

Conflict of Interest and Disclosure



Philippine Council for Health Research and Development
Philippine Association of Medical Journal Editors
Asia Pacific Association of Medical Journal Editors
**National Peer Review , Editing and Train the Trainers
(Part 2) Workshop**

Plaza del Norte Hotel, Laoag City, August 7, 2013

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University of the Philippines Manila
THE HEALTH SCIENCES CENTER

Conflict of Interest and Disclosure



I am a member of WAME and Editor of a journal that co-published the article on which this presentation is based.

I believe I have no other financial or other (including personal) relationships, intellectual passion, political or religious beliefs, and institutional affiliations that might lead to a conflict of interest in making this presentation.

DISCLOSURES



Conflict of Interest and Disclosure



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

Lorraine E. Ferris and Robert H. Fletcher

Philipp J Otolaryngol Head Neck Surg 2010 Jan-Jun; 25(1): 4-6



REFERENCE

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Conflict of Interest and Disclosure



This session will discuss:

- The definition and scope of conflict of interest
- The types of competing interests
- Declaring conflicts of interest
- Managing conflicts of interest



OBJECTIVES

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Conflict of Interest and Disclosure



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

WAME statement on conflict of interest in peer-reviewed medical journals <http://www.wame.org/conflict-of-interest-in-peer-reviewed-medical-journals>



Conflict of Interest and Disclosure



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.

WAME statement on conflict of interest in peer-reviewed medical journals <http://www.wame.org/conflict-of-interest-in-peer-reviewed-medical-journals>



Conflict of Interest and Disclosure



Medical journals and the popular media have published numerous examples of competing interests that seemed to have biased published reports.^{2,3,4}

2. Bekelman JE, Li Y & Gross CP. Scope and impact of financial conflicts of interest in biomedical research: a systematic review. *JAMA* 2003; 289(4); 454-65.
3. Lexchin J, Bero LA, Djulbegovic B, Clark O. Pharmaceutical industry sponsorship and research outcome and quality: systematic review. *BMJ* 2003;326(7400);1167-1170.
4. Altman LK “For science’s gatekeepers, a credibility gap”. *The New York Times* May 2 2006. <http://www.nytimes.com/2006/05/02/health/02docs.html?scp=58&sq=conflict+of+interest+%26+medicine&st=nyt>



Conflict of Interest and Disclosure



Organizations have expressed concern for the effects of conflicts of interest on research,⁵ publication^{1,6,7} teaching⁸ and continuing medical and nursing education.⁹

5. Institute of Medicine “Conflict of interest in medical research, education, and practice”. Washington, DC: National Academies Press, 2009 (April) <http://www.iom.edu/Reports/2009/Conflict-of-Interest-in-Medical-Research-Education-and-Practice.aspx>
6. International Committee of Medical Journal Editors (ICMJE) “Uniform requirements for manuscripts submitted to biomedical journals; ethical considerations in the conduct and reporting of research: conflicts of interest <http://www.icmje.org/ethical-4conflicts.html>
7. International Committee of Medical Journal Editors (ICMJE) “Uniform format for disclosure of competing interests in ICMJE journals. October 2009. <http://www.icmje.org/format.pdf>
8. American Association of Medical Colleges. “Industry funding of medical education: report of an AAMC task force”. June 2008.
9. Hager M, Russell S, & Fletcher, SW (eds). “Continuing education in the health professions: improving healthcare through lifelong learning. Josiah Macy J Foundation, November 2007. http://www.josiahmacyfoundation.org/documents/pub_ContEd_inHealthProf.pdf



Conflict of Interest and Disclosure



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.



WAME statement on conflict of interest in peer-reviewed medical journals <http://www.wame.org/conflict-of-interest-in-peer-reviewed-medical-journals>

Conflict of Interest and Disclosure



How does this Statement differ from earlier conflict-of-interest statements?

FIRST, WAME expands the scope of competing interests.

- a. Not just **financial ties** to industry – companies that sell healthcare products
- b. Also includes the **effects of clinical income** - lab technologies
- c. As well as **non-financial** conflicts of interest



WAME statement on conflict of interest in peer-reviewed medical journals <http://www.wame.org/conflict-of-interest-in-peer-reviewed-medical-journals>

Conflict of Interest and Disclosure



Non-financial conflicts of interest

- 1. scholarly commitments:** “intellectual passion,” (the tendency to favor positions that one has already espoused or perhaps even established);
- 2. personal relationships** (the tendency to judge the works of friends/colleagues or competitors/foes differently because of the relationship);



WAME statement on conflict of interest in peer-reviewed medical journals <http://www.wame.org/conflict-of-interest-in-peer-reviewed-medical-journals>

Editorial independence and the editor-owner relationship: good editors never die, they just cross the line.

[Lapeña JF](#). PMID: 20087545 [PubMed - indexed for MEDLINE]

Singapore Med J 2009; 50(12) : 1122

goals of the publisher^{”(5)} exists only insofar as it is tolerated, or until editors cross the line.

