and should be described in sufficient detail in the protocol for the readers to fully understand the planned steps.
- It is important to let people know when there is no reliable evidence, or no evidence about particular outcomes that are likely to be important to decision makers. No evidence of effect should not be confused with evidence of no effect.
- It is not helpful to include evidence for which there is a high risk of bias in a review, even if there is no better evidence. See Chapter 8 for a more detailed discussion of bias.
- Similarly, it is not helpful to focus on trivial outcomes simply because those are what researchers have chosen to measure in the individual studies (see Chapter 5).
- So far as is possible, it is important to take an international perspective. The evidence collected should not be restricted by nationality or language without good reason, background information such as prevalence and morbidity should where possible take a global view, and some attempt should be made to put the results of the review in a broad context.

2.3.3 Registering a protocol

The first step in the review process is to agree on a review topic with a Cochrane Review Group (CRG). The topics covered by each of the 52 CRGs are described in their scope, published in the *CDSR*. Many CRGs will have developed priorities for reviews of importance, and will require the completion of a 'title registration form'. A title will be registered, possibly after discussion among the CRG editors, and the review authors will be invited to submit a protocol. Once a protocol has been completed it will be sent to the CRG for editors and staff at the editorial base to peer review. When they are satisfied with the protocol (this may take several iterations) they will include it in the CRG's module for publication and dissemination in the *CDSR*. Editors and authors should not include a protocol in a module unless there is a firm commitment to complete the review within a reasonable time frame and to keep it up to date once it is completed.

It is Cochrane Collaboration policy that protocols that have not been converted into full reviews within two years should generally be withdrawn from the *CDSR*. If a protocol is withdrawn for any reason other than it being superseded by a review, a withdrawal notice should be published in *CDSR* for one issue. Thereafter, information on the withdrawal of the protocol should be noted in the CRG's module.

2.3.4 The review team

2.3.4.1 The importance of a team

It is essential that Cochrane reviews be undertaken by more than one person. This ensures that tasks such as selection of studies for eligibility and data extraction can be performed by at least two people independently, increasing the likelihood that errors are detected. If more than one team expresses an interest in undertaking a review on the same topic, it is likely that a CRG will encourage them to work together.

Review teams must include expertise in the topic area being reviewed and include, or have access to, expertise in systematic review methodology (including statistical expertise). First-time review authors are encouraged to work with others who are experienced in the process of systematic reviews and to attend training events organized by the Collaboration (see Section 2.3.6). The Cochrane Collaboration is committed to user-involvement in principle (the tenth principle of the Collaboration is enabling wide participation, see Chapter 1, Box 1.1a) and encourages review authors to seek and incorporate the views of users, including consumers, clinicians and those from varying regions and settings in the development of protocols and reviews. Where a review topic is of particular relevance in a region or setting (for example reviews of malaria in the developing world), involvement of people from that setting is encouraged.

2.3.4.2 Consumer involvement

The Cochrane Collaboration encourages the involvement of healthcare consumers, either as part of the review team or in the editorial process. Consumer involvement helps ensure that reviews:

- address questions that are important to people;
- take account of outcomes that are important to those affected;
- are accessible to people making decisions; and
- adequately reflect variability in the values and conditions of people, and the circumstances of health care in different countries.

Relatively little is known about the effectiveness of various means of involving consumers in the review process or, more generally, in healthcare research (Nilsen 2006). However, the Collaboration supports consumer involvement in principle. This is based on our principles, good logic, and evidence that the views and perspectives of consumers often differ greatly from those of healthcare providers and researchers (Bastian 1998).

Consumers are participating in the development of protocols and reviews in the following ways:

- supporting CRGs to establish priority lists for reviews;
- co-authoring reviews;
- contributing to a consumer consultation during protocol and review development; and
- peer reviewing protocols and reviews.

Whenever consumers (or others) are consulted during the development of a protocol or review, their contribution should be acknowledged in the Acknowledgements section of the protocol or review.

