Conflicts of interest and Cochrane Reviews

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 Funding Arbiter information about the role of the Funding Arbiter and the Funding Arbitration 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 Research 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 form 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

<table>
<thead>
<tr>
<th>Section</th>
<th>Heading</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Identifying information</td>
<td>This information, including the Cochrane Protocol or Review title, Author(s), Cochrane Review Group, and Cochrane Review ID, is added automatically.</td>
</tr>
</tbody>
</table>
| 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 disclose interactions with ANY entity that could be considered broadly relevant to the work. For example, if your article is about testing an epidermal growth factor receptor (EGFR) antagonist in lung cancer, you should report all associations with entities pursuing diagnostic or therapeutic strategies in cancer in general, not just in the area of EGFR or lung cancer.  
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. |
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.

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 Funding Arbiter 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 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 Funding Arbiter.

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 Funding Arbiter 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, at the Funding Arbiter’s discretion, and only where a majority 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.

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.
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 the 'Authorship and contributorship' section.

3. Editors and editorial staff within Cochrane Review Groups

Editors and the editorial team of each Cochrane Review Group must disclose any potential conflict of interest that they might have, both on their module published in the ‘About The Cochrane Collaboration’ database in the Cochrane Library 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

The development of derivative products from Cochrane Reviews is the responsibility of Cochrane Trading Company, supported by the Editor in Chief and the Steering Group.

In developing derivative products, these bodies will adhere to the conflict of interest policies stated in this policy for Cochrane Reviews and in the policy for Cochrane 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

8.1. Funding Arbiter

The Funding Arbiter is accountable to the Cochrane Steering Group and convenes a standing panel of four to give guidance on difficult cases. See the Funding Arbiter page for information about the role of the Funding Arbiter and the Funding Arbitration Panel and to refer a conflict of interest issue.

8.2. Scenarios and actions for editorial teams and authors

A list of potential conflict of interest scenarios and actions is available here.

Implementing the conflict of interest policy in practice

Potential scenarios and actions for editorial teams and authors

Date: March 2015
Authors: David Tovey, Ruth Foxlee, Harriet MacLehose; Cochrane Editorial Unit

In 2014, Cochrane engaged Dr Donna Odierna (University of California San Francisco) to undertake an audit of compliance with Cochrane conflict of interest (COI) policy. In the course of managing the output of that project, the Cochrane Editorial Unit team identified some common examples where application of Cochrane’s policy was either unclear or disputed. We have grouped the examples into five categories:

1. Author employment
2. Other financial support for authors from commercial sponsors or sources
3. Funding or conduct by commercial sponsors or sources
4. Author involvement in the conduct of included trials
5. Review dissemination

All the examples shown below should be considered in the context of the information provided in the Conflicts of interest and Cochrane Reviews section of the Editorial Publishing Policy Resource.
1. A ‘commercial sponsor or source’ is defined as any for-profit manufacturer or any other for-profit source with a real or potential vested interest in the findings of a specific review.

2. Authors who in the last 3 years have received financial support from commercial sponsors or sources with a real or potential financial interest in the findings of the review, should declare these interests at the earliest possible stage in the editorial process. 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, at the funding arbiter’s discretion, and only where a majority of the review authors and lead author have no relevant COIs, it may be possible for an author who has a declared interest as listed in the previous sentence to be a Cochrane review author.

