Policy: conflicts of interest and Cochrane Reviews

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October 2020: This policy was developed in 2014 and applies to all Cochrane Reviews that were registered before the launch of the Cochrane Conflict of Interest Policy for Cochrane Library Content (2020) on 14 October 2020, and any updates where the work began on the update before this date.

March 2020: This policy was developed in 2014 and applies to all Cochrane Reviews until the launch of the new *Cochrane Conflict of Interest Policy for Cochrane Library Content* (October 2020). After the launch of the 2020 policy, the policy set out below will still apply to the following content: protocols being prepared based on new titles registered before the October launch date; protocols for Cochrane Reviews already in progress before the October 2020 launch date; and Cochrane Reviews (including updates) in progress before the October 2020 launch date.

May 2014: Changes to Cochrane's Commercial Sponsorship policy were agreed by the Steering Group in April 2014 and these are reflected below. The policy has two parts: one for Cochrane Reviews (below) and one relating to Cochrane Groups.

1. Introduction

1.1. General principle

While Cochrane has adopted the uniform requirements for declaration of conflicts of interests framework produced by the International Committee of Medical Journal Editors, Cochrane and the *Cochrane Database of Systematic Reviews* (*CDSR*) differ from many journals in two ways: (1) certain types of sponsorship are forbidden; and (2) we ask for disclosure of conflicts of interests at the beginning of a review process (when submitting a Review Proposal Form (title registration form). Such declarations may be managed within the Cochrane Review Group processes or be referred to the Funding Arbiter for discussion and decision-making if there are any doubts about how the policy should be applied.

Independence: Cochrane Reviews must be independent of conflicts of interest associated with commercial sponsorship and should be conducted by people or organisations that are free of such bias.

Free from interference: The process for conducting Cochrane Reviews and the Cochrane groups and contributors responsible from producing Cochrane Reviews should operate free from interference.

Assurance: Users of Cochrane Reviews should be assured that Cochrane Reviews are produced in an independent manner.

See the here for information about the about the role of the Research Integrity Editors and Conflict of Interest (CoI) Panel in the implementation and for clarifications or guidance on funding issues.

1.2. Definition

'Commercial sponsor or source': any for-profit manufacturer or any other for-profit source with a real or potential vested interest in the findings of a specific Cochrane Review.

This definition is not intended to include government departments, not-for-profit medical insurance companies, and health management organisations; nor for-profit companies that do not have real or potential vested interests in Cochrane Reviews (e.g. banks). All funders should be considered, however, when assessing any declared conflicts of interests from authors or potential authors.

2. Authors of Cochrane Reviews

All links between Cochrane authors and commercial sponsorship or sources must be disclosed, so that Cochrane users have confidence in the process for the disclosure and management of potential commercial conflicts of interest.

When completing a Review Proposal Form (title registration form), Cochrane authors should declare their conflicts of interest using Cochrane's disclosure of potential conflicts of interest form.

Commercial interests that should be declared include, but are not limited to: income from private clinical practice (if relevant to the topic); ownership of stocks related to industry; legal advice related to the topic; consultancies; honoraria; fellowships; speaker's fees; involvement in primary research in the subject area of their review; funding for primary research in the subject area of the review; and any other interests that others may judge relevant. Employment in a clinical speciality relevant to the Cochrane Review should be declared in the interests of transparency, but this does not prevent an individual from being a review author, including taking on the role of lead (first) author. In addition, for calculating whether a team has a majority of non-conflicted authors, if this was the only declared interest, an author who was employed in a clinical speciality would count as non-conflicted.

Authors of Cochrane Reviews must complete a 'declarations of interest' form before publication of the protocol, review, update, and any amendment resulting in a new citation, and the declarations should be reviewed by the Managing Editor and Co-ordinating Editor as appropriate.

2.1. Disclosure of potential conflicts of interest by authors

The from used by Cochrane is based on the ICMJE Form for Disclosure of Potential Conflicts of Interest.

This form has five sections, as described in *Table 1*. Where there are potential conflicts of interest, authors must declare this information and provide details.

