

Cochrane Conflict of Interest 2019

Community survey results

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1 Brief report

1.1 Introduction

Cochrane's <u>Commercial Sponsorship Policy</u> was last updated in 2014. In March 2018 the Governing Board approved a proposal to revise the current policy and consider including a non-financial interest. This survey is part of programme of work, including:

- 1. a review of conflict of interest (COI) policies of other organizations and selective review of academic research;
- 2. a survey of community members; and
- 3. a series of semi-structured interviews with key stakeholders and COI experts.

This document reports the results of the community survey.

1.2 Methods

The survey had four parts with 20 questions in total:

- 1. general questions;
- 2. questions regarding financial COI;
- 3. questions regarding non-financial COI; and
- 4. questions regarding both financial and non-financial COIs.

The survey was available on SurveyMonkey© between 7 January 2019 and 21 February 2019. The survey link was disseminated to Cochrane Review Groups, Fields and Geographic Groups, Cochrane authors and the Cochrane Consumer Network Executive. We used Cochrane's Twitter and Facebook feeds, the Cochrane Connect newsletter and various internal newsletters to disseminate the survey more widely. We employed a mixed methods approach to analyze quantitative and qualitative responses.

1.3 Quantitative analysis

A total of 970 individuals completed the COI survey.

- 58% of respondents identified themselves primarily as people involved in producing <u>The Cochrane</u> <u>Library</u> content and 28% identified as users of Cochrane content. Only 6% said they had no association with Cochrane. <u>Full results of Question 1</u>
- 2. 45% of responses were from people working in academic institutions and 27% were from people working in healthcare organizations. <u>Full results of Question 2</u>
- 3. More than 85% of respondents came from Europe and North America, with 26% coming from the UK. <u>Full results of Question 3</u>
- 4. 49% of respondents said that when a Cochrane author's home institution received financial support from a commercial organization (and the author had no control over how that money was used and did not personally benefit from it) this was not a financial COI and 40% said it this was a conflict. <u>Full</u> results of Question 4
- 5. 60% of respondents said that Co-ordinating Editors of Cochrane Review Groups (CRGs) could not remain in post if they had accepted financial payments of any type from commercial organizations.

This response did not differ according to whether respondents were involved in producing Cochrane content or not. <u>Full results of Question 5</u>

- 6. 67% of respondents indicated that payments made to authors from 'not-for-profit' organizations should be treated the same as payments from 'for-profit' organizations. The absence of a definition of 'not-for-profit' may have affected this response. <u>Full results of Question 6</u>
- 7. 63% of respondents believed that health professionals should declare their profession as an interest, with more non-Cochrane respondents stating that this was important. <u>Full results of Question 7</u>.
- 65% of respondents believed that being a health professional should not be a barrier to being a Cochrane Review author, although 19% respondents did not want them to be the lead author. <u>Full</u> results of <u>Question 8</u>
- 9. 67% of respondents thought it was acceptable for review authors to have participated in clinical trials that are included in their review as long as they did not extract the data or assess the risk of bias in their own study. However, there may have been some ambiguity about the use of the term 'participated', with respondents interpreting the term differently. <u>Full results of Question 9</u>
- 10. 73% of respondents said that a researcher who had worked on an industry-funded trial that focussed on the intervention(s) being assessed in a Cochrane Review should NOT be allowed to be the lead author on the review. <u>Full results of Question 10</u>
- 11. 44% of respondents said that a review author who has worked on an industry-funded trial that uses the intervention being reviewed should NOT be allowed to be an author on a Cochrane Review at all. There appear to be concerns about the influence an industry-funded trial author could have on a Cochrane Review and this could be affected by the type of funding, the type of industry and the author's role in the trial. <u>Full results of Question 11</u>
- 12. 52% of respondents believed that review authors should declare any previously published reviews or opinion pieces in the topic area of the review. The value of clinical expertise versus the need for transparency was highlighted in the many free-text comments. <u>Full results of Question 12</u>
- 13. 60% of respondents said that someone could still be a Cochrane author if they had previously published on the topics addressed in a Cochrane Review, with similar acknowledgement of the tension between inclusivity and the need for transparent declarations. <u>Full results of Question 13</u>
- 14. 61% of respondents believed that the current policy of requiring the lead author and the majority of the author team of Cochrane Reviews to have no **financial** conflicts of interest was acceptable and 24% stated this was too lenient. <u>Full results of Question 14</u>
- 15. 51% of respondents believed that it was acceptable for the lead author and a majority of the team to have no **non-financial** conflicts of interest, while 36% felt that this addition would be too strict. There was no comments option for this question. <u>Full results of Question 15</u>
- 16. 83% of respondents said that the last author should be subject to the same conflict of interest policy restrictions as the first/lead author. <u>Full results of Question 16</u>

- 17. 60% of respondents said that relevant financial and non-financial COIs for close personal relationships (e.g. partner or close family member) that could influence the review should be declared and 33% said they should not. The difficulty of checking such declarations was noted. <u>Full results of Question 17</u>
- 18. 43% of respondents said that peer reviewers who have declared a relevant COI should be prevented from commenting on a Cochrane Review and 46% said they should not. Free-text responses highlighted the need to use peer reviewers with sufficient expertise, but also the need to publish declarations alongside the comments. <u>Full results of Question 18</u>
- 19. 40% of respondents selected three years as the most appropriate time period for declaring relevant interests before the publication of the review protocol, through to publication of the review, and 32% selected five years. There was little support for the other time frames. <u>Full results of Question 19</u>
- 20. Many respondents gave additional COI examples and feedback on matters such as how flexible Cochrane should be, specific things that Cochrane can do, and what counts as a COI in this context. <u>Full results of Question 20</u>

1.4 Qualitative analysis

Many respondents took the opportunity to provide detailed feedback (over 1300 free-text comments), which suggests that the policy issues being considered could not easily be reduced to simple 'yes/no' propositions. In addition to providing insights into specific policy issues, the responses revealed a remarkable degree of overall consistency in terms of the attitudes expressed and practical strategies recommended. The broad themes that emerged in the qualitative analysis are summarised below and can be applied to any question about who should and should not be able to work on a Cochrane Review.

1.4.1 Attitudes

Respondents emphasised the importance of acknowledging unavoidable practical realities and of being alert to risks, but at the same time not being excessively idealistic. The most common concern was that an excessively stringent policy could lead to the unwarranted exclusion of experts' contributions to Cochrane publications. It was noted that the very experts that Cochrane needs are the same people who are likely to have external interests. These experts were seen to bring invaluable insights into:

- 1. the realities of clinical practice;
- 2. rare diseases; and
- 3. technicalities relevant to the review.

Other things that were noted were:

- 1. the unavoidable necessity for interactions that can lead to COI (e.g. that many trials would not be funded at all if they were not funded by industry);
- 2. how difficult it can be to measure and/or judge the degree to which people are influenced;
- 3. how difficult it can be to institute strategies to manage COI;
- 4. excessive exclusion of potential authors may be contrary to the norms and values of science.

1.4.2 General approaches to management

Respondents strongly emphasised the importance of nuance in Cochrane's COI policy. Appropriate responses to policy issues were seen to depend on:

- 1. the directness of the link between the topic of the author/peer reviewer's interest and the topic of the review being written;
- 2. the degree to which an author/peer reviewer is likely to be personally invested in a particular outcome of a review (financially, intellectually or otherwise), including how likely an author/peer reviewer is to benefit from a particular review outcome;
- 3. the strength of the author/peer reviewer's opinions on the issue; whether they are or have been 'advocates';
- 4. the precise nature of any organization that might have an influence on the author/peer reviewer, including:
 - a. whether it is commercial or 'not-for-profit' (although the need for scepticism was expressed with respect to the latter);
 - b. whether they have a specific interest in the outcome of a review;
 - c. how they relate to the author or peer reviewer including:
 - i. whether these relationships are financial, 'in kind' (e.g. providing study drugs) or non-financial;
 - ii. if financial, the size of the contribution;
 - iii. the degree and type of influence that the external organization has over an author or reviewer;
 - iv. the strength of relationships;
 - v. the timing of relationship/influence (also noted to be arbitrary)
 - d. the influence that the Cochrane contributor will have over the whole process of producing Cochrane content;
 - e. the role that he/she will play in the review process (both officially, e.g. as lead author, and unofficially);
 - f. the centrality or otherwise of their 'interest' to the review (e.g. if a trial in which they were involved is one of many).

Another general point about management that was frequently made was that there needs to be a degree of flexibility and room for case-by-case assessment (instead of, or alongside, any predefined rules). There were, however, also a few calls for 'clear rules' that are easy to apply.

1.4.3 Specific management strategies

Transparency – particularly in the form of declaration of interests – was seen to be extremely important. This was seen to entail not only labels, but also explanations, so that the significance of what was being declared could be understood. It was also suggested that there might be a repository for declarations. However, some concern was expressed that overly detailed declarations might obscure more important interests and make interpretation difficult.

Other management strategies that were suggested were:

- 1. processes for discourse and collective assessment of influences and interests (i.e. going beyond mere declaration);
- 2. balancing strategies so that influences and interests do not have as much of an impact;
- 3. limits to the roles that those who have COIs can take on (some emphasised that any exclusions should be temporary) including:

- a. what parts of a Cochrane Review they can/cannot conduct;
- b. what roles they can/cannot play in any authorship team;
- 4. over-arching peer- and editorial- review processes so that the effects of influences and COIs can be monitored and managed;
- 5. open selection processes for authors/peer-reviewers (especially for very contentious reviews);
- 6. sanctions for non-compliance with other management strategies (e.g. with declarations).

1.4.4 Conceptual issues

Scattered throughout the free-text responses were questions about what does and does not 'count' as a COI and how COIs relate to other relevant concepts, such as bias. There were mixed views about how liberally the concept of COI should be applied.

1.5 Overall conclusions

There was a good response to the COI survey from those who create and consume Cochrane content. Respondents appeared to be particularly concerned about the role of trialists in Cochrane Reviews, the influence of the last author, and the importance of CRG Co-ordinating Editors being free of all conflicts. These survey results for all questions will be considered, along with other information, in the revision of Cochrane's COI policy.

2 Detailed report

2.1 Acknowledgements

We were fortunate to be assisted by researchers at the University of Sydney for the qualitative analysis of survey results. We would like to thank Associate Professor Wendy Lipworth, a bioethicist with an interest in COI, and Dr Riikka Prattes, an experienced post-doctoral qualitative researcher, for analyzing the free-text responses, with supervision from Angela Webster.