Where input to the review is more substantive formal inclusion in the list of review authors for citation may also be appropriate, as it is for other contributors (see Chapter 4, Section 4.2.2),

2.3.4.3 Advisory groups

Systematic reviews are likely to be more relevant to the end user and of higher quality if they are informed by advice from people with a range of experiences, in terms of both the topic and the methodology (Khan 2001, Rees 2004, Thomas 2004). As the priorities of decision makers and consumers may be different from those of authors, it is important that authors address the questions of importance to stakeholders and include relevant interventions, outcomes and populations. It may be useful to form an advisory group of people, including representation of relevant stakeholders, with relevant interests, skills and commitment. This may be of greater importance in reviews anticipated to be of high impact or for reviews of complex interventions relevant to diverse settings. [Box 2.3.a](#) outlines an example of where an advisory group was used to benefit a review.

The input of the advisory group will need to be coordinated by the review team to inform key review decisions. The Effective Public Health Practice Project, Canada, has found that six members can cover all areas and is manageable for public health reviews (Effective Public Health Practice Project 2007). However, the broader the review, the broader the experience required of advisory group members.

It is important to consider the needs of resource-poor countries in the review process. To increase the relevance of systematic reviews, authors could also consult people in developing countries to identify priority topics on which reviews should be conducted (Richards 2004). It may also be important to include vulnerable and marginalized people in the advisory group (Steel 2001) in order to ensure that the conclusions regarding the value of the interventions are well informed and applicable to all groups in society.

Terms of reference, job descriptions or person specifications for an advisory group may be developed to ensure there is clarity about the task(s) required. Examples are provided in briefing notes for researchers (Hanley 2000) or at the INVOLVE web site (www.invo.org.uk). Advisory group members may be involved in one or more of the following tasks:

- making and refining decisions about the interventions of interest, the populations to be included, priorities for outcomes and, possibly, subgroup analyses;
- providing or suggesting important background material that elucidates the issues from different perspectives;
- helping to interpret the findings of the review; and
- designing a dissemination plan and assisting with dissemination to relevant groups.

Box 2.3.a: An example of the benefits of using an advisory group in the planning process

A review of HIV prevention for men who have sex with men (Rees 2004) employed explicit consensus methods to shape the review with the help of practitioners, commissioners and researchers. An advisory group was convened of people from research/academic, policy and service organizations and representatives from charities and organizations that have emerged from and speak on behalf of people living with, or affected by, HIV/AIDS. The group met three times over the course of the review.

The group was presented with background information about the proposed review: its scope,

conceptual basis, aims, research questions, stages and methods. Discussion focused on the policy relevance and political background/context to the review; the eligibility criteria for studies (interventions, outcomes, subgroups of men); dissemination strategies; and timescales. Two rounds of voting identified and prioritized outcomes for analysis. Open discussion identified sub-groups of vulnerable men. A framework for characterizing interventions of interest was refined through advisory group discussions.

The review followed this guidance by adopting the identified interventions, populations and outcomes to refine the inclusion criteria, performing a meta-analysis as well as subgroup analyses. The subsequent product included synthesized evidence directly related to health inequalities.

2.3.5 Cochrane software for review authors and editorial bases of Cochrane Review Groups

To support the preparation and editorial oversight of Cochrane reviews, The Cochrane Collaboration uses the Cochrane Information Management System (IMS). The IMS consists of two main components, the review writing software, Review Manager (RevMan) and a central server for managing documents and contact details, Archie. The IMS functions as the electronic infrastructure of The Cochrane Collaboration and facilitates efficient collaboration between staff at editorial bases of CRGs and their author teams, often working in different continents.

RevMan is a mandatory tool for Cochrane authors to use when preparing and maintaining protocols and reviews in the format described in Section 2.2. The software is developed through a continuing process of consultation with its users and Cochrane methodologists, to support standards and guidelines for Cochrane reviews, and provides improved analytic methods, 'online' help and error checking mechanisms.

As well as supporting the preparation of a Cochrane Intervention review, RevMan supports the preparation of Cochrane Methodology reviews, Cochrane Diagnostic test accuracy reviews, and Overviews of reviews (see Chapter 22).

RevMan is free to use for authors preparing a Cochrane review and by academic institutions. Commercial companies may use the software if they purchase a license. Technical support is only provided to Cochrane authors who have registered their reviews with a CRG.

