Cochrane

Cochrane Conflict of Interest 2019

Semi-structured interviews with key stakeholders and conflict of interest experts

Contents

1 Brief report

1.1 Background

Cochrane's Commercial Sponsorship Policy is very important to those who create and consume Cochrane content. The current policy was last updated in 2014. In March 2018 the Governing Board approved a proposal to revise the policy and consider including non-financial interests. This included three discrete pieces of work:

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

This document reports the third piece of work: interviews with stakeholders.

Full background

1.2 Methods

The interview candidates were invited to participate in the hour-long semi-structured interview using an online video conference facility. The interview guide was based on uncertainties expressed by respondents in the COI survey questions and informed by the Funding Arbiters' caseload. Interviews were recorded and transcribed, and thematic analysis was used to extract key points to facilitate the preparation of recommendations for the COI policy revision.

Full methods

1.3 Results

16 interviews were conducted in February 2019. Participants included representatives of Cochrane's various stakeholder groups – funders, guideline developers, consumers, clinicians, science writers and Cochrane Review Group (CRG) leaders. Five key themes emerged, structured around the main interview questions. These are presented below:

1.3.1 Strengths of the policy, i.e. 'Elements should remain the same'

The key message was that Cochrane's current COI policy is perceived to be relatively strong. Many interviewees stressed that prohibiting the lead author and majority of authors on a Cochrane Review from having any conflicts was a key strength of the policy, which should be maintained. There was also support for prohibiting review authors who had been involved in the conduction of primary studies included in a review from extracting data, or assessing the risk of bias for their own studies.

1.3.2 Weaknesses of the policy, i.e. 'Areas for development'

Interviewees suggested that the current policy would benefit from having clearly defined key terms and scope, and from providing more information about Cochrane's COI management process, including the role of the Funding Arbiters, and how appeals are managed.

1.3.3 Non-financial interests

Many of the interviewees noted that non-financial interests were not included in the current policy, but also acknowledged that there was little empirical evidence about the impacts of non-financial COIs. The majority felt that those involved in producing Cochrane Reviews should declare non-financial interests for the sake of transparency, but that these should not present a barrier to involvement. The need to distinguish between non-financial interests and 'indirect' interests, which could lead to financial interests, was highlighted.

1.3.4 Strictness versus leniency

Many perceived Cochrane to have a strong COI policy and believed that it is important for this to remain the case. There were conflicting views on whether the current policy needed strengthening or simply clarifying. Most agreed that the consequences of inaccurate declarations should be clearly indicated in the policy to uphold the integrity of Cochrane's reputation.

1.3.5 The influence of commercial interests in healthcare

There was a general perception amongst interviewees that people receiving industry funding may not behave objectively as researchers. There were varying views about the value of introducing financial thresholds. Some noted that there is no evidence that bias is more likely when the financial gain exceeds an arbitrary threshold, and noted that the same monetary sum may have different meanings according to context (e.g. stage of career, geographical location or speciality). Interviewees discussed commercial organizations providing funding to an institution where a Cochrane author works. There was general agreement that that this was only a problem where the payment was linked to their specific Cochrane activity (e.g. work on a review) and where the Cochrane contributor had access to and control over the funds.

Full results

1.4 Conclusions

The interviewees were very engaged. The policy was perceived as being strong and Cochrane as being a leader in this area, but clarification of the current policy is needed to ensure consistent interpretation and to support implementation. The addition of declaration of non-financial interests was recommended, but should not lead to the exclusion of authors.

Full discussion of findings

2 Detailed report

2.1 Background

It is important that Cochrane has a clear and open policy to manage conflicts of interest (COIs). Cochrane's current Commercial Sponsorship Policy is unusual among those of scientific journals (although more consistent with those of major guidelines organizations) in that it not only requires conflicts of interest to be declared, but also rules that some COIs exclude people from contributing to Cochrane activities.

The Cochrane Funding Arbiters have found that some clauses in the current policy are ambiguous or missing detail, and so difficult to implement. Audits requested by the Cochrane Governing Board Co-Chairs in 2014 and 2017 showed inconsistent adherence to the policy. There has also been discussion, both within and outside of Cochrane, about the role of non-financial (academic, professional and personal) interests, and whether the policy should address these. In March 2018 the Governing Board approved a project to revise the current Commercial Sponsorship Policy and develop a non-financial or academic conflict of interest policy. An editorial in the Cochrane Library describes the background and plans for this work.