2.2 Background

Cochrane currently has a strong <u>Commercial Sponsorship Policy</u> which not only requires interests to be declared, but also rules that some conflicts will prevent authors from conducting Cochrane Reviews. Nevertheless, cases referred to the <u>Cochrane Funding Arbiter</u> indicate that authors and CRGs are sometimes unclear about when accepting financial support from a commercial organization is problematic, and audits conducted in 2014 and 2017 showed inconsistent adherence to the policy. There has also been widespread discussion about the role of non-financial (i.e. academic, professional and personal) declarations of interest and the need for a policy to address these. The current policy was last updated in May 2014, following a consultation exercise. In March 2018 the Governing Board approved a project to revise the policy and develop a non-financial conflict of interest (COI) policy. An <u>editorial</u> in the Cochrane Library described the project, which includes an organizational policy review, semi-structured interviews with key stakeholders and COI experts, along with the survey findings set out below.

2.3 Methods

2.3.1 Survey structure

The questions were structured around the existing Cochrane commercial (financial) policy, industry standards, and any differences between the two. We also collected some demographic information about respondents.

The survey was designed to take no longer than 15 minutes and largely contained closed questions accompanied by open text fields for further comment. It was created using SurveyMonkey© software and consisted of four parts:

- 1. general questions;
- 2. questions regarding financial COI;
- 3. questions regarding non-financial COI; and
- 4. questions regarding both financial and non-financial COIs.

The survey ran from 7 January 2019 until 21 February 2019 (45 days) and was accessed using a weblink (see section 4.3). Responses were anonymous. Questions about the survey or the COI project generally could be sent to a dedicated COI survey email which was monitored for the duration of the survey.

2.3.2 Pilot surveys

In December 2018, we ran three pilots to confirm that the survey could be completed within 15 minutes and ensure that the questions were comprehensible. The first pilot was internal only. The second engaged four members of the Consumers' Network Executive, the COI Project Team and Project Board (7 responses). The third and final pilot involved the Funding Arbitration Panel and Cochrane Council

members (11 responses).

2.3.3 Dissemination of survey link

It was important that the survey was completed by both those who create content for Cochrane and those who use it. Cochrane staff, Cochrane authors, healthcare consumers, clinicians, guideline developers, policymakers and research funders were all encouraged to give their opinions. There were two rounds of dissemination, initially in January and again at the beginning of February.

Cochrane's Knowledge Translation Department disseminated the survey using Cochrane's Twitter and Facebook feeds and featured it in the <u>Cochrane Community newsletter and various other internal newsletters</u>. Cochrane's Consumer Network Executive also sent the survey link to its 1500 members. Emails were sent out twice to Cochrane Geographic Centres, Review Groups (CRGs), Fields, Methods Groups and authors. We were very keen to get feedback from Cochrane authors and were helped by some CRGs posting the survey link on their websites and disseminating it via their newsletters. Personal emails were sent to contacts in regions where we believed there was likely to be under-representation, for example Africa and Far East Asia.

2.3.4 Analysis of survey

The quantitative and qualitative survey data for questions 2 to 20 are presented together. By integrating qualitative analysis of the free-text responses we were able to build a more nuanced picture of the survey findings than would have been possible by examining quantitative responses alone. This qualitative analysis helped, in some cases, to shed light on questions that may have been understood in a way that was not anticipated, and therefore produced apparently anomalous results.

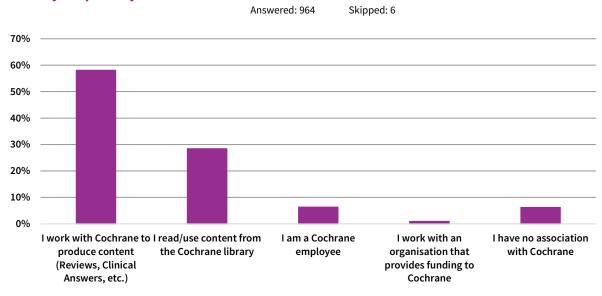
For each question, free-text interview responses were analyzed inductively by Associate Professor Wendy Lipworth and Dr Riikka Prattes, supervised by Angela Webster, to produce themes, with explanations and illustrative quotes. Related themes were organized into categories and abstracted into concepts.

2.4 Results

A total of 970 individuals completed the COI survey, taking an average of 11 minutes to complete it, with an 85% completion rate once started. Around 12% of the respondents skipped questions, suggesting perhaps that they were curious about the survey and wanted to take a look without answering the questions, or alternatively that they did not understand the questions. Up to 17% of the responses to individual questions were answered using the 'Other' category, with comments provided. The survey included 14 questions with free-text responses, which received from 37 to 199 responses each, giving a total of 1333 responses that contributed to the qualitative analysis.

2.4.1 Question 1

What is your primary association with Cochrane?



Answer choices	Responses	
I work with Cochrane to produce content (reviews, Clinical Answers, etc.)	58.09%	560
I read/use content from the Cochrane Library	28.42%	274
I am a Cochrane employee	6.33%	61
I work with an organization that provides funding to Cochrane	0.93%	9
I have no association with Cochrane	6.22%	60
TOTAL		964

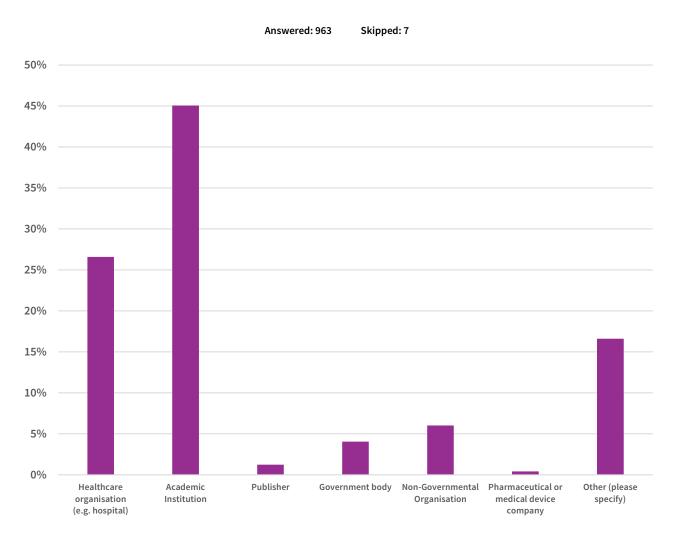
Comments

More than half of the respondents (58%, 560/964) identified themselves as people involved in producing Cochrane content. It was important to the project team that the opinions of this group of stakeholders were properly represented.

We have analyzed the survey data according to those that 'produce content' and 'users' to determine if there was a difference between the answers to the individual COI survey questions. This information is presented for each question. <u>Return to summary</u>

2.4.2 Question 2

What is your primary place of work?



Answer choices	Responses	
Healthcare organization (e.g. hospital)	26.58%	256
Academic institution	45.07%	434
Publisher	1.25%	12
Government body	4.05%	39
Non-governmental organization	6.02%	58
Pharmaceutical or medical device company	0.42%	4
Other (please specify)	16.61%	160
TOTAL		963

Comments

A total of 45% (434/963) of the respondents worked in academic institutions, and 27% (256/963) worked in healthcare organizations. A further 17% (160/963) identified themselves as 'Other' (see below). Amongst this group the most common category was patients (27%, 45/160), followed by retired people (14%, 23/160), including six retired medical doctors. <u>Return to summary</u>

Table: Analysis of 'Other' category in COI survey for primary place of work

Work (self-described)	Respons	ses
Patient*	28%	45
Retired**	14%	23
Cochrane***	7%	11
Private practice ****	10%	16
Academic	8%	13
Non-governmental organization, including charity, professional medical organization, medical association, medical specialty society	7%	11
Hospital-based research institute, UK charity providing accredited health information, not-for-profit research institution	0%	
wно	1%	2
Health Technology Assessment organization	1%	2
News media	2%	3
Other with no clear category e.g. N/A, remote working, spiritual, uni. student etc.	22%	34
TOTAL		160

*Includes patient advocates, four consumers – four acting as advocates, three ME/CFS patients, one MESH ban campaigner

** Includes six retired medical doctors

*** Includes five from Cochrane Centres, two CET

**** Includes one lawyer and one from private company not related to medicine

2.4.3 Question 3

In which country do you live?

Answer choices		Responses
United Kingdom	26.02%	249
USA	9.82%	94
Canada	9.30%	89
Australia	7.63%	73

Germany	4.81%	46
Italy	3.97%	38
Spain	3.97%	38
Denmark	3.24%	31
The Netherlands	2.51%	24
Brazil	2.19%	21
Ireland	1.67%	16
Chile	1.57%	15
Belgium	1.36%	13
France	1.36%	13
Norway	1.25%	12
Colombia	1.15%	11
New Zealand	1.15%	11
Russia	1.15%	11
Switzerland	1.15%	11
Argentina	1.04%	10
Malaysia	1.04%	10
Sweden	0.94%	9
People's Republic of China	0.84%	8
Mexico	0.84%	8
Portugal	0.84%	8
India	0.73%	7
Japan	0.73%	7
Croatia	0.52%	5
Finland	0.52%	5
Israel	0.52%	5
South Africa	0.52%	5

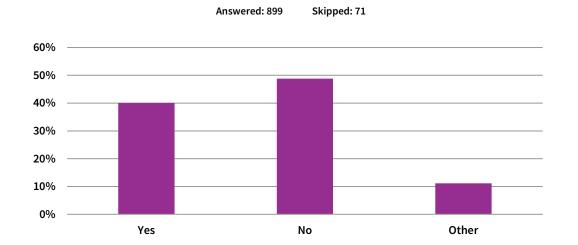
Comments

Countries from which fewer than five responses were received are not shown in the table above. More than 85% of respondents came from Europe and North America. Of these, 26% (240/970) were from the UK, which is similar to the proportion of Cochrane members overall who are based in the UK (24%). The proportion of responses from the USA (10%), Canada (9%) and Australia were similar – 10%, 9% and 8% respectively. These proportions also align quite closely with the proportion of Cochrane members who are based in these countries – USA 989/11,592 (9%); Canada 764/11592 (7%) and Australia 10% (1207/11,592).

