

Beyond Conflicts of Interest Disclosing Medical Biases

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The editors of medical and scientific journals always ask authors of papers to declare any financial conflicts of interest (COIs) related to their research. There has recently been a shift away from allowing authors to decide what constitutes a financial COI toward asking them to disclose any potential perceived COI; some journal editors even ask authors to disclose any and all financial interests that they have. But there has also been a shift away from this focus on financial COIs toward a wider conception of COI that includes other types of bias. Since 2010, all journals associated with the International Committee of Medical Journal Editors (ICMJE) have asked authors to complete a unified COI form that requires disclosure of the following:

1. *Associations with commercial entities that provided support for the work reported in the submitted manuscript (the timeframe for disclosure in this section of the form is the life span of the work being reported).*
2. *Associations with commercial entities that could be viewed as having an interest in the general area of the submitted manuscript (in the three years before submission of the manuscript).*
3. *Non-financial associations that may be relevant or seen as relevant to the submitted manuscript.*¹

Despite the third point's emphasis on "nonfinancial" associations, 1 and 2 could presumably also cover unpaid advisory relationships with companies. On the one hand, the third category widens the definition of COI immensely; any association that "may be seen as relevant" should be declared. But on the other hand, it might be casting the net too narrowly to focus on "associations." This implies that only a relationship with someone or something else can generate a problematic conflict of interest, but as recognized by the *Lancet*, "conflicts can also occur because of personal relationships or rivalries, academic competition, or intellectual beliefs."² It might actually be misleading to refer to such factors as COIs, rather than simply as another potential source of significant bias.³ Indeed, one's own attitudes can constitute a biasing factor that is just as powerful as a COI, particularly when one is writing about areas of medicine with which one has personal experience.

Medical Conflicts of Interest

Here is an example. I once wrote a paper for a medical law journal about water fluoridation, in which I argued that adding fluoride to water was medication and was therefore not permitted by the law.⁴ When I submitted the manuscript, I was asked whether I had any conflicts of interest to declare. I didn't have any financial ones to declare, but I did hesitate because at the time I taught in a dental school. However, dentists are predomi-

nantly very pro-fluoridation, so this would probably not be seen as a COI. On the other hand, I have moderate fluorosis (staining of the teeth) as a result of receiving too much fluoride as a child (although not because of water fluoridation). Was this something that I ought to declare? And even if I ought to declare it, did the fact that doing so would reveal a confidential medical fact about myself provide me with an exemption?

The first thing to note is that my having fluorosis could certainly be perceived as a COI, even if it would more accurately be described as a biasing factor. Proponents of fluoridation could argue that my conclusions were colored (no pun intended) by the discoloration of my teeth, the main side effect of water fluoridation for a small subset of the public.³ However, my argument was not actually predicated on the harms of fluoridation but on the fact that it is clearly medication, when the law does not permit mass medication of this type. Therefore, it could be argued that it shouldn't really count as a potential bias or COI. However, perceived bias is in the eye of the beholder, and the spirit of COI declarations is to err on the side of disclosure of any biasing factors. This brings us to the second question: does the fact that my potential bias concerns private medical details give me a get-out clause from disclosure? It does in the sense that I have no obligation to reveal anything in my private medical or dental records. However, if I wish the arguments in my paper to stand on their own merits, I must avoid concealing a potential bias and declare the conflict. The irony is that 99.99% of readers of the paper will never meet me and could never know about my fluorosis unless I told them. In this sense, declaring a potential bias actually generates the perception of one. But in any case, it could be argued that having dental fluorosis is not really a confidential fact anyway, unless I walk around with my mouth closed. In the end I declared that "the author has moderate fluorosis."

A similar problem arose when I wrote a paper criticizing the requirement for doctors who refuse to conduct nontherapeutic circumcisions to invoke conscientious objection.⁵ Here again, full disclosure of potential biases would mean disclosing my circumcision status. This might appear to be less of an issue than in the fluorosis case, given that a great deal of men are circumcised, while only a small minority have fluorosis. Why should I be obliged to reveal a personal fact to meet some pedantic ethical criterion? For the same reason as in the previous case: to avoid any risk of perceived bias. Most circumcised men are happy with that status, and most uncircumcised men are happy too. Being happily uncircumcised could be seen as biasing me against the practice. In fact, the reason I oppose circumcision of infants

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on religious grounds is because it is medically unnecessary surgery that poses a risk of harm in order to impose a religious identity that is not the child's chosen one. In this case, however, I chose not to reveal the potential bias, although I now think I should have. (Note that this is also different from the fluorosis case in the sense that here, I was not subjected to harm by the practice I was criticizing, but in the case of fluoride, I was.)

