

Editorial Board of the Turkish Journal of Neurology Recognizes Basic Political Statements of the CSE*

CONFLICTS OF INTEREST AND THE PEER REVIEW PROCESS

Objective

To offer guidelines useful to biomedical journals as they develop policies and procedures relating to conflict of interest in peer review.

Definition

A widely used American dictionary (Webster's 9th New Collegiate Dictionary) defines conflict of interest as a "conflict between the private interests and the official responsibilities of a person in a position of trust." In scientific publishing, the author of a manuscript, the reviewer, and the editor are all persons "in a position of trust." Conflicts of interest in the publishing can be defined as sets of conditions in which an author, editor, or reviewer holds conflicting or competing interests that could result in bias or improper decisions. The conflicts of interest may only be potential conflicts of interest or only perceived, and not necessarily even potential, conflicts. The determination of whether a conflict of interest actually exists can be extraordinarily difficult and often contentious. Recognizing the potential for conflicts of interest is usually easier; they are common and it is not their existence, but rather their potential to cause bias and failure to acknowledge or recognize conflicts, that causes concern. Such failure, which reflects an insensitivity to the potential for conflict of interest, is troubling, whether it is observed in an author, a reviewer, or an editor.

Ideally, authors are completely objective in presenting their findings, and editors and reviewers are entirely objective in evaluating them. These processes are all prey to biases. Personal, political, financial, academic, or religious considerations can affect objectivity in innumerable ways. The challenge for authors, editors, and reviewers is to recognize the potential for biases arising from conflicts of interest and to respond appropriately.

Financial Conflicts

The most evident type of potential conflict of financial interest is the situation in which a commercial product is under study and the author, reviewer, or editor stands to benefit financially if the assessment of the product goes one way or another. For example, an author reporting investigation of a specific product, at the same time he or she holds equity positions or stock options in the company that makes the products, clearly has the potential to realize direct financial gain if the assessment is favorable. A researcher in the employ of a for-profit enterprise has a slightly less direct relationship to product-related research, but still can reasonably expect to benefit financially if a product does well. In these examples, an individual's "private interests" (i.e., his or her financial interests) are potentially in conflict with his or her "official

responsibilities" (i.e., the responsibility of a scientist to seek the truth).

The situation in which an investigator studies a product of a for-profit enterprise from which the investigator has received monies previously (e.g., as a consultant or in the form of an honorarium or speaking fee) is slightly different. There is now no direct relationship between the evaluation and any personal gain the investigator may anticipate. Nevertheless, the existence of payments even in the past could conceivably influence research and must therefore be regarded as having the potential to present conflicting interest. The examples given above involve authors reporting the results of their research, non-research articles, reviews, and opinion pieces, but they could just as well involve reviewers evaluating a manuscript or editors deciding whether or not to accept a manuscript. There are some subtle differences among authors, reviewers, and editors with respect to conflict of financial interest, but the basic principles apply to all.

Some journals refuse to consider manuscripts describing research involving a commercial product when the research was supported financially by a commercial organization involved in the manufacture or sale of the product. A few journals will not permit editorials or review articles to be authored by individuals with potential conflicts of financial interest, feeling that these pieces rely especially heavily on interpretation and judgment, and thereby make conflict of interest and the potential for bias especially problematic.

Non-Financial Conflicts

Many considerations - intellectual, political, academic, and religious, to mention just a few - can represent "private interests." The challenge for authors, reviewers, and editors is to recognize the potential for these types of conflicts as well as those involving finances, and respond appropriately. Complete objectivity is not often possible, but fairness and even-handedness can reasonably be expected. For example, a reviewer strongly opposed to abortion, on religious or other moral grounds, might have difficulty evaluating a manuscript describing the use of fetal tissue in research in an objective matter. Or an editor who is also chair of a department might have difficulty in reaching objective decisions about manuscripts submitted by his or her faculty because the editor has a "private interest" as a chair in helping the academic advancement of his faculty.

Disclosure

The key to recognizing and dealing with conflicts of interest - financial or non-financial - is disclosure: disclosure to the editor when a manuscript is submitted, and disclosure to the reader when a paper is published. The

former provides a means for the manuscript to be evaluated by the editor with full knowledge of all its circumstances, and the latter assures that the reader will have sufficient information to interpret the work appropriately.