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2.4.4 Question 4

Although the current policy makes clear that a personal payment to an author from a commercial organization with an interest in the outcome of a Cochrane Review represents a financial conflict of interest, it is not clear whether or not this applies if the payment is made to the individual's employing organization. Should an author be considered to have a financial conflict of interest if a commercial organization has provided financial support to the author's home institution, but the author has no control over how that money is used and does not benefit personally from it?



Answer choices	Responses	
Yes	40.04%	360
Νο	48.83%	439
Other	11.12%	100
TOTAL	• • •	899

Comments

This question arose from the experience of the Funding Arbiters dealing with two different scenarios:

- 1. Cochrane authors working in institutions that receive funding from a commercial company for work unrelated to the topic of the review; and
- 2. Cochrane authors working in institutions that receive funding from a commercial company for work that is relevant to the review, where the authors have no control over the funds.

This question (like 11 and 18) had the least difference between 'yes' and 'no' responses (40% versus 49% respectively) and a significant number of free-text comments (100). This may indicate that respondents found the question unclear, or that it could not be answered simply.

There was a difference in opinion between Cochrane (57%, 334/590) and non-Cochrane (34%, 104/305) respondents who said 'no' to this question. Respondents who produce Cochrane content were 1.7 times

more likely to say an author does NOT have a financial conflict of interest if an institution receives commercial sponsorship. A higher proportion of non-Cochrane respondents (59%, 179/305) believed there was a financial COI compared to Cochrane respondents (30%, 179/590).

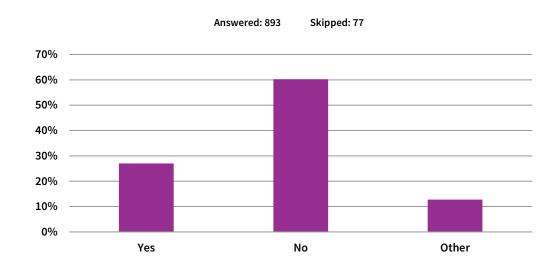
55% of respondents (226/411) based in university institutions said it was not a financial COI, compared to 33% who said it was (136/411). Most of the respondents answering Question 4 came from Europe. <u>Return</u> to summary

Insights from qualitative analysis (96 comments)

Messages for Cochrane		Question-specific opinions and illustrative quotes
	Recognizing/being alert to risks	 There is a need to recognize potential conflicts of interest related to (indirect) pressures from authors' host institutions: If the institution receives funding for other projects that the researcher is not involved in, it is usually not a COI unless there is something the institution is so strongly associated/involved with that it could impact the author if the study results aren't to its liking.
	Acknowledging unavoidable practical realities	It can be difficult to judge the degree of influence - I would say it is a potential conflict, but in practical terms it is difficult for authors to know all the funding their organization has received. Because this is completely impractical, I would say 'No'.
Things to consider and acknowledge	Responding to nuances that differentiate one situation from another (e.g. factors that might increase/decrease the likelihood/significance of a COI and may be considered in setting rules or assessing cases)	 Appropriate response depends on: Closeness between funding and author's work It depends really - it may or may not. Payments may be totally unrelated to review and then I don't think there is any conflict! The amount of the funding/contribution particularly if the amount is large The size and type of institutions In a small organization there could potentially be more influence The independence of the author within the institution Depends on the independence of the author in his/her institution!
Specific things for Cochrane to do (given the above and with the above in mind)	Ensuring that the situation is visible and therefore assessable (by Cochrane and/or by others)	I would argue that judging whether or not something constitutes a COI is not the main issue here, the main issue is declaration. If someone feels that something related to them may put them at risk of making a biased judgment, they should declare it.
Conceptual/definitional considerations (what does/does not 'count' as a COI in this context)		 A conflict of interest can exist only if the person has knowledge of the influence Difficult! It depends on how big the institution is! If it is a massive institution and the author has no knowledge of the contribution it can't be considered a conflict of interest. If the payment is made to the small department where the author sits, and the author knows about it and has the potential to be influenced by it, then it has to be considered a financial conflict of interest.

2.4.5 Question 5

Should Co-ordinating Editors of Cochrane Review Groups (the Editor in charge of the production of the Group's reviews) who have received financial support of any type (e.g. consultancy fees, travel expenses, honoraria etc.) from commercial organizations that have an interest in the disease area that the group focuses on be permitted to remain in or be appointed to the role?



Answer choices	Responses	
Yes	26.99%	241
No	60.25%	538
Other	12.77%	114
TOTAL		893

Comments

60% of respondents said 'no' to Co-ordinating Editors remaining in charge, or being appointed, if they had accepted financial payments of any type from commercial organizations. A higher proportion of non-Cochrane respondents (76%, 230/301) were stricter on this question, compared to Cochrane respondents (52%, 305/587). <u>Return to summary</u>

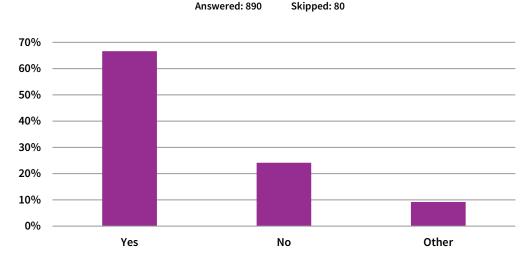
Insights from qualitative analysis (104 comments)

Messages for Cochrane		Question-specific opinions and illustrative quotes
Things to consider and acknowledge	Acknowledging unavoidable practical realities	 Exclusion may lead to the loss of people with necessary expertise A blanket ban may close the door to clinicians, and they are needed! If this means that some persons who are sought after by industry because of their competence and standing are excluded from these posts, it would be problematic. There may be circumstances where restricting Co-ordinating Editors to those with no such interests would be detrimental to the area of care – e.g. for rare conditions where expertise is sparse
How rigid versus flexible Cochrane should be (given the above)	Responding to nuances that differentiate one situation from another (e.g. factors that might increase/decrease the likelihood/significance of a COI and should be considered in setting rules or assessing cases)	 Appropriate response depends upon: Timing of financial relationship Co-ordinating Editors who have ongoing/current financial ties, as described, with a commercial organization with an interest in the disease area should not remain in or be appointed to the role. However, historical financial ties (e.g. > 3 years previously) where there is no ongoing financial relationship (e.g. shares) should not be disqualifying. I would propose to define the timeframe of this question better, for example, in the last three years. Amount/type of financial support depends on the level of financial support. If it was travel expenses, they should stay in the role, but if its consultancy fees, that seems like a major conflict. Perhaps a dollar amount of the total received should be added. Directness of link between support and subject of review I don't think they should have any involvement in reviews which directly pertain to their COI.
Specific things for Cochrane to	Making case-by-case assessments	 There is a need for adjudication This can't be an 'any financial support and you're out' ruling, there are degrees of conflict, it's just how and where to draw the line. Rather than try to establish complex hard and fast rules, how about the funding arbiter panel making adjudications?
do (given the above and with the above in mind)	Other specific management strategies (predefined or case by case)	 Conflicts of interest should be managed rather than avoided If there is an established infrastructure charged with reviewing and managing COI and the review and management is applied consistently, I don't see any reason to avoid all conflicts. It is important to manage them. Influences should be balanced out

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	 Surely similarly to authorship such people should be required to be balanced or outnumbered by non-conflicted individuals. There is a need for discourse and collective assessment Any support must be declared to the authors of the review first and if they agree then the editor could keep his role if they declared any funding/support in the review itself. But this must happen in agreement with the authors, as they might not want any conflicting interest in their review production. Rulings/exclusions should be temporary rather than permanent They could be asked to step down temporarily I would say that any person who directly receives funding from a sponsor where there is a direct conflict of interest with a particular review should step-down from co-ordinating that particular review. I don't think that they should be required to step down from the post per se - these things should be considered per review. Exclusion should be extended should also apply to Deputy Co-eds

2.4.6 Question 6

If a 'not-for-profit' organization has an interest in the outcome of a Cochrane Review, should it be viewed in a similar way to a commercial organization and any payments made by it to authors be seen as conflicts of interest?



Answer choices	Responses	
Yes	66.63%	593
No	24.16%	215
Other	9.21%	82
TOTAL		890

Comments

The responses to this question suggest that survey participants believed that 'not-for-profit' organizations should be treated the same as 'for-profit' organizations, with 67% (593/890) agreeing that payments made to authors by 'not-for-profit' organizations should be considered as conflicts compared to only 24% (215/890) saying they should not be. When this was analyzed by affiliation to Cochrane, 64% (371/583) of Cochrane respondents and 73% (220/303) of non-Cochrane respondents said 'yes' to this question.

The wording of this question was perhaps unclear, therefore the responses should be interpreted with caution. Firstly, there may have been variable understanding of what constitutes a 'not-for-profit' organization (no examples were given). Secondly, the notion of having an 'interest in the outcome of a Cochrane Review' is not the same as having a financial interest in the outcome and it is difficult to know which of these respondents had in mind. Thirdly, we used the phrase 'conflicts of interest' as opposed to 'interests' and this may also have contributed to a misunderstanding of the purpose of the question.

Perhaps those answering this question have considered 'not-for-profit' organizations as charities, aware that some charities are partly funded by industry and so may have a financial interest in research funded by these charitable organizations. However, 'not-for-profit' organizations also include nationally funded institutions like the Canadian Agency for Drugs and Technologies in Health (CADTH). <u>Return to summary</u>

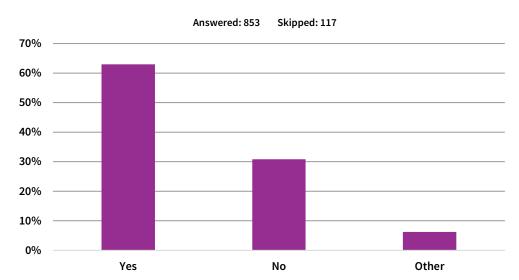
Insights from qualitative analysis (75 comments)

Messages for Cochrane		Question-specific opinions and illustrative quotes		
Things to consider and	Recognizing/being alert to risks	 'Not-for-profit' organizations (NFPs) can have (sometimes hidden) agendas stemming from commercial affiliations Many corporations (Philip Morris, Nestle, IBM) have philanthropic 'foundations' that are used to obfuscate industry influence. Many consumer groups are also heavily industry-funded. 		
acknowledge	Recognizing benefits	 NFPs can be important conduits for patients' voices It could be a patient group speaking out on behalf of people who aren't well enough to do so themselves. 		
How rigid versus flexible Cochrane should be (given the above)	Responding to nuances that differentiate one situation from another (e.g. factors that might increase/decrease the likelihood/significance of a COI and should be considered in setting rules or assessing cases)	 Appropriate response depends upon: Type/role of NFP Depends on what you mean. If from 'neutral' national /regional funding bodies not [a COI]. It depends on the role of the not-for-profit. Some provide only support to patients/carers etc. some have a lobbying and campaigning role. Degree of interest that the NFP has in the outcome: If there really is an interest in the outcome in a sense that the organization wants to lobby for something, wants to advocate for or against something, then I would consider this in a similar way as commercial organizations. 		
Specific things for Cochrane to do (given the above and with the above in mind)	Ensuring that the situation is visible and therefore assessable (by Cochrane and/or by others)	Disclosure is important - Full disclosure is important to allow the facts to stand for themselves.		