Table 1. Sections in Cochrane's disclosure of potential conflicts of interest form[a]

Section	Heading	Content
1	Identifying information	This information, including the Cochrane Protocol or Review title, Author(s), Cochrane Review Group, and Cochrane Review ID, is added automatically.
2	The work under consideration for publication	This section asks for information about the work that you have submitted for publication. The time frame for this reporting is that of the work itself, from the initial conception and planning to the present. The requested information is about resources that you received, either directly or indirectly (via your institution), to enable you to complete the work. Checking "No" means that you did the work without receiving any financial support from any third party -- that is, the work was supported by funds from the same institution that pays your salary and that institution did not receive third-party funds with which to pay you. If you or your institution received funds from a third party to support the work, such as a government granting agency, charitable foundation or commercial sponsor, check "Yes". Then complete the appropriate boxes to indicate the type of support and whether the payment went to you, or to your institution, or both.
3	Relevant financial activities outside the submitted work	This section asks about your financial relationships with entities in the bio-medical arena that could be perceived to influence, or that give the appearance of potentially influencing, what you wrote in the submitted work. You should provide details of any financial relationships or activities that are relevant to the review. Financial interests are considered relevant if the payment comes from a commercial organization that has a financial interest in the topic of the Cochrane Library content. This means that the commercial organization has developed (or is known to be developing), or distributed (anywhere in the world), an intervention or potential comparator related to the topic of the review. Report all sources of revenue paid (or promised to be paid) directly to you or your institution on your behalf over the 36 months prior to submission of the work. This should include all monies from sources with relevance to the submitted work, not just monies from the entity that sponsored the research. Please note that your interactions with the work's sponsor that are outside the submitted work should also be listed here. If there is any question, it is usually better to disclose a relationship than not to do so. For grants you have received for work outside the submitted work, you should disclose support ONLY from entities that could be perceived to be affected financially by the published work, such as drug companies, or foundations supported by entities that could be perceived to have a financial stake in the outcome. Public funding sources, such as government agencies, charitable foundations or academic institutions, need not be disclosed. For example, if a government agency sponsored a study in which you have been involved and drugs were provided by a pharmaceutical company, you need only list the pharmaceutical company.
4	Other relationships	Use this section to report other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work.
5	Declarations of interest statement	Use this section to write your declarations of interest statement for inclusion in the review.

[a]Copied directly from the form, which is based on the ICMJE Form for Disclosure of Potential Conflicts of Interest.

2.2. If a potential conflict of interest is declared

On receipt, the relevant Cochrane Review Group will assess whether an author may have a conflict of interest that, as described in this policy, would prohibit them from participating in the review team.

All potentially important conflicts (as described in the paragraphs above) should be referred to the Research Integrity Editors and CoI Panel unless it is clear that the conflicts prohibit the author or team from further involvement (e.g. the author is directly employed by a commercial organisation with an interest in the intervention or holds a patent relating to the intervention) or that the conflicts do not prohibit the author or team from further involvement (e.g., employment in a relevant clinical speciality).

For conflicts other than those related to direct employment, review funding and the holding of patents, there must be a majority of non-conflicted authors (>50%) for any particular review and the lead (first) author must have no conflicts. For example, if two authors in a review team have received travel grants from a commercial interest, there must be at least three other non-conflicted authors and the lead (first) author must have no conflicts.

2.2.1. Payment or services from a third party

Cochrane Reviews cannot be funded or conducted by commercial sponsors or commercial sources with a real or potential vested interest in the findings of a specific review.

2.2.2. Employment

Individuals who are employed by a company that has a real or potential financial interest in the outcome of the Cochrane Review (including but not limited to drug companies or medical device manufacturers), or who hold or have applied for a patent related to the Cochrane Review are prohibited from being Cochrane Review authors. In most cases, employment would be characterised by the affiliation statement made by the author at the title registration, protocol, or review stage of the Cochrane Review. Any questions about what constitutes "employment by a company with a financial interest" should be referred to the Research Integrity Editors and CoI Panel.

Health professionals might wish to evaluate an element of their practice. Any such employment should be declared. This does not prevent someone from being a review author and if this declared conflict is in isolation such an individual is counted as non-conflicted from the perspective of the need to have a majority of non-conflicted authors. Please note that this does not apply to the situation of someone who is evaluating a practice that they have been responsible for developing, or who has a specific commercial interest in disseminating this intervention to other practitioners.

2.2.3. Financial interest or support

Authors who in the last three years have received financial support from commercial sponsors or sources who have a real or potential financial interest in the findings of the Cochrane Review, but who are not covered by the restriction above may need review by the Research Integrity Editors and CoI Panel. Such financial support may include remuneration from a consultancy, grants, fees, fellowships, support for sabbaticals, royalties, stocks from pharmaceutical companies, advisory board membership, or otherwise. In such cases, provided that a majority (>50%) of the review authors and lead author have no relevant conflicts of interests, it may be possible for an author who has a declared interest as listed in the previous sentence to be a Cochrane Review author. If there is any doubt, a referral should be made to the Research Integrity Editors and CoI Panel using the referral form.