The Cochrane Commercial Sponsorship Policy was last updated in May 2014, following a consultation exercise. In November 2017 the Cochrane Governing Board asked the Editor in Chief to revise the policy. The project started late in 2018 and is now complete. The project was informed by three pieces of work:

1. an online survey of the views of Cochrane members and other interested respondents, which had nearly 1000 respondents, and provided both quantitative and qualitative data;
2. an assessment of the COI policies of other healthcare-related organizations including journals, guideline producers and healthcare research funders;
3. semi-structured interviews with 16 Cochrane stakeholders and key opinion leaders in this area.

This paper reports the results of the third piece of work: the interviews.

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2.2 Methods

2.2.1 Aims and objectives

The aim was to understand the views of people who had expertise in COI and who represented organizations whose work aligns closely with Cochrane and Cochrane values. To do this we undertook a stepwise process in which we:

1. recruited participants who would give useful and informed contributions;
2. developed an interview guide for the interviews to inform a COI policy revision;
3. explored the views of the interviewed participants through a semi-structured interview lasting up to an hour;
4. summarized the views expressed in a brief report.

2.2.2 Participants

2.2.2.1 Inclusion criteria

We aimed to invite people external to Cochrane, who either came from global organizations involved in producing or using systematic review evidence, or had a role in healthcare policy making, or had COI

expertise (funders, guideline developers and healthcare professionals). We also wanted representatives from within Cochrane, including authors, editors, centre directors and consumers. We were aware that many people within Cochrane hold several roles both in and outside of the organization and therefore we anticipated some role overlap.

2.2.2.2 Recruitment

We used a three-stage process. The COI revision project team constructed a long-list of potential interviewees, including 39 candidates derived from personal contacts and recommendations from colleagues. This was iteratively reviewed, with the aim of achieving an equitable representation in terms of gender, geography and professional perspective/experience. A list of 20 proposed candidates with 19 reserves was then sent to the COI Revision Project Board for feedback on the possible candidates and whether they had any additional suggestions. After discussion, 20 candidates were contacted in December 2018 and January 2019 for interview in February 2019. Sixteen people agreed to participate.

2.2.3 Interview structure

An interview framework was developed (Appendix 1). This was informed by the Funding Arbiters' database of previous cases referred for advice, and by preliminary findings from the community survey. All who consented to participate in the study were assured of confidentiality and anonymity. The interviews were conducted via GoToMeeting using cameras whenever possible and recorded with permission. The interview process was tested using the interview guide.

The interview was semi-structured, led by the interview candidates and tailored to their responses. At least one week before their scheduled interview all participants were sent a copy of Cochrane's current Commercial Sponsorship Policy. They were also asked to consider and discuss the following issues.

1. For systematic reviews, the extent of any COIs in an author team. Currently the existing policy states that the lead author and a majority (> 50%) of the team must have no COI.
2. The inclusion of researchers who have participated in clinical trials working as authors on Cochrane content.
3. The extent to which we should differentiate between levels of financial support received by people contributing to Cochrane content.
4. Payment of funds from commercial organizations to the home institutions of people producing Cochrane content.

2.2.4 Analysis of Interviews

The interviews were transcribed using the inbuilt GoToMeeting transcription feature and checked for accuracy by Kirsty Loudon (KL) with help from the Central Executive Team (CET). Notes made during the interviews by KL, and completed soon after the interviews, were used with the transcripts to identify key themes arising from the issues discussed. Thematic analysis followed the framework method (Spencer 1994; Spencer 2002) and was undertaken by KL with advice from Quinn Grundy (QG). In brief, the framework method used an immersive stepwise approach of sifting, charting and sorting to produce a structured output of summarized qualitative data. All interviews, analysis and interpretation of the results was undertaken by KL.

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2.3 Results

Sixteen of the 20 people approached agreed to be interviewed; these included representatives of stakeholder groups, consumers, health professionals, CRG leaders and others with COI expertise. Participants were balanced by gender and worked in different locations, including Australia, Europe, South America and the USA. The interviews lasted between 45 and 90 minutes. Many participants had prepared detailed notes to give specific feedback on the policy and feedback highlighted discrepancies or clauses that needed clarification.

There was a variety of opinions and it is likely that we did not reach 'saturation' of the range of viewpoints. Nonetheless, recurring themes emerged from participants.