	Making case-by-case assessments	An external COI committee should be created to analyze on a case-by-case basis.
Conceptual/definitional considerations (what does/does not 'count' as a COI in this context)		 The definition of an 'interest' is context dependent It depends of what is meant by " has an interest in the outcome". This will be very context dependent. Not everything should be considered an interest If 'conflict of interest' comes to be 'any interest' then the only people who could author Cochrane reviews would be people who are completely disinterested in the work and outcome of it, which of course would be stupid.

2.4.7 Question 7

Should working as a healthcare professional (whether in the private or public sector) in an area that provides the intervention(s) of interest in a Cochrane Review, or any comparators, be considered as having an interest that should be declared?



Answer choices Responses		
Yes	62.95%	537
Νο	30.83%	263
Other	6.21%	53
TOTAL		853

Comments

Most responses to this question indicated that people believed that health professionals should declare their profession as an interest when working on Cochrane Reviews (63%, 537/853). Analyzing this further, non-Cochrane respondents favoured a stricter approach regarding declarations from health professionals (73%, 213/293) compared to Cochrane respondents (58%, 324/560). <u>Return to summary</u>

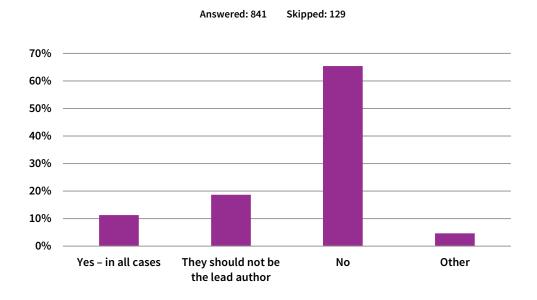
Insights from qualitative analysis (52 comments)

Messages for Cochrane		Question-specific opinions and illustrative quotes	
Things to consider and acknowledge	Acknowledging unavoidable practical realities	 Exclusion may lead to the loss of people with necessary expertise Yes and No: we generally work in the area of our reviews (else, ask somebody randomly selected to perform reviews). But as clinicians we usually have very strong biases for or against a particular intervention. I believe that there are no solutions to this problem. 	
How rigid versus flexible Cochrane should be (given the above)	Responding to nuances that differentiate one situation from another (e.g. factors that might increase/decrease the likelihood/significance of a COI and should be considered in setting rules or assessing cases)	 Appropriate response depends upon: Whether the intervention in question has a direct benefit to the healthcare professional (financial or otherwise) Only if the author is directly benefitting from treating the patient, e.g. owner of a clinic or coownership of hospital, or is paid by case/procedure treated. If they are doing more than just 'providing' the interventions, then this should be declared. If their delivery of the intervention directly influences their professional reputation - e.g. by providing training courses (even if there are no fees involved), or having a role on a special interest group or charity, or publicly writing about the intervention (including on social media) Depends. For instance, a GP may help providing mammographic screening and this is not a conflict of interest with the concerned review. But the radiologist who actually makes mammograms has obviously a conflict of interest. Whether the healthcare professional is working in the public or private sector If the person is providing a treatment, but in no way gains financially from providing or not providing that intervention, then it should not be seen as a conflict, just that they are a content expert. However, if they would gain financially from performing the intervention, e.g. private practice then it should be seen as a conflict. If working in the private area yes, otherwise no 	
Specific things for Cochrane to do (given the above and with the above in mind)	Making case-by-case assessments	It depends on many other details. The individual circumstances should be analyzed.	
	Other specific management strategies (predefined or case by case)	Influences should be balanced out - If such persons constitute a minute proportion of the reviewers, it would be ok. More than 5% of the reviewers would definitely not be appropriate.	

Cochrane Conflict of Interest Interviews 2019	25	
Conceptual/definitional considerations (what does/does not 'count' as a COI in this context)	 It is not useful to speak of 'conflict' in this context Should be declared, but obviously people who know the clinical field are crucial to make relevant reviews; so is not really a conflict in my opinion. Declarations can go 'too far:' This can be made as complicated and complex to result in becoming not useful. The key from my perspective is to be transparent and use some judgement. Otherwise the DOI [Declarations of interest] will be longer than the reviews themselves. 	

2.4.8 Question 8

Should working as a healthcare professional in an area that provides the intervention(s) of interest in a Cochrane Review, or any comparators, be considered a barrier to authoring a Cochrane Review?



Answer choices	Responses	
Yes- in all cases	11.30%	95
They should not be the lead author	18.67%	157
No	65.40%	550
Other	4.64%	39
TOTAL	· · · · ·	841

Comments

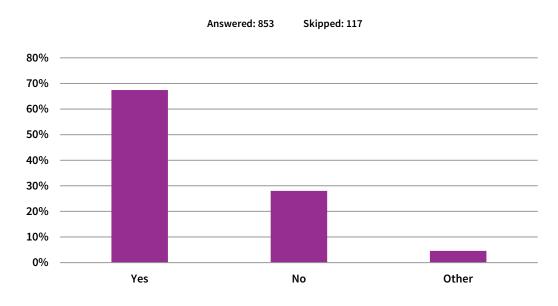
The answers to this question suggested that respondents believe that being a health professional is not a barrier to Cochrane authorship. Sixty-five percent did not agree that health professionals should be barred, although 19% believed they should not be the lead author. Analyzing this further, respondents with a Cochrane background were 1.7 times more likely than non-Cochrane respondents to say that being a health professional was *not* a barrier to being a review author (76% versus 44%). Non-Cochrane respondents were 6.5 times more likely to believe that health professionals should not author Cochrane Reviews if they work in an area related to the review topic (26% versus 4%). The number of non-Cochrane respondents saying, 'no to being the lead author' (70/285) and 'this is a barrier' (75/285) was similar, but these responses are more than the total number of non-Cochrane respondents who said this is not a problem (126). Return to summary

Insights from qualitative analysis (37 comments)

Messages for Cochrane	· · · · ·	Question-specific opinions and illustrative quotes		
Things to consider and acknowledge	Recognizing/being alert to risks	 Involving these clinicians has many problems and few advantages Whether or not clinicians or 'content experts' should be prohibited at all from conducting reviews is not to easily. However, I see many problems and few, if any, advantages of having a lead author who is involved in area on a daily basis. Who would like to discover, and be completely honest about it, that he/she has b harming his/her patients for decades? 		
How rigid versus flexible Cochrane should be (given the above)	Responding to nuances that differentiate one situation from another (e.g. factors that might increase/decrease the likelihood/significance of a COI and should be considered in setting rules or assessing cases)	 Appropriate response depends upon: The author's field Again, there is the issue of degree. If the person does not personally use the intervention or comparator himor herself (e.g. an oncologic intervention for lung cancer and a reviewer who does not see patients with lung cancer), this is not an issue. The author's status/influence over others It depends if he is a spokesperson for this speciality or only an ordinary practicing specialist; my answer would be Yes if he heads, for example, the association of cardiologists in his country, since all those associations receive financial support from industry. The author's personal investment in the intervention This depends - especially on the intervention. Do they have an investment in the intervention? How close are they to the intervention? Whether the author has ties to pharma (and strong opinions) It's a barrier if the person is known to have strong opinions, works with pharmaceutical industry then in such cases yes – should not be lead author. 		
Specific things for Cochrane to do (given the above and with the above in	Setting predefined rules/limits	 Should be part of the overall COI management plan. Applied consistently That needs a set of clearly defined rules and/or criteria. 		
	Other specific management strategies (predefined or case by case)	 Influences should be balanced out The review group should have a balance of authors' content and methods expertise. For me, the way to manage this is to ensure that there is more than one healthcare professional in an area that provides the intervention of interest acting as an author on the review. I think there also may be the situation that readers may be unwilling to take on board the conclusions of a review if a healthcare professional familiar with the intervention in question hasn't been involved in the preparation of the review. 		

2.4.9 Question 9

The current policy allows the inclusion of review authors who have participated in clinical trials that are included in the review, provided that they do not extract the data or carry out the 'risk of bias' assessment from their own study or studies. Is this acceptable?



Answer choices Response		
Yes	67.41%	575
Νο	28.02%	239
Other	4.57%	39
TOTAL		853

Comments

Questions 9, 10 and 11 are about review authors who have also been trialists on primary studies included in the systematic review. The majority of respondents (67%, 575/853) thought it was acceptable for trialists to be involved as long as they did not extract the data from their trials or assess the risk of bias. More Cochrane respondents than non-Cochrane (77% versus 48%) said 'yes,' this was an acceptable way of involving the trial authors, with more non-Cochrane respondents (48% versus 18%) saying 'no'. <u>Return to summary</u>

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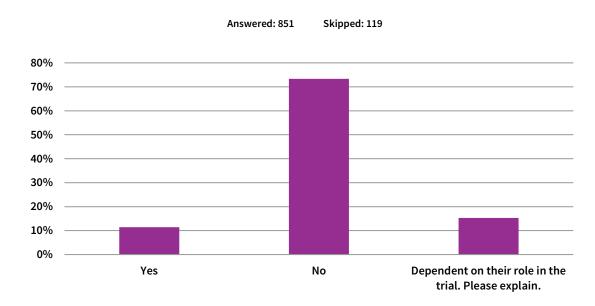
Insights from qualitative analysis (38 comments)

Messages for Cochrane		Question-specific opinions and illustrative quotes	
	Recognizing/being alert to risks	Strong oversight is needed (people cannot simply be trusted) - I would like to see better oversight of this situation rather than relying on an honour system.	
Things to consider and acknowledge	Acknowledging unavoidable practical realities	 Exclusion may lead to the loss of people with necessary expertise I think it is not ideal, but again people who run trials are the people who are interested in answering the questions. (Cochrane forced upon the review team for pericarditis the inclusion authors of all the trials that constituted the evidence base and it caused great problems!) Sometimes Cochrane reviewers whose systematic review has established a genuine and important uncertainty then go on to run a trial to address it. I think it would be counterproductive to then prevent those reviewers from updating their review. Such people often have a wealth of experience about the treatment or condition, and so it would be foolish to stop them providing useful information. Management strategies might not work It is hard to know if this orientation was really followed and it may be hard to control the RCT author not to assess data. 	
How rigid versus flexible Cochrane should be (given the above)	Responding to nuances that differentiate one situation from another (e.g. factors that might increase/decrease the likelihood/significance of a COI and should be considered in setting rules or assessing cases)	 Appropriate response depends upon: 1. Whether the study was funded by pharma If the author was part of a RCT that was NOT FUNDED by Pharma (e.g. NIH, CIHR, etc.), then may continue participating as long as he/she does not take part of the extraction, or RoB asses 	
Specific things for Cochrane to do (given the above and with the above in mind)	Ensuring that the situation is visible and therefore assessable (by Cochrane and/or by others)	- I have experienced this and I believe involvement in potentially includable trials should be stated at protocol stage, or when a new author is added.	

