

## EDITORIAL

### Conflict of interest declaration: why and what constitutes as responsible and ethical declaration?

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## ABSTRACT

This is one among a series of editorials related to ethics in publication. The present editorial deals with a key issue of the declaration of conflicts of interest (COI), which all stake holders, especially authors should be aware of. Such issues are now mandatory ethical requirements and not just for name sake. Broadly speaking, COI comes into existence when someone's position may be influenced by his vested interests. World Association of Medical Editors (WAME) says 'journals have a responsibility to raise awareness and educate the research community about COI.'

**Keywords:** Conflicts of interest; publication ethics, peer-reviewed journals

## INTRODUCTION

Few years back, I was invited by a spiritual organization to comment on the efficacy of a particular therapeutic intervention subsequent to a one-year follow-up open-label study. The request was to provide with an 'expert opinion' on whether this particular intervention worked. I surmised that the study investigators wanted my 'unconditional positive scientific approval' regarding the efficacy of their intervention. My potential bias in favour of this intervention could have been my spiritual and religious inclination and interest in the ideology of this organization, the financial remuneration I was supposed to get, the unfulfilled desire to get recognized by my peers, and a valuable certificate I hoped to get.

First, the patients spoke, very high about the intervention, telling how this intervention changed their lives. I was mindful of the potential pitfalls here and the importance of not being biased. Hence, when I was invited on the stage to give my 'expert remarks', I said, 'probably the patients responses are preliminary, biased because they belong to a vulnerable group, and also the placebo-responses could not be ruled out. One cannot draw reasonable and final conclusions based upon a study which is open-label, non-randomized, purely sponsor driven, with no proper study protocol in place.' Also, the absence of a baseline assessment of these patients at the beginning of the study was a glaring miss. I felt sorry

to have upset the organiser's aspirations; but, as an individual of science, I should not let my ulterior motives to bias my conclusions. The good part of the story is that I got all incentives that I desired for; however, expectedly I was never re invited by this organisation.

Many researchers and authors are still not literate about publication ethics and do not strictly adhere to specified guidelines.<sup>[1]</sup> One such ethical issue is declaration of conflict of interest (COI).

**Definition** COI is defined as 'a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.'<sup>[2]</sup> Behaviour that is construed as creating a COI usually is interpreted to mean actions potentially taken to satisfy private interests that may not serve the best interests of the wider community.'<sup>[3]</sup>

### ***Committee on Publication Ethics (COPE) guidelines***<sup>[4]</sup>

COPE mandates all its member journals to have their COI policy in place. According to COPE:

'17.1. Editors should have systems for managing their own COI as well as those of their staff, authors, reviewers and editorial board members.

17.2. Journals should have a declared process for handling submissions from the editors, employees or members of the editorial board to ensure unbiased review.

### *Best practice for editors would include:*

-publishing lists of relevant interests (financial, academic and other kinds) of all editorial staff and members of editorial boards (which should be updated at least annually)'

***The World Association of Medical Editors (WAME) position***

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'COI exists when there is a divergence between an individual's private interests (competing interests) and his or her responsibilities to scientific and publishing activities such that a reasonable observer might wonder if the individual's behaviour or judgment was motivated by considerations of his or her competing interests...COI exists when a participant in the publication process (author, peer reviewer, or editor) has a competing interest that could unduly influence (or be reasonably seen to do so) his or her responsibilities in the publication process.'<sup>[5]</sup>

### ***International Committee of Medical Journal Editors (ICMJE)***

'Public trust in the peer-review process and the credibility of published articles depends in part on how well COI is handled during writing, peer review, and editorial decision making. COI exists when an author (or the author's institution), reviewer, or editor has financial or personal relationships that inappropriately influence (bias) his or her actions (such relationships are also known as dual commitments, competing interests, or competing loyalties).'<sup>[6]</sup>

McCrary et al in a survey of various medical schools, research institutions, journals and federal agencies found significant variation among policies on COI. Also, many journals and grant agencies did not require declaration of COI. They concluded that 'the current standards may not be adequate to maintain a high level of scientific integrity.'<sup>[7]</sup>

