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Conflict of Interest in Peer-Reviewed Medical Journals

**Prepared by the WAME Editorial Policy and Publication Ethics Committees.
Posted March 27, 2009; updated July 25, 2009.**

This Policy Statement replaces the WAME Editorial Policy “Journals’ Role in Managing Conflict of Interest Related to the Funding of Research” and the WAME Publication Ethics Policy “Conflicts of Interest.”

Read the related editorial, “Conflict of Interest in Peer-Reviewed Medical Journals: The World Association of Medical Editors Position on a Challenging Problem” (WAME member log in required).

Conflict of interest (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 behavior or judgment was motivated by considerations of his or her competing interests. COI in medical publishing affects everyone with a stake in research integrity including journals, research/academic institutions, funding agencies, the popular media, and the public. Journals are interested in COI as it relates to a specific manuscript.

Everyone has COIs of some sort. Having a competing interest does not, in itself, imply wrongdoing. However, it constitutes a problem when competing interests could unduly influence (or be reasonably seen to do so) one’s responsibilities in the publication process. If COI is not managed effectively, it can cause authors, reviewers, and editors to make decisions that, consciously or unconsciously, tend to serve their competing interests at the expense of their responsibilities in the publication process, thereby distorting the scientific enterprise. This consequence of COI is especially dangerous when it is not immediately apparent to others. In addition, the appearance of COI, even where none actually exists, can also erode trust in a journal by damaging its reputation and credibility.

COI policies differ among journals and are evolving over time. Every peer-reviewed medical journal^[1] (herein “Journal”) should have its own COI policies for authors, reviewers, and editors. Journals should make these policies readily accessible to everyone involved in the publication process by publishing them with instructions for authors. The Editorial COI Policy that addresses editor COI should be published as well. This statement summarizes the main elements of COI policies with examples and options for disclosure and management.

Definition and Scope

Journals should publish their own definition of COI. In the context of medical publishing, 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. Among those responsibilities are

academic honesty, unbiased conduct and reporting of research, and integrity of decisions or judgments. The publication process includes the submission of manuscripts, peer review, editorial decisions, and communication between authors, reviewers and editors.

Types of Competing Interests

Many kinds of competing interests are possible. Journals often have policies for managing financial COI, mostly based on the untested assumption that financial ties have an especially powerful influence over publication decisions and may not be apparent unless they are made explicit. However, other competing interests can be just as damaging, and just as hidden to most participants, and so must also be managed. The following are examples of competing interests; they do not include all possibilities and they may coexist.

Financial ties

This conflict is present when a participant in the publication process has received or expects to receive money (or other financial benefits such as patents or stocks), gifts, or services that may influence work related to a specific publication. Commercial sources of funding, by companies that sell drugs and medical devices, are generally seen as the most concerning, perhaps because of many well-publicized examples of bias related to ties to industry. Examples of financial ties to industry include payment for research, ownership of stock and stock options, as well as honoraria for advice or public speaking, consultation, service on advisory boards or medical education companies, and receipt of patents or patents pending. Also included are having a research or clinical position that is funded by companies that sell drugs or devices. Competing interests can be associated with other sources of research funding including government agencies, charities (not-for-profit organizations), and professional and civic organizations, which also have agendas that may be congruent or at odds with research findings. Clinicians have a financial competing interest if they are paid for clinical services related to their research—for example, if they write, review, or edit an article about the comparative advantage of a procedure that they themselves provide for income. Financial competing interests may exist not just on the basis of past activities but also on the expectation of future rewards, such as a pending grant or patent application. “Insider trading,” which is the use for one’s financial gain of information obtained through participation in research, review or editing before it is available to the general public, is a special kind of financial COI that has both legal and ethical implications.

Academic commitments

Participants in the publications process may have strong beliefs (“intellectual passion”) that commit them to a particular explanation, method, or idea. They may, as a result, be biased in conducting research that tests the commitment or in reviewing the work of others that is in favor or at odds with their beliefs. For example, if research challenging conventional wisdom is reviewed by someone who has made his or her reputation by establishing the existing paradigm, that person might judge the new research results harshly. Investigators in the same field might make extra-efforts to find fault with manuscripts from competing teams, to delay publication or relegate the work to a lesser journal. While such commitments are not generally part of author’s disclosures, editors should be aware of them and their potential influence on author(s), reviewer(s), and themselves.

Personal relationships

Personal relationships with family, friends, enemies, competitors, or colleagues can pose COIs. For example, a reviewer may have difficulty providing an unbiased review of articles by investigators who have been working colleagues. Similarly, he or she may find it difficult to be unbiased when reviewing the work of competitors. Bonds to family members may be strong enough that their competing interests should be treated as if they are also present for those directly involved with a manuscript.