While RevMan is used for preparing and editing reviews, Archie is used for storing drafts and published versions of reviews. Storing all relevant versions of a review centrally, the system facilitates access to the latest published version of a review when it is due for an update. Through Archie, authors can also view previous versions of a review, and compare two versions of the same review to identify changes introduced from one version to the next. In addition, authors maintain their contact details and access the contact details of their co-authors and their editorial base. Cochrane review authors can get access to Archie by contacting the editorial base of their CRG.

The IMS is developed and maintained by the Nordic Cochrane Centre. The ongoing development of the IMS is overseen by the Cochrane Information Management System Group with guidance from the relevant advisory groups. More information about The Cochrane Collaboration's software, such as the latest versions and planned developments, is available at the IMS web site: www.cc-ims.net.

2.3.6 Training

It is important to ensure that those contributing to the work of the Collaboration have the knowledge, skills and support that they need to do a good job. Training may be needed by review authors, editors, criticism editors, peer reviewers, CRG Co-ordinators and Trials Search Co-ordinators, hand-searchers, trainers and users of Cochrane reviews. We focus here on the training needs of review authors and editors to help them to prepare and maintain high quality reviews.

While some review authors who join a CRG have training and experience in conducting a systematic review, many do not. In addition to the training materials and support to authors provided by many CRGs, Cochrane Centres are responsible for working with Methods Groups to develop training materials based on the *Handbook* and for organizing training workshops for members of CRGs. Each CRG is responsible for ensuring that review authors have adequate training and methodological support. Training materials and opportunities for training are continually developed and updated to reflect the evolving needs of the Collaboration and its standards and guidelines.

Training for review authors is delivered in many countries by Cochrane Centres, Methods Groups and CRGs. Training timetables are listed on The Cochrane Collaboration's training web site (www.cochrane.org/resources/training.htm), along with various training resources, including The Cochrane Collaboration's Open Learning Material. Details of Cochrane Centres can be found on www.cochrane.org.

2.3.7 Editorial procedures of a Cochrane Review Group

The editorial team of the CRG is ultimately responsible for the decision to publish a Cochrane review on their module. This decision will be made following peer review and appropriate revisions by the review authors. This may take several iterations.

The editorial team of each CRG is responsible for maintaining a module, which includes information about the Group, including their editorial processes. Any specific methods used by the CRG, beyond the standard methods specified in the *Handbook*, should be documented in their module, including:

- methods used to review protocols;
- standard eligibility criteria for considering studies for inclusion in reviews;
- search methods and specific search strategies used to develop and maintain the Specialized Register used by the CRG, and method of distributing potentially relevant citations or full-text reports to authors;
- additional search methods that authors are instructed to use routinely;
- standard methods used to select studies for reviews and any templates for inclusion assessment forms;
- standard criteria or methods beyond the 'Risk of bias' table used to appraise the included studies; and
- standard methods used for data collection and any templates for data extraction forms.

Descriptions of specific additional methods used by each CRG are published as part of the group's module in *The Cochrane Library*. Authors should familiarize themselves with the contents of their Group's module.

2.3.8 Resources for a systematic review

Individual Cochrane reviews are prepared by authors working within CRGs. Each CRG has an editorial team responsible for producing a module of edited reviews for dissemination through the CDSR in *The Cochrane Library*.

Because The Cochrane Collaboration is built around CRGs, it is important that each author is linked with one from the beginning of the process. Besides ensuring that Cochrane reviews are carried out appropriately, this structure reduces the burden placed on individual authors since the editorial teams are responsible for providing most or all of the following types of support:

- conducting systematic searches for relevant studies and coordinating the distribution of potentially relevant studies to authors;
- establishing specific standards and procedures for the CRG; and
- ensuring that authors receive the methodological support they need.

The main resource required by authors is their own time. The majority of authors will contribute their time free of charge because it will be viewed as part of their existing efforts to keep up to date in their areas of interest. In some cases, authors may need additional resources or, at least, be able to justify the amount of time required for a systematic review to colleagues who do not yet understand either what systematic reviews entail, or their importance.