The information collected from the interviews, including any feedback on Cochrane's current policy, and any other ideas relating to COI, have been gathered into a structured summary report with five subject headings related to the areas of discussion.

1. Strengths of the policy, i.e. 'Elements should remain the same'
2. Weaknesses of the policy, i.e. 'Areas for development'
3. The problem of non-financial interests
4. Strictness versus leniency
5. The influence of industry

These themes are described from **4.1** to **4.5** with illustrative quotes to describe the relevant issues and to indicate where view aligned or diverged. The themes were supported by data from all six respondent groups: funders, guideline developers, consumers, clinicians, science writers and CRG leaders. Transcripts and quotes are anonymized, but we have categorized the roles of the individuals supporting different views to give an indication of who was giving opinions. Individuals may have had multiple roles.

2.3.1 Strengths of the policy, i.e. 'Elements should remain the same'

The Cochrane policy was viewed as strong and important for protecting patients and users of Cochrane Reviews. A variety of policy clauses were particularly noted by interviewees, including the transparency of declarations, the need for the lead author to be free of conflicts, and for the majority of the author team to be free of conflicts. With respect to the involvement of people who have also worked on clinical studies, it was recognized that, while content expertise is valuable in the review process, trialists should not extract data from, or appraise the risk of bias of, their own trials.

Consideration for Cochrane	Role of individuals supporting this view	Illustrative quotes
Strong policy is important to prevent harm to patients	Educator, Cochrane Centre Director, Public Health Practitioner, Researcher	***Cochrane has a relatively strong financial conflict of interest policy … they've been a leader in looking at this issue … It's important to have very strong policies about this because what happens is people's lives can be significantly harmed*** **(4).**
Lead author and majority of authors free of COI	Cochrane Author, Clinician, Editor, Researcher	***I think it's important that the guarantor of the review or the main person of the review is free of conflicts of interest*** **(1).**

		There is a necessary balance of benefits and harms. I think the current [stipulation about] the lead author and the majority is probably a reasonable one. There's a compromise between known [conflicts] and the extreme of having no conflicts **(10).**
Utilize expertise of trialists undertaking primary research in the author team as long as they do not assess their own data for included trials.	Cochrane Author, Cochrane Co-ordinating Editor, Clinician, Editor, Educator, Funder, Guideline Developer, Journal Editor, Knowledge Translation Practitioner, Policymaker, Public Health Practitioner, Researcher, Publication Ethics Expert	***I think that's the reason why I don't think we should be excluding [authors] through trials because of this exclusion [in the editorial management process] by Cochrane authors. If you have a sensibly built authorship group then you can have people who weren't involved in the trials extracting those trials*** **(13).** ***The authors who have been involved in industry trials should not be completely left out … [they just] need to declare … I think many, many well-meaning individuals and organizations do get funding from industry to develop health technology*** **(3).**
Policy governance for COI is independent of Cochrane	Funder, Health Journalist, Knowledge Translation Expert, Policymaker	***The whole funding arbiter thing is great. One of Cochrane's real saving graces is that there's somebody independent of the process … clearly, they do more than just funding … but I've got no criticism of the process. Is that the right title for that role?*** **(5).**

2.3.2 Weaknesses of the policy, i.e. 'Areas for development'

Most interviewees had opinions on how to improve the current policy and suggested changes that would strengthen their confidence in it. Although the principles and content were commended, many felt that the language could be improved and be more descriptive; this included the following points.

1. Some language was not clear enough, or what it referred to specifically was unclear. Suggestions included clarifying the definitions of 'commercial sponsorship', 'vested interest' and 'appropriate funder'.
2. Clarification of the definition of a 'not-for-profit organization'. Some saw not-for-profit organizations as a spectrum, with some having for-profit funding behind them.
3. Clarification of the scope of the policy, with a more explicit description of which roles it covers.
4. Interviewees had differing opinions about the extent to which people involved in clinical trials should also be able to author reviews. Although the policy imposes some restrictions on people associated with any commercial funding for the primary research in the subject area of a review, many interpreted this as only relating to randomized trials. Some interviewees suggested this should include other study designs which may be included in Cochrane reviews, e.g. observational studies.
5. Interviewees suggested that the COI management process needed to be more clearly expressed. This should start with declaration of interests for Editors, Authors and Peer Reviewers, and extend from review registration through to publication of a review. The declaration form should clearly

indicate what should be included with an additional sign-off guaranteeing that the information was accurate.