Political or religious beliefs

Strong commitment to a particular political view (e.g., political position, agenda, or party) or having a strong religious conviction may pose a COI for a given publication if those political or religious issues are affirmed or challenged in the publication.

Institutional affiliations

A COI exists when a participant in the publication process is directly affiliated with an institution that on the face of it may have a position or an interest in a publication. An obvious concern is being affiliated with or employed by a company that manufactures the drug or device (or a competing one) described in the publication. However, apparently neutral institutions such as universities, hospitals, and research institutes (alone or in partnership with industry) may also have an interest (or the appearance of one) in the results of research. For example, investigators may have a COI when conducting research from a laboratory funded by private donors who could have (or appear to have) an interest in the results of the study, on a device for which the participant's institution holds the patent, when the institution is the legal sponsor of the drug or device trial, or if the institution is in litigation in an area related to the study. Professional or civic organizations may also have competing interests because of their special interests or advocacy positions.

Declaring and Managing COIs

COIs are ubiquitous and cannot be eliminated altogether. However, they can be managed constructively so that they make the least possible intrusion on journal content and credibility.

Journals' policies for disclosure and management of COI must take the following into consideration:

- What COI must be declared, how, to whom and when? Journals need to be as specific as possible about their definition of COI for authors and reviewers, including the kinds of competing interests they wish to have declared by those individuals, with the understanding that any operational definition will be imperfect. They should provide clear instructions about how to make declarations. It should also be clear that a journal may ask additional questions or seek clarification about declarations. For example, the journal may ask for details about future monetary gains or ask an author who works in a laboratory funded by a particular organization for written details about how their independence and research integrity was maintained.

- All declarations about COI should be requested in writing as a condition of reviewing a manuscript and asked in such a way that authors will have a high likelihood of reporting their COIs related to the manuscript.
- No generally accepted standard, nor evidence-based consensus, exists for precisely defining the degree of financial COI or the timeframe that creates a substantial risk of bias or damage to the journal's reputation. Judgments may be affected by many factors including, in the case of financial COI, the amount of money, goods, or services exchanged, how recently they were received and whether they are expected in the future, as well as the services provided in return. To guide authors in this decision, journals should publish their own standards for financial COI, including its standards on expiry on COI (e.g., only declare COI within last five years), as precisely as possible.
- Managing COI depends on disclosure because it is not possible to routinely monitor or investigate whether competing interests are present. Disclosure is about the facts that might bear on COI; assertions of integrity are not, in themselves, helpful.

The consequences for failing to declare COI: The journal should state the steps editors will take if competing interests surface from other sources after a manuscript is submitted or published. For example, the journal may investigate allegations of COI and action may be taken if found to be true. Such investigations should be completed as quickly as reasonably possible. If a manuscript has been published and COI surfaces later, the journal may publish the results of the investigation as a correction to the article and ask the author to explain, in a published letter, why the COI was not revealed earlier.

Which COIs will result in a manuscript not being considered further? Journals must be transparent about COI situations that, if present, will result in a manuscript not being considered further. Some journals have made it explicit that they will exclude authors from writing narrative (not systematic) reviews of topics in which they have a competing financial interest, on the grounds that it is more difficult for readers to detect bias in reviews than reports of original research, where methods are made more explicit. Some journals may apply internal editorial rules about which COI situations are not acceptable but these may not be explicit to those involved in the publication process; a journal COI policy needs to articulate the journal's position.

How COI will be dealt with by the journal? Journals should publish all relevant COI disclosures with the publication. Other additional management strategies include for example:

- Not considering a manuscript further
- Exclusion of those with COI from the process (e.g., reviewer or editor)
- Abstaining from decisions where COI might arise (e.g., editors)
- Investigation by impartial observers

Some research institutions provide information about their employees' COI on their Web sites. Journals should routinely ask authors to disclose such e-links as part of their COI disclosure.

Journals have a responsibility to raise awareness and educate the research community about COI. One option to increase understanding of the concept is to ask investigators and reviewers “if my competing interest becomes known to others later, would I feel defensive or would others in the publication process, readers or the public think I was hiding my other interests or could they feel I misled or deceived them?”