The amount of time required will vary, depending on the topic of the review, the number of studies, the methods used (e.g. the extent of efforts to obtain unpublished information), the experience of the authors, and the types of support provided by the editorial team. The workload associated with undertaking a review is thus very variable. However, consideration of the tasks involved and the time required for each of these might help authors to estimate the amount of time that will be required. These tasks include training, meetings, protocol development, searching for studies, assessing citations and full-text reports of studies for eligibility, assessing the risk of bias of included studies, collecting data, pursuing missing data and unpublished studies, analyzing the data, interpreting the results and writing the review, keeping the review up to date.

A time chart with target dates for accomplishing key tasks can help with scheduling the time needed to complete a review. Such targets may vary widely from review to review. Authors, together with the editorial team for the CRG, must determine an appropriate time frame for a specific review. An example of a time chart with target dates can be found in [Box 2.3.b](#).

Resources that might be required for these tasks, in addition to the authors' time, include:

- searching (identifying studies is primarily the responsibility of the editorial team of the CRG: however, authors may share this responsibility and it may be appropriate to search additional databases for a specific review);
- help for library work, interlibrary loans and photocopying;
- a second author, to assess studies for inclusion, assess the 'risk of bias' of included studies, obtain data and check data entry and analyses;
- statistical support for synthesizing (if appropriate) the results of the included studies;
- equipment (e.g. computing hardware and software);
- supplies and services (long distance telephone charges, internet connection, facsimiles, paper, printing, photocopying, audio-visual and computer supplies);
- office space for support staff; and

- travel funds.

Box 2.3.b: Timeline for a Cochrane review

Month	Activity
1 – 2	Preparation of protocol.
3 – 8	Searches for published and unpublished studies.
2 – 3	Pilot test of eligibility criteria.
3 – 8	Inclusion assessments.
3	Pilot test of ‘Risk of bias’ assessment.
3 – 10	Validity assessments.
3	Pilot test of data collection.
3 – 10	Data collection.
3 – 10	Data entry.
5 – 11	Follow up of missing information.
8 – 10	Analysis.
1 – 11	Preparation of review report.
12 –	Keeping the review up to date.

2.3.9 Seeking funding

Many organizations currently provide funding for priority systematic reviews. These include research funding agencies, those organizations that provide or fund healthcare services, those responsible for health technology assessment and those involved in the development of clinical practice guidelines.

The Collaboration has a policy that neither the preparation of Cochrane reviews nor infrastructure costs of CRGs can be funded through a commercial source or agency with a vested interest in the review (see Section 2.6).

2.4 Publication of Cochrane reviews in print journals and books

Authors may wish to seek co-publication of Cochrane reviews in peer-reviewed healthcare journals, particularly in those journals that have expressed enthusiasm for co-publication of Cochrane reviews. For The Cochrane Collaboration, there is one essential condition of co-publication: Cochrane reviews must remain free for dissemination in any and all media, without restriction from any of them. To ensure this, Cochrane authors grant the Collaboration worldwide licences for these activities, and do not sign over exclusive copyright to any journal or other publisher. A journal is free to request a non-exclusive copyright that permits it to publish and re-publish a review, but this cannot restrict the publication of the review by The Cochrane Collaboration in whatever form the Collaboration feels appropriate. To republish material published in the *CDSR* elsewhere, most particularly in print journals, authors must complete a ‘permission to publish’ form available in the Cochrane Manual (www.cochrane.org/admin/manual.htm), along with an explanation of the procedures to follow.

Authors are strongly discouraged from publishing Cochrane reviews in journals before they are ready for publication in *CDSR*. This applies particularly to Centre directors and editors of CRGs. However,

journals will sometimes insist that the publication of the review in *CDSR* should not precede publication in print. When this is the case, authors should submit a review for publication in the journal after agreement from their CRG editor and before publication in *CDSR*. Publication in print should not be subject to lengthy production times, and authors should not unduly delay publication of a Cochrane review either because of delays from a journal or in order to resubmit their review to another journal.