6. Details of how to refer cases to the Funding Arbiters and the Funding Arbitration Panel need to be clearer. It was suggested that the names 'Funding Arbiter' and 'Funding Arbitration Panel' did not reflect their management of all types of COI.
7. A few interviewees made suggestions about procedures for checking declarations using the internet, registers and external audit to ensure objectivity and transparency.

Consideration for Cochrane	Roles supporting this view*	Illustrative quotes
Clarity of language	Educator, Guideline Developer, Health Journalist, Journal Editor, Knowledge Translation Practitioner, Policymaker, Publication Ethics Expert, Public Health Practitioner, Researcher	***It's helpful to be a bit clearer about the definitions of interests that are relevant to the review* (16).** ***[Cochrane's COI policy has a] focus on pharmaceutical and medical devices [but maybe] it should consider other entities and other for-profit entities. We should also have reporting of for-profit companies giving money to research institutes* (4).** *[I'm] open to interrupted time series and other designs and … even observational study … qualitative syntheses … my inclination is to just change the language. So, it's essentially anyone, any study authors* (14).*
The role of the Cochrane Review Group Editorial Team in checking all declarations - checks early in the review process as a way of avoiding future problems.	Consumer, Cochrane author, Cochrane Co-ordinating Editor, Editor, Guideline Developer, Journal Editor, Policymaker, Researcher, Publication Ethics Expert	***The author should declare everything and then the editor decides what was relevant and what wasn't and that our decision was final* (9).** ***…(we) go in that direction, checking the accuracy of DOI [Declarations of interest] and maybe minimizing or decreasing risk of bias and doing an internet search. Is Cochrane thinking about that aspect of due diligence and checking for accuracy?* (8).** ***You should treat the patients who write comments on a review with the same standards* (6).**

2.3.3 Non-financial interests

Many interviewees had noticed that the policy did not include non-financial interests. They acknowledged that there is currently little empirical evidence of non-financial interests leading to biases, but felt it represented a lack transparency if they were not included. One interviewee said: "*Just because there's not a body of evidence to show it, doesn't mean it isn't a slippery slope"* (5).

Interviewees believed that professional interests may influence the perspective of a person, and that being a member of an advisory board or board of directors in an organization that has an interest in the topic area should be declared, even when not remunerated. There were suggestions that intellectual interests that may arise from working as a clinician could be perceived as a conflict and should be declared (this is in the current policy). Some felt that declared interests should also extend to any published commentary. There was general agreement that a contributor need not be excluded from working on Cochrane content if they had such non-financial interests.

Consideration for Cochrane	Roles supporting this view*	Illustrative quotes
Need for a distinction between non-financial and 'indirect' interests which could lead to financial interests	Cochrane Author, Clinician, Guideline Developer	***We should not say 'non-financial' because in the area of indirect interest you will find issues that could lead to secondary financial interest. For example, clinical revenue streams; if you are a known researcher in a field you might increase the number of patients coming to your clinic. We have example X with a guideline author on a very rare disease and he became so famous that he has patients from all over the world*** **(2).**
Membership of professional organizations and other professional interest	Cochrane Author, Cochrane Editor, Clinician, Ethics Expert, Researcher	***Membership of relevant organizations is an important one and it doesn't necessarily have to be exclusionary, but it has to be declared, you know, so patient support groups lobby for people, are not part of organizations and don't necessarily get any funding, but are absolutely sort of tied to it. Giving advice to government or anything like that can be quite important, and if you're involved in things like societies, you have an interest in what that society is promoting and quite often those positions are not paid at all*** **(9).** ***[Being] on panels that [have an] impact on the definition of a disease or who gets treated for a disease … If you expand the definition of X, then you're expanding your professional territory. It's actually financially good for you to expand and it's not good to contract the number of people that get treated so that does have implications for some Cochrane Reviews…For example, if you were looking at the treatment of mild hypertension the very fact that there might be a benefit to the treatment [causes] a push towards treating that group and therefore classifying them as hypertensive and wanting to manage them more actively. So those things that push boundaries are actually financial conflicts that are not recognized as financial conflicts*** **(10).**
Declaring non-financial interests but not banning engagement in	Cochrane Author, Centre Director, Clinician, Cochrane Co-ordinating Editor, Ethics Expert, Funder, Guideline	***I think it is reasonable to include those things (expertise, intellectual, reputational interest), but not to exclude people. Rather [you should] understand … who people are and where they're from and you know, there might be … conflicts. You know, they published 24 pieces in this***

review production	Developer, Journal Editor, Knowledge Translation Practitioner, Policymaker, Researcher	***area and you can go look at them. You can really understand what this individual's position is … [it will be] quite clear that they are a proponent for the technology or an opponent of the technology*** **(11).**