Other specific management strategies (predefined or case by case)	 Roles should be limited with respect to: The role that the author can have in study design/analysis As long as he/she does not take part in the extraction, or RoB assessment It's acceptable as long as they are not the ones devising the protocol as leads, or as long as checks are in place to ensure the review methods do not favour their design, definition or operationalisations of conditions and outcomes Such authors should not be allowed to extract the data or carry out the risk of bias assessment from any of the included study or studies in the review no matter if it is their own or others'. The place/authority of the author in the team Yes. Not as lead and with clear documentation regarding how managed; i.e. did not conduct screening, RoB, etc. for their trial(s). I would suggest they are not lead authors at least. The other authors of the review should not be their sub-ordinates or in control of their authority by any means. Influences should be balanced out Probably not all of the review authors should be connected with clinical trials that are included in the review. Peer/editorial oversight should be in place It is a very grey area, as even if the author does not carry out RoB assessment or extracts data, can still heavily condition the interpretation of results and the discussion. This should be carefully managed by the editorial team, for instance by considering whether the trial led by the author follows the same direction as the remainder. I suggest another author could assess the data, and if it shows any discordance a third party will
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2.4.10 Question 10

Should a researcher who is an author on an industry-funded trial that uses the intervention(s) of interest being assessed in a Cochrane Review, or any comparators, be allowed to be lead author on the review?



Answer choices		
Yes	11.40%	97
Νο	73.33%	624
Dependent on their role in the trial. Please explain.	15.28%	130
TOTAL		

Comments

This question produced one of the clearest answers of all the survey questions, with 73% (624/851) saying 'no' to a review author from an industry-funded trial that used the intervention of interest being the lead author. There was a higher percentage of non-Cochrane respondents of this opinion than Cochrane respondents (83% versus 68%) and double the percentage of Cochrane respondents (18% versus 9%) said the determination of a conflict was dependent on their role in the trial. <u>Return to summary</u>

Note: Some respondents appeared not to differentiate between questions 10 and 11 therefore the themes in the analyses of both questions are very similar.

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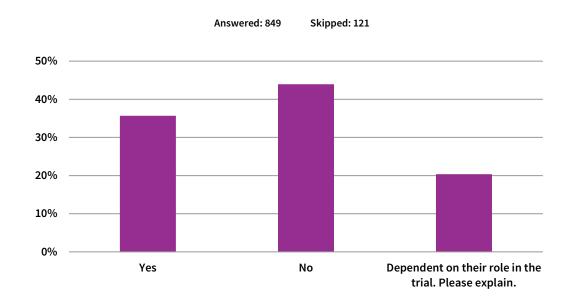
Insights from qualitative analysis (130 comments)

Messages for Cochrane		Question-specific opinions and illustrative quotes
Things to consider and acknowledge	Acknowledging unavoidable practical realities	 Trials need to be funded by industry For rare conditions, funding is often only available through industry. Please define industry-funded trial. Again, in my country, we are increasingly having to find matched funding to obtain research grants. Industry can be a partner in these grants (in fact it is encouraged) – would an investigator-initiated grant with some industry funding be considered an industry-funded trial? Exclusion may lead to the loss of people with necessary expertise Some of these interventions will be applicable to a relatively select population so the trials may [not] have many centres and excluding all of them for the duration of the trial (which could be many years) seems excessive.
How rigid versus flexible Cochrane should be (given the above)	Responding to nuances that differentiate one situation from another (e.g. factors that might increase/decrease the likelihood/significance of a COI and should be considered in setting rules or assessing cases)	 This also depends on who the other authors are. For example, if all other authors are from the same organization or more junior to this person, then the risks are high. 3. The type/extent of industry funding Depends on what the industry funding was (e.g. donation of study drugs, which I don't

Specific things for Cochrane to do (given the above and with the above in mind)	Making case-by-case assessments	 Creating a simplistic rule is likely to be harmful. I think the Dols and rationale is critical, but I would like Cochrane also to demonstrate some faith and confidence in their own editorial processes to address these concerns. This doesn't mean universal acceptance of such reviews, but a careful analysis of the justification and impact of proposed authorship arrangements.
	Other specific management strategies (predefined or case by case)	 Roles should be limited with respect to The role that the author can have in study design/analysis/writing They should not be the researcher who eliminates other studies or similar interventions. The researcher should be allowed to organize and manage the review. Phrasing the conclusions and recommendations should not be made by that person alone. The place/authority of the author in the team As long as their involvement in the review is collaborative and their opinion is not the overriding one in the review Peer/editorial oversight should be in place Our protection from bias is largely in transparency of methods and quality of editorial scrutiny.

2.4.11 Question 11

Should a researcher who is an author on an industry-funded clinical trial that uses the intervention(s) of interest being assessed in a Cochrane Review, or any comparators, be allowed to be an author at all?



Answer choices		
Yes	35.69%	303
Νο	43.93%	373
Dependent on their role in the trial. Please explain.	20.38%	173
TOTAL		849

Comments

There was less certainty over being an author at all, compared to being allowed to be the lead author, with 44% (373/849) of the respondents saying 'no'. The majority of respondents who believed a researcher involved with industry funding should not author a Cochrane Review at all were non-Cochrane (63%, 181/289) compared to the less stringent approach from Cochrane respondents (34%, 189/556). <u>Return to summary</u>

Note: Some respondents appeared not to differentiate between questions 10 and 11 therefore the themes in the analyses of both questions are very similar.

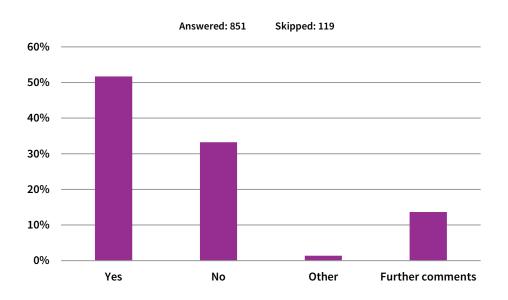
Insights from qualitative analysis (171 comments)

Messages for Cochrane		Question-specific opinions and illustrative quotes	
Things to consider and acknowledge	Acknowledging unavoidable practical realities	 Exclusion may lead to the loss of people with necessary expertise See comments regarding authorship of reviews involving rare conditions where the community of trialists, researchers and reviewers are likely to have to overlap or there will be no subject expertise available to the review. If you exclude them, you may be excluding the most experienced and knowledgeable person. Sometimes these researchers have information about critical issues that the review needs to address (for example, important outcomes and their measurement). 	
How rigid versus flexible Cochrane should be (given the above)	Responding to nuances that differentiate one situation from another (e.g. factors that might increase/decrease the likelihood/significance of a COI and should be considered in setting rules or assessing cases)	 Appropriate response depends upon: How the trial was conducted Depends on how trial was conducted What 'industry funding' actually entailed; what type of industry was involved depends on what 'industry-funded' means. Accepting industry funding does not necessarily mean the individual has gone 'to the dark side'. It depends on which organization. In the tobacco field we view the pharmaceutical and tobacco industry differently and believe anyone who takes money from the tobacco industry should not be an author at all. The author's role on the trial I think it depends on how involved they were in the trial and if they actually worked for the industry or were just associated with the trial. The number of trials available to assess the intervention If the trial is one of many and contributes less than (say) 20% of the patients this would be acceptable. However, if this is the major definitive trial contributing a high portion of the patients, probably not. 	
Specific things for Cochrane to do (given the above and with the above in mind)	Ensuring that the situation is visible and therefore assessable (by Cochrane and/or by others)	COI and clarity should provide enough information without volunteers being excluded as authors.	

Making case-by-case assessments	A judgement call for the Co-Ed.	
Other specific management strategies (predefined or case by case)	 Roles should be limited: and dependent on their role in the author team. Minor involvement in a trial, like blinded outcome assessor, and not principal position on the author team, like provision of clinical expertise on diagnostic subtleties, should not create problems, provided the authorship and the role in a trial and a Cochrane review are clearly and explicitly declared. Must be very clear to outline the roles that they play in the review, however. Inclusion/exclusion decisions are important tasks where COI should be managed. Not to extract data or assess risk of bias They could be allowed the right to reply, and this could form part of the review, but I don't understand how anyone can be an unbiased reviewer of their own work. Influences should be balanced out Although the majority should be none conflicted. As in my answer to 8 - there may be times when there are benefits to having someone with an interest in the intervention as an author. But the author team needs to be balanced, and that person should not be doing review tasks 'independently' (i.e. use two or more reviewers for tasks etc). 	

2.4.12 Question 12

Should publishing any previous review or opinion piece (including using social media platforms) addressing the intervention(s) of interest in a Cochrane Review, or any comparators, be considered as having an interest that should be declared?



