



EDITORIAL

Cochrane's plans to update its COI policy: truth and fiction

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Cochrane has a stricter financial conflict of interest (COI) policy than almost all journals,[1] and this encompasses all aspects of Cochrane Review production and applies to everyone from authors to the editorial staff. A key tenet of the policy is that declaration of relevant conflicts is essential but sometimes not sufficient, to the extent that some conflicts will prevent an author from joining a Cochrane Review team. The policy is overseen by independent funding arbiters, supported by a panel that combines experienced Cochrane editors and methodologists with experts from outside the organization. The funding arbiters report directly to Cochrane's Governing Board.

In April 2018, the Governing Board approved a proposal to undertake a broad review of Cochrane's commercial sponsorship policy, which has been in place since 2004 and has been updated several times, most recently in 2014.[2] The board also approved a proposal to develop a new non-financial conflict of interest policy in parallel. We want to ensure that the revisions to the existing policy will lead to greater clarity and a continuing transparent and strict approach to this issue. In addition, as an evidence-based organization, it is important that where possible the policies are informed by empirical evidence and current best practice in related organizations, such as research funding bodies, clinical practice guideline agencies, and biomedical publishing organizations. Cochrane's current commercial sponsorship policy is clear that end-users of Cochrane Reviews must be confident that the reviews are not influenced inappropriately by commercial and other conflicting interests.[2] As a result, an individual author may be prevented from leading or even contributing to a Cochrane Review if a conflict is deemed to be sufficiently serious. A Cochrane Review may not be supported by a commercial organization that has an interest in the findings of the review, and the majority of the review authors must be free of any relevant conflicts.

Recent comments on social media and elsewhere have suggested that the opportunity to revise the COI policy will lead to a weakening of the financial policy and even that it signals that Cochrane wishes to work more closely with industry. We wish to state here

categorically, and for the record, that these allegations are entirely unfounded and untrue.

One might ask why it is necessary to change the policy now. From our perspective, there are three important reasons. Firstly, we have accumulated a large body of experience of handling COI questions, and we are aware of scenarios that currently are ambiguous or fall outside the existing policy. Secondly, our ongoing audit of policy adherence demonstrated some inconsistencies in how rigorously the current policy is applied by Cochrane Review Groups. The audit also revealed systems issues which mean there can be significant differences between COI declarations published in the *Cochrane Database of Systematic Reviews* and those held in Cochrane's content management system. Lastly, we are aware of examples where author teams have clear non-financial interests that have been an obstacle to achieving the necessary equipoise, leading to the potential for 'spin' or worse in reporting or interpreting the results of their reviews.

Cochrane's current policy prevents individuals who are employed directly by companies, or who hold or have applied for patents relating to the review interventions or comparators, from being Cochrane Review authors.[2] In addition, it requires a majority of authors in any author team, including the lead (first) author, to be free of relevant conflicts. When this was agreed in 2014 it represented a compromise position, between those who wished Cochrane to go further, perhaps by avoiding any involvement from individuals with competing interests, and those who argued that such restrictions make it too difficult to attract high-quality researchers in some disciplines and that barring all links with industry is contradictory to public policy messages given to researchers in many countries. In our judgement it is unthinkable that Cochrane would now relax its policy. The key question is the extent to which it is strengthened.

The current policy makes no allowance for the magnitude of conflict: extremely different levels of exposure are treated equally. The impact of involvement in sponsored research and of employment in areas that may be perceived as representing a

conflict (working in private medical or allied health practice in the topic area of research, for example) may need to be revisited. The current policy is insufficiently clear on the issue of research funding, and exempts employment except when with industry. We recognize that under the existing policy review authors are required to declare whether they are engaged in private practice in the area of interest, but this is not managed consistently across our community. These areas might need to be strengthened to represent current best practice and minimize the risk of bias. It will be important that the financial and non-financial policies are closely aligned.

In addition to conflicts relating directly to Cochrane Reviews, we will also consider those that relate to other Cochrane publications such as Editorials and Cochrane Clinical Answers. It may also be timely to consider how emerging initiatives such as Cochrane Crowd (crowd.cochrane.org) and Cochrane TaskExchange (taskexchange.cochrane.org) need to be incorporated within Cochrane's COI policies, given how the 'micro-tasks' carried out by people contributing through these platforms may exercise an increasing influence on review production.

