5.3: Conflicts of interest in biomedical publications

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The International Committee of Medical Journal Editors says that “A conflict of interest exists when an author (or the author’s institution), reviewer, or editor has financial or personal relationships with other persons or organizations that inappropriately influence (bias) his or her actions (such relationships are also known as dual commitments, competing interests, or competing loyalties).” One can distinguish between conflicts of interest (COIs) arising from (a) financial interests; (b) performing conflicting roles; and (c) bias arising from intellectual commitments and schools of thought. Sometimes two or more of these kinds of conflicts of interest overlap. This chapter focuses on financial COIs in biomedical research.

Conflicts in biomedical publications are part of conflicts of interest that affect universities, research, medical practice and public life. COIs can compromise the integrity of scientific research and publications and consequently undermine scientific knowledge and medical practice. Public trust in medical publications depends in part on how well COIs are handled during writing, peer review, and making editorial decisions.

Sources of conflicts of interest and key actors
There are four key sources of conflicts of interest.

Funding of clinical research
Clinical studies can be funded by commercial firms, private foundations, or government agencies. Research institutes and researchers depend on funding for their livelihood and so may perform studies to promote goals of funders in ways that compromise the neutrality of the research protocol and analysis. Today, the overwhelming share of clinical research is funded by commercial firms. Often, they fund clinical trials to convince regulatory authorities that their products are safe and effective and therefore merit governmental approval for marketing. They also fund clinical research to help promote products already on the market. Commercial firms therefore have an interest in results that portray their product positively.

A systematic review of biomedical research in 2003 concluded that “Financial relationships among industry, scientific investigators, and academic institutions are wide spread [and] ... can influence biomedical research in important ways.” Research sponsored by for-profit companies tends to support the financial interests of those companies in comparison to similar research funded by government or not-for-profit sources.

Researcher conflicts
Researchers may have financial ties to the firms whose products they test. They might own equity in the firms or patents for the products, or depend on these firms for consulting work. Investigator conflicts of interest can also arise from their compensation, for example, they may be paid a fee for each patient they enroll in a clinical trial and these payments may induce researchers to enroll patients who do not meet the criteria established in the research protocol.

Physicians sometimes work both as clinicians who treat patients and as clinical researchers. Since the goals of medical treatment and research are different, performing these two roles simultaneously creates conflict. The physician may suggest to the patient that he or she participate in the research and lead the patient to believe that participation will help resolve their medical problem. These role conflicts can also involve financial conflicts due to the physician’s financial interest in the research.

Ownership and funding of scientific publications
Medical journals may be owned by publishing companies, medical or professional organizations, or scientific societies. The owner’s interest in generating revenue or promoting a particular message can conflict with the journal’s editorial independence and independent evaluation of research. Journal owners can hire and dismiss the editor and may seek to influence editorial decisions to boost the aims and objectives of the organization.

Medical journals also have COI when they depend on financial support from commercial interests that have a stake in the research findings. The journals can be owned by commercial interests or depend on commercial interests for income through advertising, purchase of reprints, funding of journal supplements, or grants.

Financial ties of journal editors and peer reviewers
Journal editors can have financial interests that compromise their work. They may have ties with firms that could be affected by their journal’s publications. Their ties may result from investments or consulting and other contract work. For example, the Journal of Spinal Disorders & Techniques published many papers from studies supported by a medical
device industry. The chief editor was engaged in research with this industry, receiving millions of dollars of royalties. Journal editors may also have role conflicts if they work as editors part time and simultaneously work as directors of a related business, as reviewers, or as medical school professors. They may use their editorial authority to advance their financial or non-financial interests in their work outside the journal.

Peer reviewers are typically not compensated for their work, and their names are usually not revealed to the authors whose manuscripts they evaluate. Reviewers might be competing or allied researchers who can promote their own work to help shape the reputation of their employers by giving positive or negative evaluations. Peer reviewers may have financial ties (such as equity or stock options, or consulting arrangements) to firms that can be affected by the research they evaluate. Individuals who conduct peer reviews may obtain information that is not publicly available about a firm’s products. They may use that information to make investments even though doing so violates securities laws that prohibit stock trading based on insider information.11

Copying with COIs
There are several options to preclude, mitigate or manage COIs.

Precluding COI
Many sources of interest arise because clinical research or journals depend on funding from sources that have an interest in promoting publications that favor their products. These conflicts can be precluded by finding alternative methods of financing research through grants or journals. However, there have been proposals to public fund the clinical trials used by regulatory authorities to decide whether to approve the market of a drug. Alternatively, others have proposed that pharmaceutical firms continue to fund studies used to evaluate individuals who conduct peer reviews may obtain information that is not publicly available about a firm’s products. They may use that information to make investments even though doing so violates securities laws that prohibit stock trading based on insider information.11

Disclosure
Journals can require that authors and reviewers disclose their financial ties or other conflicts to alert editors and readers of potential bias. Disclosure does not eliminate the potential source of bias, and may lead readers to mistakenly believe they can counter potential bias. Consequently, some writers suggest disclosure has limited value.11,13 However, disclosure may allow the public to more carefully scrutinize the articles. One study suggests that when publications disclose that research was funded by a firm with a financial interest in the product studied, physician readers were more skeptical about the study’s validity.13

Medical journals now typically require that authors disclose their financial ties but other journal policies vary in what they say authors must disclose. Furthermore, many journal policies lack clear definitions of COI or information on what they will manage conflicts of interest through their review manuscripts. Even when policies are clear, often authors are not well informed about what they must disclose. Most important, journals do not have a means to monitor compliance with their disclosure policies. A study of articles promoting drugs for unapproved uses revealed that 15% of authors adequately disclosed their COI.14 Numerous other studies also reveal poor compliance with journal disclosure policies.15

Policies for disclosure of editors’ and reviewers’ COIs are much less developed than those for COIs of authors and often these policies are not public.16 In the United States and many other countries, universities and medical schools have institutional review boards to oversee clinical research ethics. However, a survey of Institutional Review Board (IRB) policies showed that a high proportion did not require that voting IRB members disclose financial ties to industry.16 To help journal editors and authors, the ICMJE developed a standard disclosure form and a glossary of conflicts of interest so that in the future, there may be a standard disclosure form for research in the life sciences. One option to promote transparency is to create a national non-profit organization that serves as a repository for disclosure of researcher financial interests.17

Many organizations have ethical guidelines on research that direct them to designate those with conflicts of interest.18

Government agencies, funders and other parties can bar individuals from participating in research when they have financial ties that could affect their work.

Oversight
Authorities can ban individual researchers or reviewers with conflicts of interest to participate in work but subject their work to expert evaluation. Authorities require that pharmaceutical firms continue to fund studies used for research proposals, publications and public communications as well as in all review activities.19 A group of representatives from research and industry organizations issued Guidelines on Good Publication Practices for articles communicating company-sponsored medical research.20

Compliance and sanctions
Measures to preclude, mitigate or manage conflicts of interest will not be effective unless there are means to ensure compliance. This is the weak link in current policies. A few journals say they will ban authors who failed to disclose COIs, and not accept papers submitted by these individuals (and their institutions). Few journals that discover non-disclosure of a COI by an individual go on to report this information to the individual’s university or research institute.

References

Further reading