Answer choices	Responses	
Yes	51.70%	440
Νο	33.25%	283
Other	1.41%	12
Further comments	13.63%	116
TOTAL	· ·	851

Comments

52% (440/851) of respondents stated that authors should declare if they had published any previous reviews, commentaries or opinion pieces addressing the intervention(s) of interest covered in a Cochrane Review they were contributing to. A greater percentage of non-Cochrane respondents (63%, 182/290) compared to Cochrane (46%, 256/557) were of this opinion. There was, however, a lot of feedback for this particular question with 14% (116/851) of respondents commenting. <u>Return to summary</u>

Insights from qualitative analysis (116 comments)

Messages for Cochrane		Question-specific opinions and illustrative quotes
Things to consider and acknowledge	Acknowledging unavoidable practical realities	 Exclusion may lead to the loss of people with necessary expertise Too inclusive as an exclusion; commentary on social media would eliminate a lot of experts with no substantial COI. This could also have a chilling effect on scientific discourse in social media, which can be casual or formal. Wondering who would complete Cochrane reviews if this was the case? Automated review completion on the horizon? This is difficult to assess; we want experts in the field to perform the review. Therefore, it is almost expected that they have published before. No - this precludes all translational work, and this is what Cochrane needs to do more of. Not consistent with the way science works or the norms of academic freedom Common for experts to 'tweet' new trial results presented at conferences to colleagues and patients, I do not think this precludes them from conduction review. No. This to me would violate principles of academic freedom. This would encourage self-censorship, contrary to the spirit of scientific debate and Cochrane. But this is paranoid again. What is an opinion piece? What is an opinion? Is it WRONG? It might be an opinion based on very sound evidence. Some of my 'opinions' have been influenced by Cochrane reviews - but does that now make them right? IF I have sent a tweet saying 'Exciting results about A or B' does that make me biased? If this is the criteria, then we are all screwed. Evidence generation and review is value-laden, we will never get away from this. What we need to do is be transparent about it and minimise external factors that may exert undue influence on one's ability to review the evidence as best we can.
How rigid versus flexible Cochrane should be (given the above)	Responding to nuances that differentiate one situation from another (e.g. factors that might increase/decrease the likelihood/significance of a COI and should be	 Appropriate response depends upon: 1. The strength of the person's opinion It depends. If someone has a history of strong ideological commitment that is well documented (e.g. an anti-vaxxer), then yes. If an author simply has previous editorials or research papers on the subject, then no. 2. Whether the person is making money by promoting a point of view

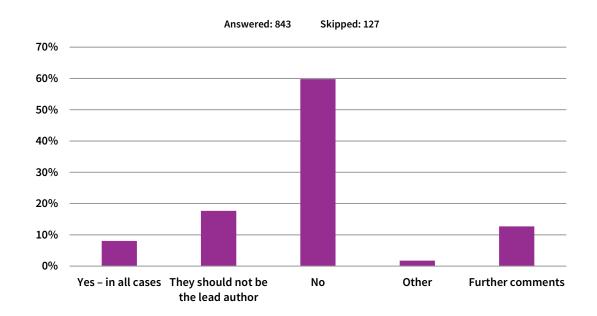
Cochrane	Conflict of	Interest	Interviews 2019
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	considered in setting rules or assessing cases)	 an opinion is not a financial bias, so this should only be a factor if the person is consistently making substantial amounts of money through promoting a particular point of view. 3. How long ago the opinion was expressed I suggest that a time limit apply for this, as opinions do change with time. People can change their minds over time and social media can't be deleted easily 	
Specific things for Cochrane to do (given the above and with the above in mind)	Ensuring that the situation is visible and therefore assessable (by Cochrane and/or by others)	 It may not be a conflict, but should be declared Of course, it should, without doubt. To be honest I can't believe you're even asking this question. Isn't it obvious that this is an unacceptable conflict of interest? What we need to do is be transparent about it and minimise external factors that may exert undue influence on one's ability to review the evidence as best we can. Probably but there is a danger that all/many authors will end up with a long list of CoIs and that might actually dilute the effect by burying really important CoIs. Still, if an author has been promoting a particular intervention for years then it would be good to know that. I ticked YES (faulty survey). I can see the connection with case PG. Shouting loudly that the pharma industry is a form of organized crime means one has a strong predisposition. But if declared, I wouldn't think this would be a major problem. 	
	Other specific management strategies (predefined or case by case)	 Having a selection process for reviewers If the review is potentially so controversial that this level of insight is needed, it is probably advisable to have an open selection process for the review team, and for the selection process to include a search and assessment of relevant opinion channels. 	
Conceptual/definitional considerations (what does/does not 'count' as a COI in this context)		 Bias is not the same as COI I am very biased in my work in these areas - but only biased by my own review results. This is r a conflict. Declaration may be needed but not as a declaration of an 'interest' Previous reviews should be cited in the background of the review. Having an 'a priori' approat to the intervention (i.e. a strong belief it works, or it doesn't) is probably worth being declared however, probably not on the Declaration of interest. Having a new section of the review indicating whether authors use or not the intervention and/or comparator, and their 'a prior believes on them, might be useful. Lists of COIs may become too long Probably but there is a danger that all/many authors will end up with a long list of CoIs and the might actually dilute the effect by burying really important CoIs. Still, if an author has be promoting a particular intervention for years then it would be good to know that. 	

2.4.13 Question 13

Should publishing any previous review or opinion piece, including using social media platforms), addressing the intervention(s) of interest in a Cochrane Review, or any comparators, be considered as a barrier to authoring a Cochrane Review?



Answer choices	Responses	
Yes- in all cases	8.07%	68
They should not be the lead author	17.67%	149
No	59.79%	504
Other	1.78%	15
Further comments	12.69%	107
TOTAL		843

Comments

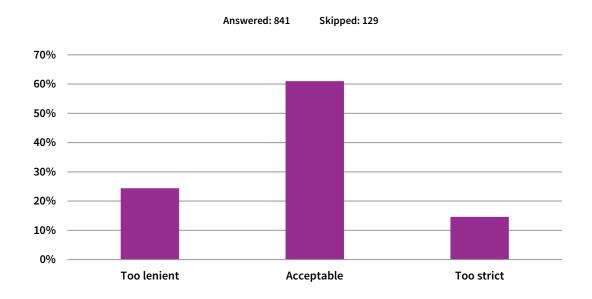
60% of respondents indicated that a person could still be a Cochrane Review author if they had previously commented/published on the topic of interest. More Cochrane respondents (68%, 373/551) than non-Cochrane (45%, 129/288) believed this to be the case. However, the biggest difference between the groups was 'yes – in all cases', with 10 times (20% versus 2%) more non-Cochrane respondents stating that a previously expressed opinion was not a bar to authorship. 18% stated they should not be the lead author (149/843), with more non-Cochrane respondents (22%, 63/288) than Cochrane respondents (15%, 85/551) stating this was important. Again, there were many comments on this question (107/843). <u>Return to summary</u>

Insights from qualitative analysis (107 comments)

Messages for Cochrane		Question-specific opinions and illustrative quotes
Things to consider and acknowledge	Acknowledging unavoidable practical realities	 Exclusion may lead to the loss of people with necessary expertise It would be hard to identify authors with a sound understanding and interest in the topic who have not ever written anything about a topic to undertake a review. We would only be left with systematic review specialists, and no content understanding. Perhaps in an ideal world. But now that opinion pieces and social media are so widely used, it may be impossible to find any authors without this barrier. This is difficult to assess; we want experts in the field to perform the review. Therefore, it is almost expected that they have published before. Is policing social media necessary?
How rigid versus flexible Cochrane should be (given the above)	Responding to nuances that differentiate one situation from another (e.g. factors that might increase/decrease the likelihood/significance of a COI and should be considered in setting rules or assessing cases)	 Appropriate response depends upon: The degree to which the person has been an advocate for the intervention It depends on the slant. Yes, if someone has been an advocate for an intervention on social media as there is a COI. No if the opinion piece could conversely be calling attention to an evidence gap. Depends on content. Publishing a well-balanced review or critique should not be a barrier. Being an advocate for an intervention or having expressed strong opinions should preclude authorship. The nature/form of the previous publication Scientific publications and platforms should only be considered Another review? That is no issue, but opinion pieces, if these are biased then they should not be lead author.
	Setting predefined rules/limits	This is going to make life very complicated. You need to make the rules simple, straightforward and transparent.
Specific things for Cochrane to do (given the above and with the above in mind)	Other specific management strategies (predefined or case by case)	 Roles should be limited: I feel they should not take a lead role and should not be allowed to make conclusions. No, provided a declaration of 'intellectual independence' (i.e. readiness to change idea if necessary) is given. Rather than exclude people with engagement for health interventions, consider reminding them upon agreeing to review that science is about neutrality and openness to results possible transcending one's own clinical experience. Review teams should be balanced - so include different views. If possible, include those with equipoise - not just those who have strong views.

2.4.14 Question 14





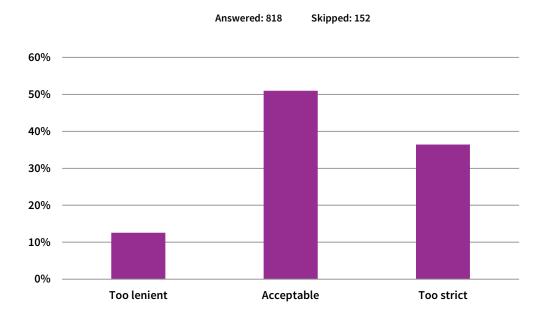
Answer choices	Responses	
Too lenient	24.38%	205
Acceptable	61.00%	513
Too strict	14.63%	123
TOTAL		841

Comments

The majority of respondents (61%, 513/841) said the current policy of allowing no financial conflicts of interest for the lead author and the majority of the review team was acceptable, significantly more than the 24% (205/841) who felt this was 'too lenient'. More non-Cochrane respondents (33%) than Cochrane respondents (20%) took a stricter approach. Overall however those favouring a strict approach were in the minority. When the 'too strict' and 'acceptable' responses were combined, 76% (636/841) of respondents were **not** in favour of tightening up the current rule. <u>Return to summary</u>

2.4.15 Question 15

Do you think it is acceptable to have a policy stating that the lead author and a majority of the team must have no non-financial conflicts of interest?