2.3.4 Strictness versus leniency

A consistent theme throughout the interviews was that Cochrane's policy was seen as strong and that this was important for its reputation. Some interviewees were concerned that, because the policy states that "a majority of the review authors have no relevant COIs" this might mean conflicted authors still might have influence, and therefore favoured having author teams that were completely free of financial conflict. One interviewee suggested that this stricter approach could be phased in over a few years to help authors extract themselves from conflicting relationships. However, others noted that making the policy stronger (e.g. author teams with no financial conflicts, or restricting authorship for those with non-financial interests, or both) could lead to review teams with insufficient practical clinical expertise. Retracting reviews that breach the policy was seen as positive, emphasising a strict approach. It was suggested that the consequences of inaccurate declarations should be clear in the revised policy.

Consideration for Cochrane	Roles supporting this view*	Illustrative quotes
Divergent views on policy strictness	Cochrane Author, Cochrane Co-ordinating Editor, Cochrane Centre Director, Funder, Policymaker	***I think we could go tighter and make sure that no conflicts of interest exist in Cochrane Reviews. All of the Cochrane Reviews were free of any kind of conflicts of interest; not all of the authors, but all of the reviews*** **(1).** ***It's also about very strict requirements for the first and last [authors] and then we can have more lenient requirements for the middle authors, but there should still be conflicts of interest that we could not accept for those authors*** **(12).** ***I think if it remains in this form or a stronger form you'll probably lose a lot of authors. You'll probably lose whole groups because it doesn't work in the real world*** **(13).**
Repercussions for not providing accurate Declarations of interest should be more widely known and included in the COI policy	Cochrane Co-ordinating Editor, Cochrane Centre Director, Guideline Developer	***I think it should be clearly stated that that we do take [conflicts of interest] seriously, to the extent that we will go to the length of retracting reviews if people do not live up to our requirements and that's not currently actually in the policy*** **(12).**

2.3.5 The influence of commercial interests in healthcare

It was noted by interviewees that Cochrane authors who have received healthcare industry funding might be biased in their decision-making. The significant body of evidence regarding systemic bias in industry-funded studies was noted by one interviewee. There were different views on the need to set financial thresholds. Some said that funding from commercial sources, e.g. for travel, consultancies, etc., were context dependent. They could be interpreted differently and have different impacts, depending on the author's geographical location, stage of career, clinical role and medical speciality. The policy currently states that "renumeration from a consultancy and speaker's fees should be declared". Some suggested assessment on a case-by-case basis, while others pointed out that there was no empirical evidence base for setting thresholds.

There was general agreement that authors who work in institutions that receive industry funding should declare such institutional funding (if known), and the amounts of funding could be a factor in deciding whether there is a conflict of interest. However, unless it is received directly by and under the control of the review author, it was considered unlikely that such funding would be perceived as a financial COI.

Interviewees were asked about review authors who had worked on clinical trials (particularly industry-funded) but not been specifically named in subsequent trial publications. It was suggested that there may be bias, or a perception of bias, relating to such individuals if they join a Cochrane Review author team and that best practice would be for other members of the author team to extract data and carry out risk of bias assessment for these trials.

Consideration for Cochrane	Roles supporting this view*	Illustrative quotes
The importance of independence from industry	Cochrane Author, Clinician, Cochrane Co-ordinating Editor, Cochrane Editor, Health Journalist, Knowledge Translation Practitioner, Researcher	***If an author of a trial does not have a very independent mind there is … a possibility that their judgment might be affected*** **(3).** ***The evidence on the systemic bias in industry-funded studies is overwhelming and indisputable, and so to have trialists who have been involved in industry-sponsored studies being involved in reviewing those industry-sponsored studies is to my mind compounding and amplifying that systemic bias*** **(7).** ***I think the more important thing is not so much the amount of money. It's the potential for ongoing funding from that source. If they don't have any ongoing relationship that's not a conflict*** **(10).**
Divergent views on setting thresholds for financial interests	Cochrane Author, Clinician, Cochrane Co-ordinating Editor, Educator, Guideline Developer, Health Journalist, Journal Editor, Researcher, Knowledge Translation Practitioner, Policymaker,	***It's partly geographical, middle-income country versus upper-income, but it's also about specialty; different groups who are just going to have fundamentally different dollar values that attract their attention*** **(14).**