The policy revision project is now up and running. Kirsty Loudon is an experienced evidence synthesis researcher with strong links to Cochrane and will bring a high level of expertise and experience to the role of Project Officer. She will be supported by Cochrane's Editorial and Methods Department and the funding arbiters. Two project boards have been appointed, and these include members of the Governing and Editorial Boards and representatives from the Cochrane Council. In the initial stages, we will explore how the available evidence and experience in other related organizations can guide and inform our policies. The project will also include substantial consultation with internal and external stakeholders. We aim to bring the revised financial and new non-financial policies to the Governing Board for ratification.

In our judgement, there is now an opportunity for Cochrane to institute policies and processes that consider a wider range of possible inherent biases that authors and others must consider. All of us have biases; they are an unavoidable part of who we are. Therefore, we want to be clear from the outset that this policy is about declaring all potentially relevant interests, not simply those that some arbitrary rules define as 'conflicts' requiring action.

Examples of issues we might want to address are:

- Working as a health professional in an area that uses the intervention(s) of interest or any potential comparators
- Participating in research that investigates the intervention(s) of interest or any potential comparators
- Publishing any previous review or opinion piece addressing the intervention(s) of interest or any potential comparators
- Having any other specific personal interest in the intervention(s) of interest or any potential comparators

It may be necessary to institute some exclusions to authorship relating to non-financial conflicts, but in the main we anticipate that

clarity and transparency will be sufficient. Full disclosure of non-financial conflicts should help to eliminate the need for guesswork on the part of Cochrane Review users, who would be fully aware of the author team's experiences and likely perspectives. To be clear, we do not regard having specialist knowledge and experience as undesirable and to be avoided - on the contrary, it is an important component of a review author team. But if all the authors are super-specialists who have published widely on the intervention then one might be more sceptical about the conduct of the review even if they were free of financial conflicts. Equally, if the author team is entirely made up of systematic reviewers without specialist knowledge one might worry that important clinical implications could be missed. A COI policy providing clear and transparent expectations of the information required would also make it easier for editors and peer reviewers to be alert to potential biases in draft reviews, and also for authors to decide what they need to declare.

Once approved, the policies will need to be integrated into a single declaration process, which we anticipate will be intuitive and easy to understand for all parties. It will demonstrate the potential overlap between financial and non-financial conflicts. We believe that by combining financial and non-financial declarations it will be easier to develop questionnaire tools for use by authors and editors that address the important issues and do not leave it to the authors to decide what is or is not relevant. It is an important message that Cochrane is not only interested in industry influence and financial conflicts of interest but also in the broader issues of conscious and unconscious bias, with the goal of providing users of Cochrane Reviews with assurance and transparency about the independence and reliability of the review.

We will also need to carefully consider implementation, to mitigate inconsistencies in how the policies are applied, and in doing so we will build on recent experience of policy development in other areas. The implementation plan will include follow-up training, guidance, and audit, with a progressive sanctions process for Cochrane Review Groups and teams that fail to adhere to the policies.

Preventing avoidable risk of bias and the perception of bias in systematic reviews is a crucial part of Cochrane's commitment to assuring quality. It is timely to revisit and revise our financial COI policy and also to explore the challenging waters of non-financial COIs.

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Declarations of interest

David Tovey is employed by Cochrane as Editor in Chief of the Cochrane Library and Deputy Chief Executive Officer. Fergus Macbeth and Angela Webster are joint funding arbiters for Cochrane, since 2015. The role of the funding arbiter is to oversee the implementation of the commercial



sponsorship policy ([more details](#)). This is a voluntary role and there is no remuneration for this work. Fergus Macbeth is also joint Co-ordinating Editor of [Cochrane Lung Cancer](#) and co-chair of the [Cochrane Council](#); these positions are both voluntary and unpaid. Angela Webster is an editor and former deputy Co-ordinating Editor for [Cochrane Kidney and Transplant](#). This is a voluntary and unpaid role. Angela Webster is also an author on multiple Cochrane Reviews, undertaken with several Cochrane Review Groups on a broad range of topics, and has received no payment for any of this work. Angela Webster is employed part-time by the University of Sydney, holding a personal chair as Professor of Clinical Epidemiology and with an [active research program](#). Angela Webster is also employed part-time by Western Sydney local health district as a Senior Staff Specialist in renal medicine and transplantation; this is a clinical role in the public sector. Angela Webster undertakes no private medical practice. Ruth Foxlee has been employed by Cochrane since 2002 and as a member of the Cochrane Central Executive staff since 2011. Ruth Foxlee has never been employed by

or received financial support from any commercial organization operating in the healthcare field.

Provenance and peer review

This Editorial was commissioned and was not peer reviewed.

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