Responsibilities of Participants

Authors. All authors should be asked to report their financial COI related to the research and written presentation of their work and any other relevant competing interests. Journals should publish all COI (or their absence) reported by authors that are relevant to the manuscript being considered. In addition to financial COI, policies for authors should be extended to other types of competing interests that might affect (or be seen to affect) the conduct or reporting of the work. Journals should disclose all COIs that they themselves thought were important during the review process. Declarations should require authors to explicitly state funding sources and whether the organization that funded the research participated in the collection and analyses of data and interpretation and reporting of results.

Reviewers. Reviewers should be asked if they have a COI with the content or authors of a manuscript. If they do, they should be removed from the review process. In general, it is best to avoid reviewers from the same institution as the authors, unless the institution is so large that authors and reviewers are not working colleagues.

Editors. Editors should not make any editorial decisions or be involved in the editorial process if they have or a close family member has a COI (financial or otherwise) in a particular manuscript submitted to their journal. For example, if editors have political/religious COI or personal COI with respect to the authors or their work, the editors should remove themselves from the decision-making process. An editor may also be in a COI if a manuscript is submitted from their own academic department or from their institution (if it is small); in such situations, they should have explicit policies, made in advance, for how to manage it. When editors submit their own work to their journal, a colleague in the editorial office should manage the manuscript and the editor/author should recuse himself or herself from discussion and decisions about it. Some journals list editors’ competing interests on their website but this is not a standard practice. Readers should refer to the WAME Policy on the Relationship Between Journal Editors-in-chief and Owners for additional comment about COI as it relates to editors.

Prepared by Robert Fletcher and Lorraine Ferris and the WAME Publication Ethics and Editorial Policy Committees.

Approved by the WAME Board as a WAME Policy Statement on March 25, 2009; and on July 15, 2009 (with further clarifying language).

[1] For definitions see WAME By-Laws available at <http://www.wame.org/wame-bylaws>

Conflict of Interest in Peer-Reviewed Medical Journals: The World Association of Medical Editors (WAME) Position on a Challenging Problem

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Conflict of interest in medical publishing exists when a participant's private interests compete with his or her responsibilities to the scientific community, readers, and society. While conflict of interest is common, it reaches the level of concern when “a reasonable observer might wonder if the individual's behavior or judgment was motivated by his or her competing interests”(1). Having a competing interest does not, in itself, imply wrongdoing. But it can undermine the credibility of research results and damage public trust in medical journals.

In recent years, the extent of conflict of interest in medical journal articles has been increasingly recognized. Medical journals and the popular media have published numerous examples of competing interests that seemed to have biased published reports (2,3,4). Organizations have expressed concern for the effects of conflicts of interest on research (5), publication (1,6,7), teaching (8) and continuing medical and nursing education (9).

The World Association of Medical Editors (WAME) is one of the institutions engaged in this discussion. WAME was established in 1995 (10,11) to facilitate worldwide cooperation and communication among editors of peer-reviewed journals, improve editorial standards, and promote professionalism in medical editing (12). Membership in WAME is open to all editors of peer-reviewed biomedical journals worldwide; small journals in resource-poor countries are well represented. As of December 2009, WAME had 1595 individual members representing 965 journals in 92 countries. WAME has broad participation as there are no dues and WAME activities are largely carried out through the member list serve and the member password-protected website.

In March 2009, WAME released an updated policy statement, “Conflict of Interest in Peer-Reviewed Medical Journals” (1). It details the issues WAME believes journals should address when establishing their own policies for conflict of interest. The editors of this journal thought that the issues were important enough to share with its readers. A summary of the statement is presented in the Table and the full statement (1) can be found on WAME’s website (12).

How Does This Statement Differ From Earlier Conflict-of-Interest Statements?

First, WAME expands the scope of competing interests. Other statements have been concerned almost exclusively with conflicts of interest related to financial ties to industry – companies that sell healthcare products. The assumption is that financial incentives are especially powerful and are not readily recognized without special efforts to make them apparent. WAME has extended the concept of financial conflict of interest to include the effects of clinical income. For example, physicians who earn their livelihood by reading mammograms or performing colonoscopies may be biased in favor of these technologies. WAME has also included non-financial conflicts of interest (or the appearance of one) related to scholarly commitment: “intellectual passion,” (the tendency to favor positions that one has already espoused or perhaps even established); personal relationships (the tendency to judge the works of friends/colleagues or competitors/foes differently because of the relationship); political or religious beliefs (the tendency to favor or reject positions because it affirms or challenges one’s political or religious beliefs); and institutional affiliations (the tendency to favor or reject results of research because of one’s institutional affiliations).