	Publication Ethics Expert, Public Health Practitioner	***I think that the sums should be declared, and I think it's kind of a qualitative rather than a quantitative decision. I don't think there is reasonable evidence for these thresholds*** **(2).** ***As I understand it, they are supposed to [declare] but it never does have [amount], and I do think that's a problem. I don't know that it's got an easy solution but there is a huge difference between somebody once having sat on some panel at a conference where a USD 200 airfare got paid and somebody having five employees whose livelihood depends on continuing to get three million dollars a year*** **(5).**
Perceptions of commercial organizations providing funding to institutions where a Cochrane author(s) works	Cochrane Author, Cochrane Centre Director, Cochrane Co-ordinating Editor, Cochrane Editor, Educator, Funder, Guideline Developer, Health Journalist, Journal Editor, Policymaker, Knowledge Translation Practitioner, Publication Ethics Expert, Public Health Practitioner, Researcher	***I don't think that should count me out as an author unless the money that the institution obtained was linked in any way to the intervention of interest or to a comparator intervention. If we get money from Novartis to look at people's fear of needles in the context of insulin and management of diabetes, and I want to be involved in a Cochrane Review on the use of a drug for Alzheimer's, I don't see a problem with that at all*** **(11).** ***I think the magnitude [of the financial support] probably does make a difference because I could imagine that the reviewer could get pressure from their Vice Chancellor or Head of Department about a review, if they were coming to conclusions that may annoy their funder … It would only be relevant funding [if it came from] the pharmaceutical company that produces the product that you're reviewing for example or one of the competitive products*** **(10).** ***If you have any control, any discretion over the expenditure of the funds, yes, that would be different than if your hands are off and you have no relationship to it*** **(8).**
Perceptions about co-	Cochrane Author, Clinician, Cochrane Co-ordinating Editor,	***Those co-investigators are usually folk who recruited patients to the study. [They]***

investigators who are not named authors in trial publications	Cochrane Editor, Educator, Funder, Guideline Developer, Journal Editor, Knowledge Translation Practitioner, Policymaker, Publication Ethics Expert, Public Health Practitioner, Researcher	***don't bring the same intellectual contribution to the review. They may have ties to the pharmaceutical company [or] they may have none at all*** **(10).** ***If I'm not an author, but an investigator, then I won't extract the data from that trial, but I will have no idea who the other 115 patients in the trials data were and I have no influence on any of those. This is not necessary. But actually it's demonstrating to people that by doing that we've done our best to exclude any sources of bias*** **(13).**

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3 Discussion

Through these interviews Cochrane sought to elicit important feedback from individuals who represented the interests of our key stakeholder groups. All 16 interview participants engaged enthusiastically and made valuable contributions. As the interview was semi-structured with very open questions at the start and finish this gave the interviewee the opportunity to give additional input that had not been anticipated. Although there were differing opinions, there were some interesting suggestions and areas of common agreement.

Although not unanimous in their views on the how strict the policy should be, most thought that Cochrane's approach to managing conflicts of interest is very strong and should not be diluted. There was some confusion about terminology, which many felt could be improved to ensure that policy users know exactly what is expected by Cochrane. Some interviewees made more radical suggestions. We acknowledge that these are individual opinions and that there is a lack of empirical evidence to support things like the use of financial thresholds and declaration of non-financial interests. As there were only a few individuals within the different stakeholder groups – funders, guideline developers, consumers, clinicians, science writers and Cochrane Review Group leaders – we need to be cautious about over-interpreting the perspectives from any single group, particularly as individuals often had multiple roles. However, it did not appear that different stakeholder groups had radically different views.

Those interviewed were all given the same information beforehand but, because they had different levels of engagement with Cochrane, they had differing knowledge of how the current policy worked. For instance, several did not know that there was a website for declarations of Cochrane Groups and individuals: community.cochrane.org/organizational-info/people/conflict-interest. This lack of awareness may relate to how closely the interviewees worked with Cochrane, but it also highlights the importance of developing a comprehensive implementation plan for the new policy to ensure that the new policy is widely understood and used.

