

EDITORIAL

Conflict of Interest (Part 2)

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The first step in addressing conflicts of interest in research is to identify their existence. While financial conflicts of interest (COI), where the researcher stands to gain financial benefits such as payments from a drug developer for a successful outcome, are well recognized, other COI may be more difficult to determine. These include the pressure to publish, career advancement, desire for peer recognition or simply, strongly held personal views or beliefs.

COI in research has the potential to influence the conduct, analysis, interpretation and application of research. Therefore, once a potential COI is recognized is necessary to determine the possible effect on the research. The possible effect of the COI on the development of a hypothesis, selection of study design and methods, plan for statistical analysis, interpretation of data, and even the decision to publish or not publish should be considered. Once the magnitude of the effect of the COI is determined, a decision has to be made whether the COI can be managed or whether they are so great that the conflicts have to be terminated or the research has to be abandoned. Termination of the COI could include actions such as selling shares or turning down research funds from industry. If no other source of research funds are available, the research may have to be abandoned.

If the COI are such that they can be managed, steps should be taken to mitigate the effects on the research. Mitigation should include actions taken to regulate individual researchers, actions taken to mitigate the effect of COI on the research process and actions taken to inform the ultimate consumer of the presence of such conflicts so that they may critically assess the findings in the full knowledge of the potential COI.

Steps to mitigate the effects of COI on conduct and interpretation of research finding include public disclosure of the COI to the ethics review committee, which will evaluate the quantum and acceptability of the, to the research participants, through the information sheet and to the research community via a declaration in the paper submitted for review and in the published article. This disclosure should include all payments, including funding of research, shares given to the researcher or immediate

family members, patents and other intellectual property rights that may be commercialized etc.

In addition, the researchers should take action to minimize the risk of bias, which may even include restricting or excluding some investigators from the recruitment process at their institution or performing some or all of the study at a different institution. The process of obtaining informed consent may have to be tightened with transparent disclosure of the COI to the potential research participants and monitoring the integrity of the informed consent process.

Aspects of minimizing the risk of bias will include mandatory registration of clinical trials in a publicly accessible clinical trials registry, objective determination of the safety of subjects by appointment of independent data safety monitoring boards (DSMBs) and adequate blinding of the research participants, clinicians and statisticians and randomized allocation to the different arms. It is well documented that clinical trials where a COI has been declared are more likely to report favourable outcomes at lower level of evidence than trials conducted using public funds. Independent analysis of the data can help to mitigate this by ensuring an acceptable level of evidence during the process of interpretation and presentation of the results. A pretrial commitment to publish the findings, even if negative, is now a condition for registration of clinical trials. Training of peer reviewers to detect and evaluate the effect of COI while undertaking peer review of submissions will be useful as they are the gatekeepers for dissemination of research findings to the scientific community and the general public.

Reference

Romain PL. Conflicts of interest in research: looking out for number one means keeping the primary interest front and center. *Curr Rev Musculoskelet Med*. 2015 Jun;8(2):122-7. PMID: 25851417; PMCID: PMC4596167. <https://doi.org/10.1007/s12178-015-9270-2>