Disclosure of potential financial conflicts of interest is meant to maintain the integrity of professional judgment and to maintain the public's confidence in professional judgment. A disclosure does not infer that scientists are unduly influenced by financial gain. Rather, disclosure in such cases gives readers the information to allow them to make an informed decision because it is often difficult to determine when research has been inappropriately influenced by financial gain. Informing readers is the responsibility of the journal. Some, however, would argue that mandatory financial disclosure actually does not allow a manuscript to be judged solely on its merits. They believe that such disclosure is based on the faulty assumption that only financial considerations influence authors and that all authors are influenced. They further believe that such disclosure unfairly prejudices the reader against the author. See Rothman J.J. Conflict of Interest: the New McCarthyism in Science. JAMA 1993; 269:2782-2784.

Authors

Many journals require that financial support of the work reported be identified with the submitted manuscript. Some examples, taken from the "Information for Authors" section of different journals follow: The checklist for submission to Science includes an item requiring inclusion of "any information about the authors' professional or financial affiliations that may be perceived to have biased the presentation." The Journal of the American Medical Association (JAMA) requires all authors to sign a statement disclosing "any affiliations with or financial involvement in any organization or entity with a direct financial interest in the subject matter or material discussed in the manuscript (e.g., employment, consultancies, stock ownership, honoraria, expert testimony, current or pending patents." Obstetrics and Gynecology uses similar wording and a time limit of three years is specified. Most journal policies ask authors to disclose their relevant financial interests when they submit their manuscripts. It is then the editor's responsibility to interpret this information and, if the paper is ultimately accepted, decide how (if at all) it is to be relayed to the reader.

How should authors' disclosure of financial interests be handled during the peer review process? Journals seem to have differing policies on this point. Some make the information about financial disclosure available to reviewers and ask them to evaluate this, along with the scientific merit of the paper. The reviewers' opinion about the authors' financial interest may then weigh heavily in the editor's decision and may result in a form of publication bias. Other journals keep as recommended by ICMJE (International Committee of Medical Journal Editors) such information confidential during the review process, and have it considered by the editor (perhaps with outside evaluation on this point as well) only after scientific merit is assessed. This latter approach has the advantage of dividing the question into clearly identifiable portions. Readers have the right to know any potential conflicts of interest. The considerations that interest journals the most are financial, which are usually the easiest to disclose. However, financial conflicts may not be easily detected without disclosure. Financial conflicts include salary, consulting fees and honoraria, stock or equity interests, and intellectual property rights (patents, royalties, and copyrights). Most journals require authors to declare any potential financial conflicts of interest they may have with the subject matter of their manuscripts. Some journals ask authors to disclose any financial interests they may have with any entity that could affect their work. The authors are responsible for declaring these

potential conflicts of interests. Journals don't research possible conflicts of interest and are not expected to "police" authors. However, journal editors must be alert to the possibility of conflicts of interest because the authors may not declare them. An author's failure to declare a financial interest conflicts with the reader's entitlement to know this potential source of bias. Such information can help readers decide whether a particular sponsorship unduly influenced the investigator and whether the research findings are different than what they would otherwise have been.

Examples of disclosure statements

The Journal of the American Medical Association requires financial disclosure, in "Authorship criteria and responsibility, financial disclosure, assignment of copyright, and acknowledgement:"

"Financial disclosure - I certify that any affiliations with or financial involvement in any organization or entity with a direct financial interest in the subject matter or materials discussed in the manuscript (e.g., employment, consultancies, stock ownership, honoraria, expert testimony) are disclosed below. Any financial project support of this research is identified in an acknowledgment in the manuscript."

Obstetrics and Gynecology requires each author to sign an agreement form that must accompany the manuscript submission with a section on financial disclosure: "I affirm that I have no financial affiliation (e.g., employment, stock holdings, consultancies, or honoraria) within the last 3 years with any organization with direct financial interest in the subject or materials discussed in this manuscript, except as disclosed in an attachment."