Second, WAME did not prescribe a universal standard for when meaningful conflict of interest exists. Rather, it defined and recommended elements of conflict of interest policies and encouraged journals to establish their own standards. WAME left operational definitions and standards on the basic issues to member journals, recognizing that journals exist in very different contexts across the globe, standards for conflict of interest are evolving, and some journals already have well-established policies and standards. WAME does not presume to judge which conflicts require action and what the appropriate action may be, although its policy does offer factors to consider (1). Obviously, excessive concern for these and more comprehensive lists of possible competing interests could paralyze the peer review and publication process and is not feasible. Editors must make judgments as to the strength of the conflict, but to do so must have uncensored information. Similarly, readers need transparency about conflicts, and therefore editors should publish with every article all relevant author disclosures (1).

Third, WAME confirms the seriousness of failure to disclose conflict of interest by indicating that editors have a responsibility for investigating, and if relevant acting, if competing interests surface after a manuscript is submitted or published. The intent is that allegations of failure to declare conflicts of interest must be taken seriously by journals.

Finally, WAME has addressed in a single statement the conflicts of interests threatening all participants in the research and publication continuum, including authors, peer reviewers, and editors. Conflicts between editors and journal owners, which might affect both the accuracy of articles and the credibility of journals, have been addressed in another WAME policy statement (13).

What Can Be Done About Conflict of Interest in Medical Journals?

Conflicts of interest cannot be eliminated altogether but it can be managed so that it has the smallest possible effects on journal content and credibility. The backbone of managing conflicts of interest is full written disclosure; without it, nothing else is possible. Currently, authors may not reveal all of their competing interests and even if they do, journals too often do not publish them (14), so there is plenty of room for improvement. Even so, disclosure alone is an imperfect remedy; editors still must determine whether a conflict has sufficient potential to impair an individual's objectivity such that the article should not be published. Even more work may be needed on reviewers' and editors competing interests, given their critical role as gatekeepers for the medical literature.

No statement will solve the conflict of interest problem, nor will it ever be solved altogether. As understanding of the problem and its management evolves, journals should be given latitude to establish their own standards, matching their policies to the best standards of their discipline and culture. WAME believes journals should make these policies readily accessible to everyone. All of us —editors, authors, reviewers, and readers— should be paying more attention to conflict of interest than we have been. We hope this statement serves that purpose.

Table 1. Summary of Key Elements for Peer Reviewed Medical Journal's Conflict of Interest Policies

Element aspects	Key	Comments
1. Definition and scope	A clear definition the journal uses as to what is conflict of interest and who is captured in the definition.	Sample definition: Conflict of interest 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 (submission of manuscripts, peer review, editorial decisions, and communication between authors, reviewers and editors).
2. Types of competing interests	A clear statement of examples of the types of competing interests (and their definitions) the journal says must be declared. Should include the following as examples but there could be others: (a) Financial ties (b) Academic commitments (c) Personal relationships (d) Political or religious beliefs (e) Institutional affiliations	There is a need to consider a wide range of competing interests (and a recognition that they can coexist) which the individual assess as to whether they unduly influence (or be reasonably seen to do so) his or her responsibilities in the publication process. Examples and definitions of what competing interests should be declared needs to be articulated with Journals moving beyond just financial conflict of interest.

Continue

Table 1. Summary of Key Elements for Peer Reviewed Medical Journal's Conflict of Interest Policies (cont.)

Element aspects	Key	Comments
3. Declaring conflict of interests	Clear statements on (a) what is to be declared, when and to whom; (b) format for declaration; (c) a journal's role in asking additional questions or seeking clarification about disclosures; and, (d) consequences for failing to disclose before or after publication.	Journals rely on disclosure about the facts because routine monitoring or investigation is not possible. This creates a particular onus on the declarer to report carefully and comprehensively. It also means that journals should ask about conflict of interest in such a way that there will be a high likelihood of reporting relevant conflict of interest.
4. Managing conflict of interests	A clear statement on how conflict of interest will be managed by the journal, including the position that all relevant conflict of interest disclosures (or the declaration of no conflict of interest) will be published with the article and clarity about what conflict of interest situations will result in a manuscript not being considered.	Journals use various rules about how they will deal with conflict of interest and conflict of interest disclosures and these need to be made known to all those involved in the publication process.

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Conflict of Interest

As a WAME Director, Lorraine Ferris did not participate in the WAME Board vote to approve the statement or the vote to endorse the editorial.

The authors have no conflicts of interest to declare.

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Journals in which this Editorial has been published:

Indian Journal of Medical Infomatics

The IJOEM

National Medical Journal of India

Neurosurgery

Pharmacognosy Magazine

Journal of Young Pharmacists

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