2.2.4. Cochrane Review author also an author on a study listed in the review

Cochrane authors who include primary studies (which they had conducted) in their Cochrane Review should declare this in the review in the 'Declarations of interest' section. Authors of primary studies should not extract data from their own study or studies. Instead, another author(s) or an editor(s) should extract these data, and check the interpretation against the study report and any available study registration details or protocol.

Also, the relevant authorship of the primary studies should be disclosed in Cochrane's disclosure of potential conflicts of interest form and therefore the Cochrane Review.

Clarification (October 2014): Authors who have, within the past three years, conducted research funded by commercial sponsors should also declare this, but this will not in isolation constitute a barrier to remaining an author and such authors will count as non-conflicted for the purposes of creating a majority of non-conflicted authors.

2.2.5. Editors or editorial staff authoring Cochrane Reviews from their Cochrane Review Groups

See text in Authorship and contributorship.

3. Editors and editorial staff within Cochrane Review Groups

This section has now been superseded by the Cochrane Conflict of Interest Policy for Cochrane Library Content (2020). Please see Section 6: Rules relating to declared interests (specifically Section 6.2: Rules for Cochrane Review Groups/Networks and the Editorial & Methods Department).

Editors and the editorial team of each Cochrane Review Group must disclose any potential conflict of interest that they might have, both on Cochrane Community website and on the Cochrane Review Group website.

Editors with conflicts of interest with a given product/drug/non-drug intervention should not undertake peer review or be a contact editor, or provide sign-off on a Cochrane Review that involves that product, drug, non-drug intervention, or a competing intervention. Co-ordinating Editors with conflicts of interest should assign the relevant Cochrane Review to another editor within their group.

Editors are prohibited from being employees of a pharmaceutical company or medical device manufacturer.

Employment in a clinical speciality relevant to the Cochrane Review should be declared in the interests of transparency, but this does not prevent an individual from being a review editor.

The conflict of interest declaration statements, updated annually (between 1 January and 31 March), are available for Co-ordinating Editors and for all members of the Cochrane Review Group editorial team.

4. Peer reviewers

Peer reviewers will be asked to declare conflicts of interest using the statement in the peer reviewer forms and checklists (*Figure 1*).

Employment in a speciality relevant to the Cochrane Review should be declared in the interests of transparency, but this does not prevent an individual from being a peer reviewer.

People with a direct financial interest in a particular intervention (for example, employees or shareholders of a company that manufactures an intervention or a direct competitor, or holders of patents or trademarks for an intervention) should not be involved in the peer review of that intervention.

Figure 1. Potential conflicts of interest: peer reviewer statement

Do you have any potential conflict of interest? **Yes (add details below)** **No**
You should declare and describe any present or past affiliations or other involvement in any organisation or entity with an interest in the outcome of the review that might lead to a real or perceived conflict of interest. You should report relationships that were present during the past 36 months, including, but not restricted to, financial remuneration for lectures, consultancy, travel, and whether you are an author of, or contributor to, a study that might be included in this review. You should declare potential conflicts even if you are confident that your judgement is not influenced.
Conflict of interest statement:

5. Funders of Cochrane Reviews

Cochrane Reviews are commonly funded by granting bodies. Granting bodies are not permitted to interfere in the design and release of reviews and that funding is transparently declared:

- Funders of Cochrane Reviews cannot interfere with the design or conduct of reviews.
- Funders cannot delay or prevent the publication of a Cochrane Protocol, Review, or its update.
- Funding for the Cochrane Review should be declared in the 'Sources of support' section of the review, which should include reference to the role of any sponsors.

6. Derivative products

In relation to derivative products, Cochrane will adhere to the conflict of interest policies stated in this policy for Cochrane Reviews and in the policy for Coc hrane Groups (available with Cochrane organizational policies).

7. Royalties from reprints of Cochrane Reviews

Authors and Cochrane Review Groups should not receive royalties on sales of reprints of their Cochrane Reviews, since these sales are likely to have been made to commercial sources and might, therefore, be assumed to be equivalent to direct sponsorship of the Cochrane Review or Group. Therefore, the current policy that royalties on reprint sales go to The Cochrane Collaboration centrally, via the Collaboration Trading Company, will continue.

8. If a Cochrane Review Group has questions about conflict of interest

This section has been updated in line with the new CoI case referral process.

Resources are available on the CoI portal, including FAQs and flowcharts to help guide you through how to apply the CoI Policy.

In addition, the Research Integrity Editors and Conflict of Interest Panel provide advice on implementation of the policy and arbitrate potential policy breaches. More information about the role Research Integrity Editors and Conflict of Interest Panel can be found here.