3. The ‘lead author’ is the first named author in the review by-line.

1. Author employment

<table>
<thead>
<tr>
<th>No.</th>
<th>Scenario</th>
<th>Compiles with policy?</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>An author(s) is employed by a commercial sponsor that does not produce the intervention covered in the review nor any competing intervention.</td>
<td>Unclear</td>
<td>Refer to the funding arbiter. The onus is on the author(s) to justify why the employment does not constitute a conflict.</td>
</tr>
<tr>
<td>2</td>
<td>An author(s) is employed by a commercial sponsor that does not produce the intervention covered in the review but does produce a competing intervention.</td>
<td>No</td>
<td>Review cannot proceed with conflicted author(s). If disputed, refer to Funding Arbiter.</td>
</tr>
<tr>
<td>3</td>
<td>An author(s) goes to work for commercial sponsor at some point during the preparation of the protocol or review.</td>
<td>No</td>
<td>Author(s) cannot continue to work on the review. Refer to Funding Arbiter if there is concern that author(s) might have influenced the review such that it should not be published.</td>
</tr>
<tr>
<td>4</td>
<td>An author(s) goes to work for commercial sponsor after the review is published.</td>
<td>Unclear</td>
<td>Seek clarification from the author(s) on whether this move was known prior to publication. If not, no action (compliant) but remove author for update. If the team had knowledge of the move before publication, get details and refer to the Funding Arbiter. The onus is on the author(s) to justify compliance.</td>
</tr>
<tr>
<td>5</td>
<td>An author(s) is employed by an organisation that conducts clinical trials, some of which are funded by a commercial sponsor with an interest in the intervention under investigation.</td>
<td>Yes</td>
<td>None.</td>
</tr>
<tr>
<td>6</td>
<td>An author(s) was paid through a commercially-funded clinical fellowship, with no mention of what restriction applied to the fellowship.</td>
<td>Unclear</td>
<td>In most cases this would be compliant but the Group should request details from the author(s) about what (if any) restrictions applied to the fellowship. If unrestricted, review considered as compliant (although should be declared). If restricted, refer to Funding Arbiter, for example if the terms of the clinical fellowship required completion of the review in question.</td>
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</table>

2. Other financial support for author(s) from commercial sponsors or sources
<table>
<thead>
<tr>
<th>No.</th>
<th>Scenario</th>
<th>Complies with policy?</th>
<th>Action</th>
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<tr>
<td>7</td>
<td>50% or more of the author(s) have ties to commercial sponsors or sources other than being paid directly (e.g. consultancy, grants, fees, fellowships, support for sabbaticals, travel bursary, etc.)</td>
<td>No</td>
<td>Author with this type of conflict cannot be lead author. If not lead author and there are a majority of non-conflicted authors, review can proceed. If half or more of the authors have a conflict, review cannot proceed or should be referred to Funding Arbiter.</td>
</tr>
<tr>
<td>8</td>
<td>Research grants and/or honoraria from commercial sponsors or sources are received by research accounts/groups to which an author(s) belongs, but are not received directly by the author(s).</td>
<td>Unclear</td>
<td>Refer to Funding Arbiter.</td>
</tr>
<tr>
<td>9</td>
<td>An author(s) attended an academic programme sponsored by a commercial sponsor.</td>
<td>Unclear</td>
<td>If actual attendance not funded, as declared by author(s), no action – compliant. If attendance funded, it is considered conflicted, therefore review cannot proceed (if the majority of authors are conflicted). If disputed, refer to Funding Arbiter.</td>
</tr>
<tr>
<td>10</td>
<td>An author(s) is recipient of a fellowship or studentship that is partially funded by a commercial sponsor.</td>
<td>Yes</td>
<td>None.</td>
</tr>
<tr>
<td>11</td>
<td>Only one of several author(s) on the review (i.e. less than 50%) acted as a consultant for the manufacturer of one of the interventions being considered in the review.</td>
<td>Unclear</td>
<td>If not first author(s), no action – compliant. If first author(s), non-compliant and that author(s) cannot be the first author(s).</td>
</tr>
<tr>
<td>12</td>
<td>An author(s) who declares no specific conflicts of interest is the partner of another author(s) on the review who does declare potential conflicts.</td>
<td>Unclear</td>
<td>Refer to Funding Arbiter (if lead author or the majority of authors are conflicted). The onus on author(s) to explain why the conflict declared by partner does not apply.</td>
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3. Funding or conduct by commercial sponsors or sources