Science includes on its checklist for submission: "Also include with your manuscript:...any information about the authors' professional and financial affiliations that may be perceived to have biased the presentation."

Some journals (e.g., New England Journal of Medicine and Obstetrics and Gynecology) do not allow any financial conflict of interest for authors who write editorials or review articles, because analysis pieces rely heavily on interpretation and judgment. It is considered difficult for readers to discern conflicts of interest in opinion pieces. At least one journal (Obstetrics and Gynecology) discloses financial matters in a "call-out" box, which is displayed on the front page of the published manuscript. When the editor feels that financial conflicts should be disclosed, he or she advises the corresponding author and indicates how the "financial disclosure" statement should be worded. This situation may occur if any of the authors have financial connections to a particular product or company and the article could be interpreted as favorable to that product or company. Acceptance of the manuscript is contingent upon the author's accepting the disclosure.

Reviewers

Conflicts of interest regarding reviewers concern not only financial issues, but also rivalry, academic scientific and technologic competition, and philosophical values and beliefs. Reviewers, when asked to review a manuscript, should be instructed specifically with respect to conflicts of interest. Precisely because they are experts in the field under consideration (i.e., they are peers), reviewers are apt to have conflicts of interest, financial or otherwise. Thus the existence of a conflict is not really the issue, but rather whether the conflict is sufficient to limit the reviewer's ability to evaluate the manuscript fairly and objectively. Journals should instruct their reviewers to disqualify themselves if they feel they cannot render fair and objective assessments. If reviewers have

any questions in this regard, they should be urged to consult with the editor. Most journals approach this issue with fairly general and open-ended advice. However, JAMA requires reviewers to complete a specific section of the review form disclosing any potential conflicts of interest. This assures that the reviewer consider the issue and make a direct statement that he or she has or does not have any such conflicts. Some reviewers believe that a conflict exists if they have reviewed a manuscript before for another journal. If a reviewer still believes the manuscript can be reviewed objectively, many editors prefer to send the manuscript to the same reviewer again. That reviewer is in a good position to judge whether the manuscript has been improved.

Editors

The journal editor is responsible for establishing and maintaining the highest possible standards in the contributions that fill the pages of the journal as well as for maintaining the integrity of the journal itself. Editors are primarily responsible for ensuring a fair review process of manuscripts submitted to a journal and should give unbiased consideration to all submitted manuscripts. Editors should not have personal financial involvement in manuscripts they consider for publication. An editor should disqualify him- or herself from any decision-making role on a manuscript addressing a subject on which he or she has a potential conflict of interest. Some journals stipulate that editors may have no financial interests in any business that might influence the publication of a manuscript. Other journals request editors to sign financial disclosure forms annually.

Editors may also disqualify themselves from evaluating submissions by local colleagues or friends or submissions that clash with their religious convictions. For example, an editor may preclude him or herself from being involved in the review process of a manuscript written by a close colleague. In these instances, the editor, who is usually blinded to the reviewers of the manuscript, generally asks a guest editor or associate editor to oversee the review process. The guest editor makes the final decision on the manuscript. Some editors consider reviewing manuscripts submitted by members of the journal's editorial board a conflict and will ask a guest editor to oversee those manuscripts. Editors are, after all, human and subject to many of the same biases and conflicts as reviewers and authors.

Recommendations

The Editorial Policy Committee recommends that:

- Journals require authors to explicitly state all sources of funding for research and to include this information in the acknowledgement section of the published paper.
- Journals require authors to state other potential conflicts of interest in the cover letter of the manuscript submission.
- Journals publish financial interests or support with an article. The editor should decide ether to include a description with the published article or letter of all financial support or any conflicts of interest the editor feels the readers should know. This should be published as a footnote on the first page of the manuscript.
- Journals should have a policy about how to handle undisclosed conflicts after they are identified by a third party and some explanation to the readers.
- Journals should have a policy and plan of action regarding undisclosed financial interests that are identified after publication. Editors may choose to publish a notice of "Failure to Disclose Financial Interest."
- All authors, editors, and reviewers should disclose potential conflicts of interest. Authors and reviewers should disclose to the editor; the editor should disclose potential conflicts of interest to the publications committee, or its equivalent.