Cooper et al observed that most of the journals focussed on COI policy for authors, but not for peer-reviewers or editors. Many times though the COI information was collected, it was not published, calling this a 'secret disclosure'.<sup>[8]</sup> Hirsch criticized journal editors for being inconsistent in accepting or rejecting manuscripts based on set COI standards.<sup>[9]</sup> Meerpohl et al analysed author instructions of 41 pediatric open access journals. While the Uniform Requirements for Manuscripts of the ICMJE were endorsed by 27 (66%) of these journals, only 25 (61%) journals declared COI policies.<sup>[10]</sup>

Even editors have the ethical obligation to declare COI. Smith et al commented that researchers and general public do not have accessibility to editor COI policy of some of the leading medical journals; this may negatively affect the trust bestowed on such journals.<sup>[11]</sup> Sadly, this puts academic science and peer review process in disrepute.<sup>[3]</sup>

Lexchin et al eloquently summarised how commercial interests may influence the content of journals, i) journal publishers get significant financial benefits from sponsored supplements, ii) journal advertisements give more financial returns to not-for-profit doctors'

organisations, more than what is received from membership fees, iii) in the absence of advertisements, it is difficult for the journals to sustain financially, iv) manuscripts which are 'anti-pharma' may lead to significant financial loss for the journals. The authors conclude that the 'not-for-profit medical societies' are actually not engaged in any charity; because of huge finances needed for publishing good quality journals the publishers are under economic pressures which may defeat the very purpose of scientific publishing.<sup>[12]</sup>

### **What constitutes COI?**

Research and publication may be influenced by various stakeholders; including (but not limited to) author, editor, reviewer, publisher, sponsor (pharmaceutical company, governmental / non-governmental organizations), media, and consumer themselves. This influence may be in the form of peer pressure, publication bias, financial,<sup>[13]</sup> and non-financial<sup>[14]</sup> incentives, etc.

Various examples of COIs 'include equity interests; corporate relationships (e.g., employment); patent rights; consultancies (such as speakers bureau and advisory board); family relationships and funding provided for research grants. Other conflicts include personal relationships that are not financial, along with political and religious beliefs.'<sup>[3]</sup> Apart from authors, other stakeholders such as study sponsors e.g. pharmaceutical companies, charitable foundations and government agencies may also be interested in the outcome of study.

### **Types of COI<sup>[5]</sup>**

*Financial ties:* These include benefits such as fee, patents, stocks, gifts, or services, etc. The pharmaceutical companies and sponsors of clinical trials have a major role here. Also, government agencies, charitable organizations, may have specific interests.

*Academic commitments:* Researchers may have strong beliefs regarding a particular idea. For example, a psychiatrist who has a strong belief that pharmacotherapy is the only way of treating psychiatric illnesses may negatively peer review a manuscript submitted by a cognitive behavioural therapist. This more commonly happens when 'conventional wisdom' is challenged. Hence, even peer reviewers are supposed to declare their COI before and during peer review.

*Personal relationships:* Because of this, the editor or reviewer may expedite or delay the processing of manuscript submitted by an author who is friend or otherwise. Hence, many journals recommend that the peer review should not be done if the authors are closely associated. Some journals give an option to the authors to declare the name of individuals who should not review their manuscripts.

*Political or religious beliefs:* Affiliation to a particular religious / political view might positively or negatively influence the publication.

*Institutional affiliations:* When a participant affiliated with an institute is involved in a publication, wherein the institute has some interest in the outcome of publication, COI is said to exist. For example the author associated with a company that manufactures a device publishes a study related to that device.

### Why such much fuss?

Smith, the ex-editor-in-chief of the BMJ made a categorical statement regarding COI, 'the quality of the journal will bless the quality of the drug'.<sup>[15]</sup> Friedman and Richter analysed all original published studies in two leading general medicine journals. The prevalence of COI was 19-29%, and was strongly associated with positive study results.<sup>[16]</sup>

The readers have the right to know how a paper could be potentially biased by unknown stakeholders. Once the COI is known, the reader reads and interprets the study findings in the light of potential bias which could have crept in at various stages of publication. It also helps author be unbiased in his presentation. Media and public awareness have aided the reputed journals to make COI disclosure mandatory.<sup>[18]</sup>

### What if COI is not declared?

The journal needs to specify the consequences of non-disclosure.<sup>[5]</sup> COPE guidelines suggests, if the non-disclosure of a COI is detected before publication, editor should send 'strongly worded rebuke to the authors' and ask for declaration. However, if this is detected after publication, the same should be published as an erratum.<sup>[17]</sup> The author can also be asked to explain his reasons for earlier non-disclosure in the form of published letter.<sup>[5]</sup> Some journals may take a stricter approach like prohibiting the author from publishing for a specified period of time, cancellation of society membership, etc.