<table>
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<tr>
<th>No.</th>
<th>Issue</th>
<th>Complies with policy?</th>
<th>Action</th>
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</thead>
<tbody>
<tr>
<td>13</td>
<td>The original review was supported by an unrestricted educational grant from a commercial sponsor and published in a non-Cochrane journal. It was subsequently converted to a Cochrane Review and then updated without the support of any commercial sponsor.</td>
<td>Yes</td>
<td>None.</td>
</tr>
<tr>
<td>14</td>
<td>The original review was conducted as part of a guideline development project, which</td>
<td>Unclear</td>
<td>If health care comm...</td>
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</table>
was supported through an unrestricted educational grant from a commercial sponsor, and then updated with the support of a health charity.

15
The original review was supported by a commercial sponsor but was subsequently updated without any further support from commercial sources.
Unclear
Refer to Funding Arbiter.

16
The original review was supported through an unrestricted grant from a commercial sponsor; however this grant was used to support research on a range of treatment options, not just those produced by the commercial sponsor. The update is proceeding without commercial support.
Unclear
Refer to Funding Arbiter.

17
Financial support for the original review was provided by a commercial sponsor through an unrestricted educational grant (with no mention of whether the subsequent update was carried out without the support of any commercial sponsor).
Unclear
Refer to Funding Arbiter.

18
One source of support listed is from a commercial organisation but not one with an obvious interest in the intervention being considered.
Unclear
Refer to Funding Arbiter.

4. Author(s) involvement in the conduct of included trials

<table>
<thead>
<tr>
<th>No.</th>
<th>Issue</th>
<th>Complies with policy?</th>
<th>Action</th>
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</thead>
<tbody>
<tr>
<td>19</td>
<td>An author(s) conducted a study that was funded by the manufacturer of intervention(s) being considered.</td>
<td>Yes</td>
<td>None if COI, do not appraise their own studies for inclusion or risk of bias, and are not responsible for data extraction.</td>
</tr>
<tr>
<td>20</td>
<td>An author(s) conducted an investigator-led RCT that evaluated the intervention of interest in a related condition (not the condition considered in the review), for which financial support was provided by a manufacturer of the intervention(s) being considered.</td>
<td>Yes</td>
<td>None if appraising the risk of bias, assess the risk of bias and declare it when it is major.</td>
</tr>
<tr>
<td>21</td>
<td>An author(s) is undertaking a trial that would possibly been eligible for inclusion in the review at the time of writing.</td>
<td>Yes</td>
<td>None if appraising the risk of bias, assess the risk of bias and declare it when it is major.</td>
</tr>
<tr>
<td>22</td>
<td>After the review was published an author(s) received funding from a manufacturer of the intervention(s) being considered to conduct an investigator-led study in that same area.</td>
<td>Yes</td>
<td>None if appraising the risk of bias, assess the risk of bias and declare it when it is major.</td>
</tr>
<tr>
<td>23</td>
<td>An author(s) was involved in the recruitment of patients into clinical trials funded by a commercial organisation.</td>
<td>Yes</td>
<td>None if appraising the risk of bias, assess the risk of bias and declare it when it is major.</td>
</tr>
</tbody>
</table>
commercial sponsor.

5. Review dissemination

<table>
<thead>
<tr>
<th>No.</th>
<th>Issue</th>
<th>Complies with policy?</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>24</td>
<td>The author(s) received funding from a manufacturer of the intervention being considered to disseminate the findings of the original review (with no mention of whether the subsequent update was carried out without any commercial sponsor involvement)</td>
<td>Yes</td>
<td>None if a subsequent update carried out without any commercial sponsor involvement and if the author(s) who received the funding is still in the author team.</td>
</tr>
<tr>
<td>25</td>
<td>On completion of the review, the author(s) received funding for translation of the review from a manufacturer of the intervention(s) under investigation.</td>
<td>Yes</td>
<td>None if a subsequent update carried out without any commercial sponsor involvement and if the author(s) who received the funding is still in the author team.</td>
</tr>
</tbody>
</table>