

The Role of Journal Editors in the Responsible Conduct of Industry-Sponsored Biomedical Research and Publication: A View from the Other Side of the Editor's Desk

Journal editors are keepers of the integrity of the research record, demanding accountability from authors, maintaining a competent and objective review process, ensuring adherence to ethical practices, and publishing corrections and retractions. Recently, editors have acknowledged that their role also includes ensuring the disclosure of conflicts of interest (COIs) when publishing scientific reports. Like publishing the contributions of each author of a study, requiring transparency of COIs substantially enhances the credibility of research reports. As a professor of medicine and an academic administrator long concerned with the ethical conduct of research, I would like to take this opportunity to offer—from the other side of the editor's desk—some perspectives on the role of the journal and the journal editor with regard to COIs and industry-sponsored academic research.

Defining, Determining, and Disclosing Conflicts of Interest

The International Committee of Medical Journal Editors (www.icmje.org) ties COI to potential bias—but COIs are an integral element in an investigator's relationships and must be defined independently of bias. A COI is any benefit—whether direct or indirect—transmitted from sponsor to investigator-author. Contrary to some stated opinions, it is up to the reader to judge the credibility of a research report. Journal editors are obliged to give readers all the information necessary to make such judgments—publishing COIs routinely and openly to permit the reader to evaluate the investigators' relationships surrounding their research, to assess possible bias, and to determine whether a COI diminishes the credibility of a study.

Ensuring Adequate and Transparent Peer Review

Problems in the design of industry-sponsored studies should be a focus of the peer-review process, but reviewers often become intent on commenting line by line and become unable to see the forest for the trees. Especially for reports of clinical trials, peer review should finely dissect the study design. After ensuring that the statistical approaches are sound, the reviewer must seek bias in the study design, make sure

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that conflicting literature is discussed fully, and see to it that the conclusions are fully warranted by the data. Editors should give reviewers appropriate instruction not only for dissecting clinical studies but also for providing a “gestalt review”, inasmuch as a holistic review is also essential.

Editors can do more to make COIs transparent. Potential reviewers of reports of original research should be queried routinely regarding their own COIs before they are sent a paper to review—few will not recognize their COIs on hearing the title of the paper, and seldom is a reviewer with a COI irreplaceable.

Expert authors of review articles do research in the field and may be consulting with all of the commercial players. As a con-

sequence they have COIs. It is not feasible to avoid selecting experts to write review articles. The solution is to scrupulously disclose all the experts' COIs. Recognizing the dilemma, the *New England Journal of Medicine* recently adopted that policy (2002;346:1901-2).

Ensuring Adequate Disclosure of Study Design and Adverse Events

Sponsors have the right and the obligation to design studies and analyze their data, and they should have the right to offer them for publication with or without the benefit of academic authors. That is not to say that they should in any way be sheltered from responsible research practices and the ethical principles and standards that journal editors require.

The design of industry-sponsored research may require scrutiny—for example, it is not unheard of that doses and treatment schedules in comparison studies may be designed to favor the sponsor's product for efficacy or safety. Nonetheless, the suggestion made by some editors, that the investigators must take the primary role in designing industry-sponsored studies, is largely unrealistic, in that the sponsor is constrained to include design features that meet specified Food and Drug Administration requirements. To achieve a middle ground, editors might require that COI disclosures state in detail the role of the sponsor in designing the study and the roles of the authors in analyzing the results.

Disclosure is necessary not only for the study design but also for the results. Although efficacy data on many new agents are readily available, critically important safety data are often lacking. Severe but infrequent adverse events—particularly events that might not be obviously attributable to the agent and those arising during substudies—may be

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understated or go unreported. Journal editors should require each author to affirm that all serious adverse events of which he or she is aware are fully and honestly presented in the paper.

Journal editors might require authors within and outside the industry, including academic investigator-authors participating in the industry-sponsored research, to confirm in writing that they approved the protocols, endorsed the results, were cognizant of the data analysis, and support the conclusions individually and specifically. If the authors are not able to do that, they should not lend their names to the publication.

Data and safety monitoring committees—which now play key roles in ensuring the integrity of clinical research in both sponsored and National Institutes of Health-supported clinical research—should be acknowledged in published clinical studies. If journal editors asked that the data and safety monitoring committee endorse reports of studies when they are submitted for publication, it would strengthen the hand of the committees and strengthen the research—and isn't that what we want?

Assessing Editorial Conflicts of Interest

A journal's publisher may be the source of COIs despite the best intentions of its editors. Some journals are known to ensure that articles, and even whole issues, supporting a sponsor's product receive favorable reviews. The prosperity of some journals and the very existence of others depend on industry sponsors' buying large numbers of reprints for distribution to physicians. The editor should have no COIs in relation to reviewing specific papers. To maintain transparency, a footnote on the first page of an article should disclose industry sponsorship, for example, "The industry sponsor has purchased or intends to purchase 500 copies of this article."

Questions regarding editorial integrity

How Journal Editors Can Foster Responsible Conduct of Industry-Sponsored Biomedical Research and Publication

- Define conflict of interest (COI) as any benefit—whether direct or indirect—transmitted from sponsor to investigator-author.
- Publish all COI disclosures in a footnote on the first page of the article and in the abstract.
- Give readers all information necessary to judge the credibility of a research report, disclosing and publishing all COIs without editorial judgment.
- State in detail, in COI disclosures, the role of the sponsor in designing the study and the roles of the authors in analyzing the results.
- Require authors to affirm that all serious adverse events are fully and honestly presented in the paper.
- Require all authors named in a report, whether from industry or academe, to confirm in writing that they approved the protocols, endorsed the results, were cognizant of the data analysis, and support the conclusions individually and specifically.
- Ask for the endorsement of the institution's data and safety monitoring committee to accompany and be acknowledged in clinical studies submitted for publication.
- Routinely query potential peer reviewers about their potential COIs before sending them a paper to review.
- Give peer reviewers instruction and guidelines both for dissecting clinical studies to assess study design and for providing a holistic review.
- Disclose all COIs of experts who write review articles.
- Publish editorial COIs and disclose industry sponsorship of a publication.
- Establish a dedicated board of trustees whose sole responsibility is keeping the journal ethical.

may be relatively few, but the ones that arise are often mishandled or ignored. Each journal should have a board of trustees—separate from the board charged with keeping the journal solvent—whose sole responsibility is keeping the journal ethical.

Conclusion

Frank, full, and open disclosure is perhaps the most powerful antidote to the ambiguities that lead to mistaken reporting and even misconduct in science. Most important is that COI disclosures be printed prominently on the first page of the published article and in the abstract—not

placed in microscopic print at the end of an article. Disclosure of COIs is more important to the reader than much of the verbiage of most research reports. 🔥

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Note: A version of this material was presented during the open meeting of the Editors' Council Task Force at the 2002 CSE annual meeting. Susan Eastwood helped convert it to the current form.