### What is done with COI disclosure?<sup>[5]</sup>

Journals should clearly mention to what extent a COI may be allowed. Some journals explicitly disallow authors from writing reviews on a topic where there is a clear competing interest.

- All COI declarations are published along with the manuscript.
- Some COIs are so significant that the manuscript may not be further considered for publication.
- Not allowing those with COI to take part in publication process (e.g., reviewer or editor)
- Not allowing holders of significant COI to take

decisions regarding publisher. (e.g., editors)

- Handling or investigation by unbiased observers

### Who all should declare COI<sup>[5]</sup>

Authors should declare their financial and other competing interests relevant to manuscript. They should mention the source of funding, and whether this was anyway involved in data collection, analysis, and interpretation and reporting.

Reviewers should declare and abstain from peer reviewing if they feel they may influence the review process.

Editors should refrain from publication process if their close family member has a COI concerning the manuscript in question. He may also consider non-involvement with a manuscript submitted from his own institute. If he is an author for the same journal, another member in the editorial office should handle the manuscript.

### How to declare COI?

While it is not possible to eliminate all COI, journals should clearly define COI; specify what interests need to be declared, by whom, along with time frame and how to make such declarations. For example some journals want COI within previous five years. Sometimes, the journal may even ask the authors about possible future financial gains, or how the research integrity in their place of work was maintained when the said study was being carried out.<sup>[5]</sup>

All authors including co-authors should declare in writing, their association with people or institutes that could bias the publication in question; even if they think it has not. If there is no COI, declare so! It is appreciated that this should be declared even if not asked for. Alfonso et al suggest that if you are not sure, 'err on the side of over-disclosure' and let the editors decide.<sup>[18]</sup> Some institutes publicly declare their employees' COI on their web sites, and journals may thus have access to authors' COIs.<sup>[5]</sup>

The PLoS Medicine editors recommend how journals can reduce possible bias during publication, 'i) recognize and declare editorial interests, ii) be aware of interests beyond the commercial, iii) consider whether there is a ghost in the machine, iv) where's the spin? Remember the protocol, v) anti-spin: consider whether the data are important even if the results aren't exciting.'<sup>[14]</sup>

According to Neale et al, the entire research community is responsible for working with this important publication ethical issue. As much as possible, COI should be avoided. Authors should take personal responsibility to declare them. A point worth remembering is that the presence of COI does not mean that the study is invalid; however, reviewers should be made aware of this. Peer reviewers

who have the responsibility of reviewing the study should critically analyse how conflicts may have affected the study findings. Last but not the least, readers should read the manuscript with the awareness that there could be a potential conflict; they should actively participate in post-publication peer review by writing letters to the editor, or through comments.<sup>[19]</sup> Alfonso et al categorically stated that the editors cannot function like 'policemen', but, they should act when misconduct is detected.<sup>[18]</sup>

## CONCLUSION

This editorial hopes to highlight on a key ethical publication issue as 'ignorance is not an excuse.' Presence of COI in itself is not a ground for rejection, but, the same needs to be declared.<sup>[5]</sup> As per AP J Psychol Med COI guidelines, if the editor happens to be an author or a co-author, the manuscript would be handled by another editorial board member who would be designated as the 'handling editor'. Further details are given in the peer reviewer guidelines if this journal. This journal is in the footsteps of several leading medical journals in this regard. This is imperative and unavoidable because research policies are increasingly being scrutinized and questioned even by laymen and consumers. Public faith does matter as they are at the receiving end of what ultimately happens in research.

'We recognize that today there are many, and increasing, pressures on authors and journals to bias this record. If this pressure is not resisted, journals may increasingly become closer to works of fiction telling the stories dictated by various lobbies rather than works of science.'<sup>[20]</sup>

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