Journals can also request revision of a review for editorial or content reasons. External peer review provided by journals may enhance the value of the review and should be welcomed. Journals generally require shorter reviews than those published in *CDSR*. Selective shortening of reviews may be appropriate, but there should not be any substantive differences between the review as published in the journal and *CDSR*. If a review is published in a journal, it should be noted that a fuller and maintained version of the review is available in *CDSR*. Typically, this should be done by including a statement such as the following in the introduction: ‘A more detailed review will be published and updated in the *Cochrane Database of Systematic Reviews*’. The reference should be to the protocol for the review published in *CDSR*. A similar statement should be included in the introduction if a review is published in *CDSR* prior to publishing a version of the review in a journal. After a version of a Cochrane review has been published in a journal, a reference to the journal publication must be added under the heading ‘Other published versions of this review’. Authors are also encouraged to add the following statement to versions of Cochrane reviews that are published in journals:

‘This paper is based on a Cochrane review first published [or most recently substantively amended, as appropriate] in The Cochrane Library YYYY, Issue X (see <http://www.thecochranelibrary.com/> for information). Cochrane reviews are regularly updated as new evidence emerges and in response to feedback, and The Cochrane Library should be consulted for the most recent version of the review.’

The following modification of the disclaimer published in *The Cochrane Library* should be added to Cochrane reviews published in journals.

‘The results of a Cochrane review can be interpreted differently, depending on people’s perspectives and circumstances. Please consider the conclusions presented carefully. They are the opinions of review authors, and are not necessarily shared by The Cochrane Collaboration.’

The passage below can be provided to journal editors upon submission of a review for publication, and the letter of submission should be copied to the CRG editorial base for information. This policy and procedure may be new to some journal editors and may require direct discussion with the journal editor. The CRG editorial base should be informed of any problems encountered in this process. The following passage is suggested for inclusion in letters of submission to journal editors:

‘This systematic review has been prepared under the aegis of The Cochrane Collaboration, an international organization that aims to help people make well-informed decisions about healthcare by preparing, maintaining and promoting the accessibility of systematic reviews of the effects of healthcare interventions. The Collaboration’s publication policy permits journals to publish reviews, with priority if required, but permits The Cochrane Collaboration also to publish and disseminate such reviews. Cochrane reviews cannot be subject to the exclusive copyright requested by some journals.’

2.5 Publication of previously published reviews as Cochrane reviews

Most reviews that have been conducted by authors outside of The Cochrane Collaboration (referred to as ‘previously published reviews’ here) require substantial additional work before they can be published as a Cochrane review in *CDSR*. In light of this additional work and substantial differences from the previously published review, the Cochrane review can be considered a new publication. The

previously published version of the review must be referenced in the Cochrane review under the heading 'Other published versions of this review'. However, it is generally not necessary to seek permission from the publisher of the previously published review.

Occasionally a Cochrane review will be similar enough to a previously published review that the only change is in the formatting of the review. In these cases authors should obtain permission from the publisher of the previously published review prior to publishing the review in *CDSR*. If authors are in doubt about whether they should request permission, they are encouraged to do so. This is unlikely to present a problem, provided it is done well in advance of the planned submission to *CDSR*. If it is known in advance that there is interest in publishing in *CDSR* a version of a review already published in a journal, authors should not assign exclusive copyright to the journal (see Section 2.4). The Cochrane Collaboration does not require exclusive copyright. It is therefore not a problem to publish a version of a Cochrane review in a journal after it has been published in *CDSR*, provided it is not called a Cochrane review and that it is acknowledged that it is based on a Cochrane review (see Section 2.4).

2.6 Declaration of interest and commercial sponsorship

Cochrane reviews should be free of any real or perceived bias introduced by the receipt of any benefit in cash or in kind, any hospitality, or any subsidy derived from any source that may have or be perceived to have an interest in the outcome of the review. There should be a clear barrier between the production of Cochrane reviews and any funding from commercial sources with financial interests in the conclusions of Cochrane reviews. Thus, sponsorship of a Cochrane review by any commercial source or sources (as defined above) is prohibited. Other sponsorship is allowed, but a sponsor should not be allowed to delay or prevent publication of a Cochrane review and a sponsor should not be able to interfere with the independence of the authors of reviews in regard to the conduct of their reviews. The protocol for a Cochrane review should specifically mention that a sponsor cannot prevent certain outcome measures being assessed in the review.