Relatives' Confidentiality and Medical Biases

In cases where the medical bias is the author's, it can be left up to him or her to decide whether to disclose it. But what if it concerns a family member? I recently wrote a paper about the pressure put on new mothers to breastfeed, in which I was critical of the one-sided information given to mothers, and the climate of guilt that surrounds failed attempts at breastfeeding. Here, too, I have a potential bias: a family member attempted to breastfeed both her sons when they were born, but was unsuccessful through no fault of her own. Should I declare this when submitting the paper? Again, having witnessed firsthand the potential negative effects of breastfeeding, I could be accused of being biased, and not taking a wider view of the overall benefits of breastfeeding. Therefore, I probably should declare this as a potential bias. However, I can hardly do that without my relative's permission. Does my obligation to disclose extend to disclosing confidential information about someone else? No: any such obligation could never override my relative's right to confidentiality. Even if she were willing for me to disclose information, it would be inappropriate to do so. Furthermore, it hardly seems fair for disclosure of a bias or COI to depend on whether an author's family member grants permission for private data to be shared with a journal's readership.

Although it seems to be going too far to insist that I should reveal confidential information about another person, there are cases in which it may be necessary to disclose certain facts about a family member. As a member of a clinical ethics committee, I was once approached about a singular problem involving a major cancer trial. The doctor who was principal investigator in the trial had a family member who was dying of the same type of cancer that was the focus of the trial. This potential bias had not been declared at the funding or research ethics committee phases, and the trial had initially proceeded well. However, the doctor was now making potentially dangerous treatment decisions for

patients in the trial that seemed to be related to his offspring's worsening condition. The question posed to the clinical ethics committee was: should the doctor's colleagues inform someone about this COI? And who should they tell? We ultimately replied that this bias (COI was the concerned party's term) was not the main issue, but that someone should certainly be told about the bad decisions being made and the risk of harm. Nonetheless, this case does raise the issue of whether such biases should be raised earlier to avoid such situations arising. In the absence of any problematic effects, it would probably seem strange for a PI to mention at an ethics committee meeting that a family member had the same disease as that being investigated. The doctor in this case probably genuinely believed that this was not a COI and that it wouldn't cause any problems. Nonetheless, it did. While reporting such biases may not be necessary at the publication stage, when any confidential information would be broadcast to thousands of readers, such important biasing factors should be mentioned at the funding and review stages of research projects.

Conclusions

Focus on financial COIs has tended to obscure the fact that other biasing factors can seriously compromise an author's impartiality and objectivity. I hope to have persuaded the reader that it is not only "associative" COIs or potentially biasing intellectual beliefs that need to be reported—medical biases are also very important. It may be necessary in some cases for authors who wish to avoid charges of bias or concealing potential COIs to disclose confidential medical information about themselves in publications, and even about others at the study-design and approval phase. As a general rule, authors should disclose potential medical biases to editors unless the information revealed could expose them to discrimination or concerns a third party. In most cases this information should also be shared with readers. While medical facts should normally remain confidential, the duty of researchers to the scientific community and the republic requires that a very high standard of research integrity be met; this necessitates disclosure of medical biases. This might seem to be going too far in the pursuit of transparency, but it should not really be surprising that one's own deeply personal medical experiences might play a significant role in affecting one's assessment of evidence. And of course, had I not declared my various medical biases, I could never have written this paper.

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1. Declaration of competing interests. *BMJ*. <http://www.bmj.com/about-bmj/resources-authors>

[/forms-policies-and-checklists/declaration-competing-interests](#).

2. Information for authors. *Lancet*. <http://download.thelancet.com/flatcontentassets/authors/lancet-information-for-authors.pdf>.

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