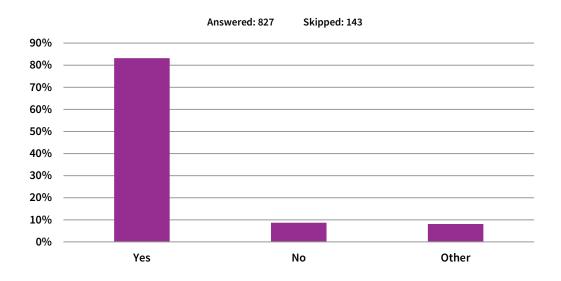
Answer choices	Responses	
Too lenient	12.59%	103
Acceptable	50.98%	417
Too strict	36.43%	298
TOTAL		818

Comments

The proportion of respondents who believed it was acceptable to have a policy with the lead author and a majority of the team with no non-financial interests (51%, 417/818) was similar to the proportion believing the same in regard to financial conflicts (61%, 513/841) (See Q.14). However, more respondents (36%, 298/818) thought that having a lead author/majority rule for non-financial conflicts was too strict compared to a lead author/majority rule for financial conflicts (15%, 123/841). The biggest difference between the Cochrane and non-Cochrane groups did not concern the 'acceptable' category, but whether or not this was 'too lenient' or 'too strict' with 8% versus 21% and 43% versus 24% respectively. There was no commenting option for this question, so there is no qualitative analysis. <u>Return to summary</u>

2.4.16 Question 16

Currently only the lead author's conflicts of interest are handled with more scrutiny than the author team. Should the senior/last author have the same restrictions as the lead/first author?



Answer choices	Responses	
Yes	83.19%	688
Νο	8.71%	72
Other	8.10%	67
TOTAL		827

Comments

A clear majority of respondents (83%, 688/827) agreed that the last author should be subject to the same restrictions as the first author. There was little difference between Cochrane and non-Cochrane respondents (80% and 89% respectively). <u>Return to summary</u>

Insights from qualitative analysis (65 comments)

Note: the answers to this question did not follow the same patterns as the other questions

All authors should be assessed by the same criteria

- Everyone should be scrutinized! Just because you are not first, or last author doesn't mean you don't have great impact on the analysis and decisions that are made during the review process.
- Our CRG would consider any of the authors' DOI open for equal scrutiny.

In large part because position does not necessarily reflect influence

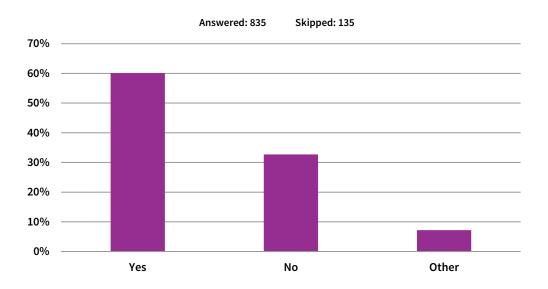
- Author doing most of the work for an updated review may not be the lead/contact person, first or last author so all authors should be scrutinized.
- Sometimes the last author is not a senior author but a consumer, or the author who has contributed the least.
- Authorship order is often difficult to determine and somebody with a minor role in the review work [hence a minor position in the list] could have a loud/influential voice within the team.
- The last author is not always the senior author. Perhaps Cochrane should specify that the senior author must be identified as such.
- How would you detect the most senior person on the team? It could be the first author, it could be the second author, giving their mentee a break, or it could be the last author. Too difficult to detect.
- It is unclear to me how widely accepted the 'senior/last author convention' is. How would you identify who the 'senior' authors are in a review? It would need to be self-declared.

And because people might game the system

- Potentially yes - but this could lead to all sorts of additional gaming of author lines! scrutinise the whole team to the same standard – it's impossible for you to identify who actually did the most work / had greatest influence on review - and conflicted authors may deliberately game the system by being a middle author.

2.4.17 Question 17

Should the policy be extended to require Cochrane Review authors to declare relevant financial and non-financial conflicts of interest for close personal relationships (e.g. partner, spouse, immediate family member, long-term close friend)?



Answer choices	Responses	
Yes	60.12%	502
Νο	32.69%	273
Other	7.19%	60
TOTAL		835

Comments

60% of the respondents (502/835) agreed that relevant financial and non-financial personal relationships should be declared, while 33% said they should not (273/835). A much higher percentage of non-Cochrane were in favour of declaring personal relationships compared to Cochrane (72% versus 54% respectively). Free-text suggestions were that they should be included if relevant to the Cochrane Review, but the difficulty of checking these declarations was highlighted and it was acknowledged that frequently it is after publication that COIs become known. <u>Return to summary</u>

Insights from qualitative analysis (59 comments)

Messages for Cochrane	tive analysis (55 comments)	Question-specific opinions and illustrative quotes
Things to consider and acknowledge	Acknowledging unavoidable practical realities	 Monitoring/enforcement is impossible This would not be possible to police. I don't think this is workable. I don't know the details of my wife's share portfolio. I have seen such disclosures made by some researchers working for RAND (for example). But in Cochrane, I am not sure where we would stop, or how we would enforce this. Monitoring/enforcement might violate privacy rules This is not wrong per se, but I am not sure that Cochrane is allowed to request personal information on anyone not directly involved in the review - this is about privacy. Unsure - I spoke at a conference recently that asked for this type of declaration – I had to survey my immediate family members, when I don't normally pry into their private affairs How would publishing a relative's info comply with something like the EU's General Data Protection Regulation? On the other hand, if my partner/spouse happened to work for a drug company that might benefit I should inform the world. Tough choices.
How rigid versus flexible Cochrane should be (given the above)	Responding to nuances that differentiate one situation from another (e.g. factors that might increase/decrease the likelihood/significance of a COI and should be considered in setting rules or assessing cases)	 Appropriate response depends upon: Whether the relationship is financial or non-financial Financial only, not non-financial Financial conflicts of interest should include income for spouses/partners (e.g. spouse is CEO of a pharma company) as this can pose a conflict, though this is often typical. The specific role that the family member has Only in exceptional circumstances. Should be dependent on type of role in e.g. pharma company. Only if relevant e.g. spouse is patent holder of xx device that is being reviewed that seems relevant. Your brother works for Pfizer does not seem relevant. How closely related the family member is Limit to members of immediate family (including spouse/partner). Yes, for close familiar relationships, including friends seems excessive.
Specific things for Cochrane to do (given the above and with the above in mind)	Ensuring that the situation is visible and therefore assessable (by Cochrane and/or by others)	 These things tend to come out afterwards too – it is in the reviewers' interest to declare up front. I think any information that if subsequently disclosed would lead to thoughts of conflict of interest and challenge validity of the Cochrane product, should be disclosed, even if that is a bit intrusive.

2.4.18 Question 18



Should peer reviewers who have declared conflicts of interest be prevented from commenting on a Cochrane Review?

Answer choices	Responses	
Yes	42.99%	362
No	45.84%	386
Other	11.16%	94
TOTAL		842

Comments

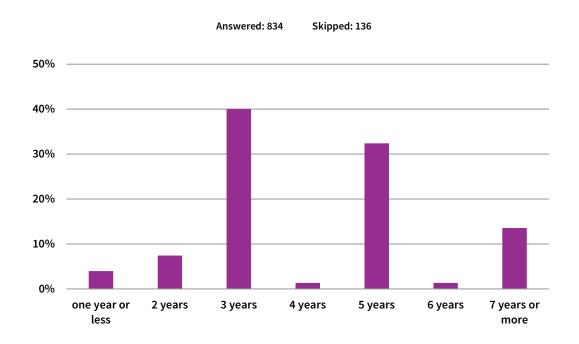
There was little difference between the numbers of respondents who thought peer reviewers who have declared conflicts should be prevented from commenting on a Cochrane Review (43%, 362/842) versus those who did not (46%, 386/842). The ratio of 'yes' to 'no' answers from Cochrane and non-Cochrane respondents was similar, with more non-Cochrane respondents saying 'yes' than 'no' (47% versus 43%) and more Cochrane saying 'no' than 'yes' (48% versus 41%). When planning the survey, the question had been considered a marginal one, but it generated a sizeable number of comments (n = 94). Return to summary

Insights from qualitative analysis (91 comments)

Messages for Cochrane		Question-specific opinions and illustrative quotes
Things to consider and acknowledge	Acknowledging unavoidable practical realities	 Exclusion may lead to the loss of people with necessary expertise If it is a real COI then yes, but having received for example a speaker fee might not be a problem, if there is real bias you will be able to identify it based on their review and then take further action; you will lose a lot of perfectly unbiased experts otherwise. The reviewers' interests should be managed. You specifically want reviewers with expertise in the area of the topic. Preventing them from participating could result in a review team which did not have sufficient expertise, and I regard this as a greater risk than involving reviewers with conflicts (which are appropriately managed). Yes, but it depends on what the COI is. We need current, practicing clinicians to comment on our reviews. If we say clinicians who use the technology have a COI then it will be nearly impossible to find peer reviewers, even when casting a wide net on Twitter and TaskExchange in search of a suitable person.
How rigid versus flexible Cochrane should be (given the above)	Responding to nuances that differentiate one situation from another (e.g. factors that might increase/decrease the likelihood/significance of a COI and should be considered in setting rules or assessing cases)	 Appropriate response depends upon the type of conflict of interest It depends on their conflicts of interest. An employee that works at or supports a medica company that are biased towards supporting or opposing the experimental or contro intervention in a Cochrane review, should be prevented from becoming a peer-reviewer.
Specific things for Cochrane to do (given the above and with the above in mind)	Ensuring that the situation is visible and therefore assessable (by Cochrane and/or by others)	 They should have the same rights as other members of the public to comment. Any conflict of interest should be declared. Comments are only to be published if the declared conflicts of interest are published with the comment. If there is a way to show their COI next to their comments, then that would be acceptable.
	Making case-by-case assessments	- It depends. The editorial base can make some judgements on this.
	Other specific management strategies (predefined or case by case)	 Peer/editorial oversight should be in place (in this case, reviewing the reviewers) No, but if the reviewer shows signs of bias during the review process, the editor should have the discretion to consult another reviewer.

2.4.19 Question 19

Currently relevant interests for the three years before the publication of the review protocol need to be declared as well as any accrued subsequently, until the publication of the final review. What is the appropriate time period for which interests should be declared?



Answer choices	Responses	
One year or less	3.96%	33
2 years	7.43%	62
3 years	40.05%	334
4 years	1.32%	11
5 years	32.37%	270
6 years	1.32%	11
7 years or more	13.55%	113
TOTAL		834

Comments

Respondents were only allowed to pick one time period for declaring interests. Most chose three years (40%, 334/834), with five years being the second choice (32%, 270/834). More Cochrane respondents chose three years than non-Cochrane (46% versus 28%), with non-Cochrane respondents selecting five years as their first choice for the disclosure time period (34%). <u>Return to summary</u>

2.4.20 Question 20

Please use the box below to include any additional feedback and examples of Conflict of interest.