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4 Disclosure

Disclosures for KL can be viewed at: https://community.cochrane.org/organizational-info/people/conflict-interest/cet/person/EE04F79282E26AA2012B523C8011EF9A. KL declares no conflicts of interest in undertaking this review for Cochrane. KL had no prior expertise in the field of Conflicts of Interest or in-depth knowledge of the issues around COI which could be perceived to have biased interviews. Her previous work in research and teaching has been in research methodology, trial design and nursing.

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6 Appendix 1

Interview Guide for semi-structured interviews

Preamble: ***I am a Project Officer with the Cochrane Editorial and Methods Department, in the team revising the commercial interest policy and integrating non-financial aspects. This interview is part of a large project re-assessing Cochrane's conflict of interest policies, both financial and non-financial. Thank you for agreeing to be interviewed.***

Number	Question	Prompts	Notes
1	To start with, I'd be interested in your thoughts about Cochrane's current COI policies in general and how they compare with other organizations you have associations with.	What would you recommend? Could you share particular experiences from your own organizations/work where conflicts of interest are managed well? Do you think there is a difference between the importance of financial and non-financial conflicts of interest, and how does this impact on their management … please explain?"	

Number	Question	Prompts	Notes
2	What do you consider to be the strengths of Cochrane's conflict of interest policy?	Please share examples or particular experiences you had as an editor/researcher/guideline developer/policymaker where you felt the policy was successful. What was the nature of the conflict of interest? Why was it significant in this situation? How was it dealt with?	
3	What do you consider to be the weaknesses of Cochrane's conflict of interest policy?	Please share particular experiences you as an editor/researcher/guideline developer/policymaker where you felt the policy was inadequate. What was the nature of the conflict of interest? Why was it significant in this situation? How was it dealt with? How could we improve the Cochrane COI policy?	
4	Which non-financial conflict of interest you think the policy should consider, if any?	Cochrane currently has a commercial policy. Do you think we should add non-financial interests?	
5	Cochrane's current policy states that the lead author and a majority of the team must have no financial conflicts of interest. What do you think about this?	Do you think it is fine as it stands? Too lenient? Too strict? Add in non-financial so all conflicts of interest?	
6	What do you think about the inclusion of review authors who have participated in clinical trials that are included in the review? Cochrane's current policy states that this is fine as long as it is declared and that they do not extract the data or carry out the	Is there anything else you would think might be worth considering to prevent potential bias?	

Number	Question	Prompts	Notes
	risk of bias assessment from their own study or studies …		
7	I have a follow up question, so what are your views on Cochrane review authors and trials in which they have participated where there was industry involvement? So, we have identified three scenarios. What are your views? 1. 'Industry sponsored' – all funding for the trial is provided and industry determines study design and analysis. 2. 'Industry-funded' – some funding from industry but researchers retain control over study design, methods, analysis and reporting. 3. 'Industry supported' – industry provide some materials, perhaps intervention or placebo, but play no other role in the conduct or reporting. **Would you treat all of these scenarios as being equivalent?**		
8	Thinking about Cochrane Review authors – do you think there is a difference between a review author who is specifically named in the trial publication, compared with someone who is listed as a trial co-investigator but not as author?	Do you think they should be treated more leniently for instance?	
9	Currently the policy does not differentiate between levels of financial support for Cochrane Review authors**.** Do you think there should be financial thresholds for conflicts of interest? For instance: 1. a Cochrane reviewer receiving a modest travel grant from an industry source to attend a Harms Committee meeting compared with; 2. a reviewer on a much larger industry-funded grant to travel round the world presenting their research; or 3. receiving personal payment for consultancy. Do you think these scenarios should be treated the same way, and if not please elaborate?		
10	What do you think about the fairly common situation where a commercial organization(s) provides funding to institutions where a Cochrane Review author works?	Do you think that is OK? Do either the magnitude of the funding, or the degree to which the review author has access to or control over the funds received affect your judgement in this situation?	

Number	Question	Prompts	Notes
	Thank you for taking the time to talk to me. Is there anything you would like to add before we finish?		Conclusion for every interview
	If you think of anything further to add then please get in touch and send me an email.		Conclusion for every interview
	I have a few questions that we didn't have time for, I would be very grateful if you could take a look at them and give me your considered response.		Follow up email if did not cover all the questions.