These rules also apply to 'derivative products' (containing Cochrane reviews) so that commercial sponsors cannot prevent or influence what would be included in such products. Receipt of benefits from any source of sponsored research must be acknowledged and conflicts of interest must be disclosed in *CDSR* and other publications that emanate from the Collaboration.

The Cochrane Collaboration code of conduct for avoiding potential financial conflicts of interest appears in [Box 2.6.a](#). If a proposal for undertaking a review raises a question of serious conflict of interest, this should be forwarded to the Collaboration's funding arbiter (fundingarbiter@cochrane.org) for review. It is not mandatory to send funding proposals to the local Cochrane Centre or Steering Group prior to accepting them. However, this would be desirable in the cases of restricted donations, or any donation that appears to conflict with the general principle noted above.

It is impossible to abolish conflict of interest, since the only person who does not have some vested interest in a subject is somebody who knows nothing about it (Smith 1994). Financial conflicts of interest cause the most concern, can and should be avoided, but must be disclosed 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 risk of bias in included studies or the interpretation of results) should be disclosed. A common example occurs when a review author is also an author of a potentially eligible study. This should be disclosed in the review and, where possible, there should be an independent assessment of eligibility and risk of bias by a second author with no conflict of interest.

Disclosing a conflict of interest does not necessarily reduce the worth of a review and it does not imply dishonesty. However, conflicts of interest can influence judgements in subtle ways. Authors should let the editors of their Cochrane Review Group know of potential conflicts even when they are confident that their judgements were not or will not be influenced. Editors may decide that disclosure is not warranted or they may decide that readers should know about such a conflict of interest so that they can make up their own minds about how important it is. Decisions about whether or not to publish such information should be made jointly by authors and editors.

To help ensure the integrity and perceived integrity of Cochrane reviews, all authors must sign the relevant statements in the form giving The Cochrane Collaboration permission to publish their review in addition to declarations of interest, and the editorial team of each CRG must also disclose any potential conflict of interest that they might have, both on their module and within relevant reviews.

Box 2.6.a: The Cochrane Collaboration Code of Conduct for Avoiding Potential Financial Conflicts of Interest

General Principle

The essential activity of The Cochrane Collaboration is co-ordinating the preparation and maintenance of systematic reviews of the effects of healthcare interventions performed by individual authors according to procedures specified by The Cochrane Collaboration. The performance of the review must be free of any real or perceived bias introduced by receipt of any benefit in cash or kind, any hospitality, or any subsidy derived from any source that may have or be perceived to have an interest in the outcome of the review. All entities that constitute The Cochrane Collaboration must accept this General Principle as a condition of participation in the organization.

Policy

- (i) Receipt of benefits from any source of sponsored research must be acknowledged and conflicts of interest must be disclosed in the Cochrane Database of Systematic Reviews and other publications that emanate from The Cochrane Collaboration.
- (ii) If an author is involved in a study included in his/her review, this must be acknowledged, as it could be perceived as a potential conflict of interest.
- (iii) If a proposal raises a question of serious conflict of interest, this should be forwarded to the local Cochrane Centre for review (and the Steering Group notified accordingly). If the issue involves a Cochrane Centre, the issue should be referred to the Steering Group.
- (iv) It is not mandatory to send funding proposals to the local Cochrane Centre or Steering Group prior to accepting them. However, such reviews would be desirable in cases of restricted donations, or any donation that appears to conflict with the General Principle.
- (v) The Steering Group should receive (and review at least annually) information about all external funds accepted by Cochrane entities. The Steering Group will use this information to prepare and distribute an annual report on the potential conflicts of interest attendant on The Cochrane Collaboration's solicitation and use of external funds.
- (vi) The Steering Group is considering constituting an Ethics Subgroup to view potential conflicts of interest, to offer recommendations for their resolution, and to consider appropriate sanctions to redress violations of the General Principle.

2.7 Chapter information

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