Note: Since this was an open question, answers varied quite substantially. Below please find a brief summary of themes that extend or add to those themes found in other questions

Insights from qualitative analysis (199 comments) Return to summary

Messages for Cochrane		Question-specific opinions and illustrative quotes
How rigid versus flexible Cochrane should be (given the above)	Responding to nuances that differentiate one situation from another (e.g. factors that might increase/decrease the likelihood/significance of a COI and should be considered in setting rules or assessing cases)	 Appropriate responses depend upon 1. Things OTHER than time frames I think that the timeframe is arbitrary. Sometimes one year may be irrelevant for a small collaboration with industry (receiving honoraria for a lecture), whereas serving as a Board member seven years ago might be highly relevant.
Specific things for Cochrane to do (given the above and with the above in mind)	Ensuring that the situation is visible and therefore assessable (by Cochrane and/or by others)	 There should be punishments for non-declaration There should be stated consequences for non-declaration. There should be a central repository for declarations It would be helpful for there to be a central repository for COI declarations that could be updated rather than having to state the whole thing time after time. Perhaps this is too much to ask given GDPR. Declarations should be detailed only for large payments I think you could have a blanket statement that the author has multiple, non-substantial conflicts of interest, not otherwise specified and then ask them to be more specific about major conflicts of interest (e.g.:->\$10,000 to themselves, institution or relative in previous three years or >\$100,000 at any time). Authors should provide further details of any major personal income (let's say >10% of their total income), stocks or employment and any research grants for >\$1million. This should include grants from charities etc. Asking for a lot of minor detail means that real conflicts can get lost in the mess of detail.
	Setting predefined rules/limits	Time-frames need to be clearly predefined

		- The 'three year' rule for declarations needs to be clarified in more detail in the policy – at the moment it seems to be a moving feast and needs to be a definitive timeframe.
	Other specific management strategies (predefined or case by case)	 Considering COIs that arise and play out AFTER publication How about post-publication conflict of interest. Is there a way to record it? What if authors receive travel grants, honorarium etc to talk about the review/interventions after the publication? There is an issue of someone leading a review and then moving into industry. You should try to capture post-publication conflicts that may reveal prior conflicts, or I'm sure industry will start cutting secret deals of these kinds with authors. Taking the responsibility away from managing editor; making assessments centrally The current process for managing and reporting potential COIs is cumbersome and places too much of a burden on Managing Editors, both administratively and in terms of decision-making. Declarations of Interest and decisions on author eligibility based on these should be managed centrally by Cochrane.
Conceptual/definitional considerations (what does/does not 'count' as a COI in this context)		 Cochrane needs to define COI and related concepts more clearly I think Cochrane needs to very clearly define 'conflict of interest.' The distinction between financial and non-financial seems blurry in this survey. It would be helpful to define this term based on clearly delineated concepts such as primary interest, duty and bias. Cochrane should pay more attention to non-financial COIs Many researchers are deeply invested in an intervention even if they do not have only a minor (if any) financial interest. These non-financial interests are not currently treated strictly enough. Cochrane already has a strict COI policy, and it is good to see they are keen to take this issue more seriously. Would like to see more weight on non-financial COIs, as these are often neglected and more difficult to measure. I find it odd that issues relating to industry are focused on, when authors' activities at things such as anti-vaccine conferences or other media platforms (journalism, radio shows) attract little attention. Cochrane should make it clear that conflicts of interest do not just arise from commercial sources or professional interests. Patient groups or lobby groups also have interests, some very strong, that can influence their judgement.

3 Discussion

3.1 General

The number of respondents to this public consultation on Cochrane's <u>Commercial Sponsorship Policy</u> was higher than expected. We used Cochrane's standard dissemination methods – newsletters and social media – as well as internal email discussion lists to reach our target audiences of Cochrane Review Group editorial staff, Cochrane authors, healthcare consumers, clinicians, guideline developers, policymakers and research funders. We believe that by allowing six weeks to complete the survey, we optimised our feedback to inform revising the policy.

The survey questions were informed by issues faced by the Funding Arbiters and other COI debates that we know are ongoing in the wider Cochrane community. The project team felt it was particularly important to investigate stakeholder perceptions of how strict Cochrane should be in regard to any conflicts in an author term, whether the individual or institution receives the relevant payment, the involvement of trialists in Cochrane Reviews and the possible impact of non-financial interests. Overall the free-text comments indicate a wide range of responses. Some respondents – usually those not directly involved in producing Cochrane content – were inclined toward a stricter approach in any revised COI policy, but there was also a strong message about ensuring the policy is workable and does not prevent us from using a wide range of people with relevant clinical and research expertise.

We were particularly keen to get feedback from Cochrane authors because any policy changes could have a potentially significant impact on that group. 58% of responses were from respondents involved in producing <u>Cochrane Library</u> content. Cochrane is an international organization, with members and supporters in 130 countries, but our survey was mainly completed by respondents in Europe and North America. However, there are understandable issues with dissemination in, for instance, in China and African countries.

3.2 'Not-for-profit' organizations

The majority of respondents thought that 'not-for-profit' organizations which have an interest in the outcome of a Cochrane Review should be viewed in a similar way to commercial organizations, with any payments made by them to authors seen as conflicts of interest. However, this result may be difficult to interpret, for several reasons. Firstly, there may have been variable understanding of what constitutes a 'not-for-profit' organization. Secondly, the notion of an 'interest in the outcome of a Cochrane Review' is not the same as having a financial interest in the outcome, and it is difficult to know which of these the respondents had in mind. Thirdly, we used the phrase 'conflicts of interest' as opposed to 'interests' which we used in other questions and this may also have contributed to a misunderstanding of the purpose of the question.

Perhaps those answering this question have considered 'not-for-profit' organizations as charities, aware that some charities are partly, sometimes fully, funded by industry and therefore would have a financial interest in research outcomes. However, 'not-for-profit' organizations also include nationally funded institutions like the Canadian Agency for Drugs and Technologies in Health (CADTH).

3.3 Healthcare professionals

While the majority of respondents did not think that being a healthcare professional should be considered a barrier to authoring a Cochrane Review, there was a difference in Cochrane versus non-Cochrane responses, with more non-Cochrane respondents believing this to be problematic. The qualitative analysis suggested that professional and intellectual interests, (e.g. advisory board membership) should be declared and managed by health professionals. However, the problems associated with implementing a very strict policy that prevented health professionals with real-world healthcare delivery expertise from participating in Cochrane Review production was also noted.

3.4 Clinical trialists

The current policy states that review authors who have participated in clinical trials included in the review should not extract the data or undertake risk of bias assessment for their own studies and the majority of respondents believed this was acceptable. More Cochrane than non-Cochrane respondents said this was not acceptable, perhaps being more aware of other areas that trialists could influence the review, e.g. by defining the inclusion criteria and selecting outcomes measures.

When asked if a researcher on an industry-funded trial should be allowed to be the lead author on a review (if they use the intervention(s) of interest to the review), the majority of respondents said 'no'. Fewer said this was dependent on their role in the trial, e.g. principal investigator versus junior investigator. The issue of rare disease research was highlighted as something requiring a 'case-by-case' management approach. The qualitative analysis indicates here may have been variable understanding of the term 'industry-funded trial'. There is a difference between trials that are run independently, but supported (wholly or in part) by industry funding (directly or indirectly via a research organization), and those which are run completely by industry with control of the data and their analysis. The current policy does not capture that important nuance.

The question about whether industry-funded clinical trialists should be allowed to be an author generated more free-text responses than any other question in the survey. However, it appeared that the difference at the end of Question 10 ("be an author at all") and Question 11 ("be the lead author") was not noticed by some respondents. Regardless, there appear to be concerns about the influence an industry-funded trial author could have on a Cochrane Review. If authors are treated in a similar way to the tobacco industry, then they would be banned from being on the review team; alternatively, they should declare the full extent of their role in an industry-funded trial and their input should be managed carefully to reduce risk, while making use of the trialist's expertise.

3.5 Review authors and Co-ordinating Editors

The majority of responses indicate that it is important that the majority of review authors and review group Co-ordinating Editors be free of financial conflicts. One suggestion was to manage rather than avoid, and a 'case-by-case' management process was suggested by some respondents to ensure that rare disease areas are not starved of content experts. There were suggestions from some non-Cochrane respondents that the current policy is too lenient, with a proposal that either two-thirds or all of the review team, plus the lead author, should have no financial COI.

Results for the question about non-financial interests for the lead author and a majority of the team were problematic. We did not provide a definition of non-financial interests, therefore the results may be hard to interpret. Also, we did not provide a comments option, which was a weakness in the survey. However, it is interesting to note that more non-Cochrane than Cochrane respondents said that having a policy stating that the lead author and a majority of the team must have no non-financial conflicts of interest was 'too lenient'. This viewpoint is in line with other feedback from non-Cochrane respondents, specifically, that being a heath-professional is a barrier to being a Cochrane Review author, and that any previous reviews, commentaries and opinion pieces should be declared.

3.6 Non-financial interests - opinion pieces and commentaries and use of social media

There was acknowledgement that Cochrane Reviews need appropriate subject matter expertise, but respondents also noted the importance of full declarations in promoting transparency. There was no strong support for banning participation based on a person having expressed opinions on the review topic publicly.

3.7 Last author

The idea that the last author is often the most senior person and therefore is in a position to influence the conduct of the review appears to be born out in the survey results. There was a clear majority advocating that the last author in a trial publication should be treated the same as the first author.

3.8 Personal relationships

More non-Cochrane than Cochrane respondents thought that personal relationships should be declared, with suggestions that these should only be included if relevant to the Cochrane. The issue of checking these declarations was highlighted, with the understanding that, unfortunately, these types of COI only tend to be uncovered after publication.

3.9 Peer reviewers

When planning the survey, the question about peer reviewers had been considered a marginal one, yet it produced an unclear answer, perhaps indicating that it is a point of contention of which we were previously unaware. Free-text responses suggested that Cochrane should use peer reviewers with sufficient expertise, publish declarations alongside their peer-review comments and ensure appropriate checks of declarations of interest to minimise the potential impact of a conflicted peer reviewer.

4 Conclusions

There was a great deal of interest in this public consultation on Cochrane's current COI policy, from those who create content for Cochrane and those who consume it. The difference in opinion between Cochrane and non-Cochrane respondents will need to be considered, perhaps through increasing awareness about the issues involved and taking precautions to address potential bias. The wide range of responses, from nearly 1000 respondents, many of whom took the time to give extra feedback in free-text comments, will be useful in developing recommendations to inform the revision of the COI policy.