As Ajai Singh, editor of Mens Sana Monographs, observed:⁽¹²⁾

- (1) Journals and editors, for all their uprightness and scientific merit, since they are under the thumb of associations and their office bearers, are always walking a tight rope. Whenever they appear inconvenient to the latter beyond a point, they will always be summarily dismissed.
- (2) The outcry, loud and impassioned, will as surely abate, because it lacks the teeth to convert its anger into collective action.
- (3) The editors will lose any battle in this fight, for the odds are stacked against them. This in spite of the fact that they are on the right side.
- (4) History will continue to repeat itself.

CONCLUSION

they are sacked, is eventually for the good. For, in the wake of the outcry, managements have to spell out with greater clarity where and when they will intercede. This itself is a significant step... Ultimately, with every such action, although a battle in the form of an editor sacked is lost, the war for editorial independence is being won.^{”(12)}

DISCLOSURES

The author does not have any relevant relationships to disclose, aside from his professional and personal friendship with the Editor of the Singapore Medical Journal, Professor Wilfred CG Peh, who ends his term, in the author's opinion, prematurely, with this issue. The views expressed are solely those of the author and do not reflect those of any journal or organisation with which he is associated.

REFERENCES

1. Kassirer JP. Editorial independence. NEJM 1999; 340:1671-2.
2. Smith B. Another editor hits the dust. There is needed a balance

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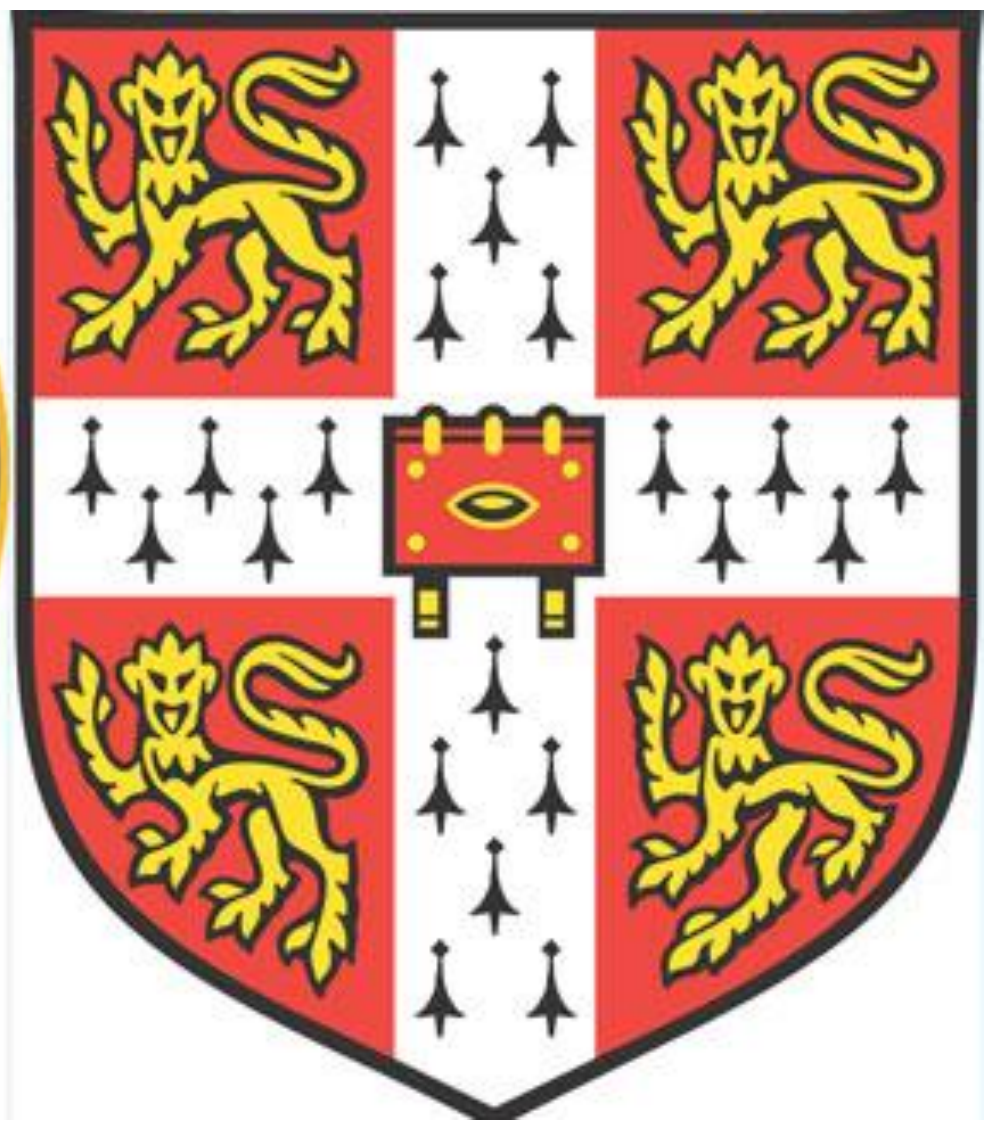


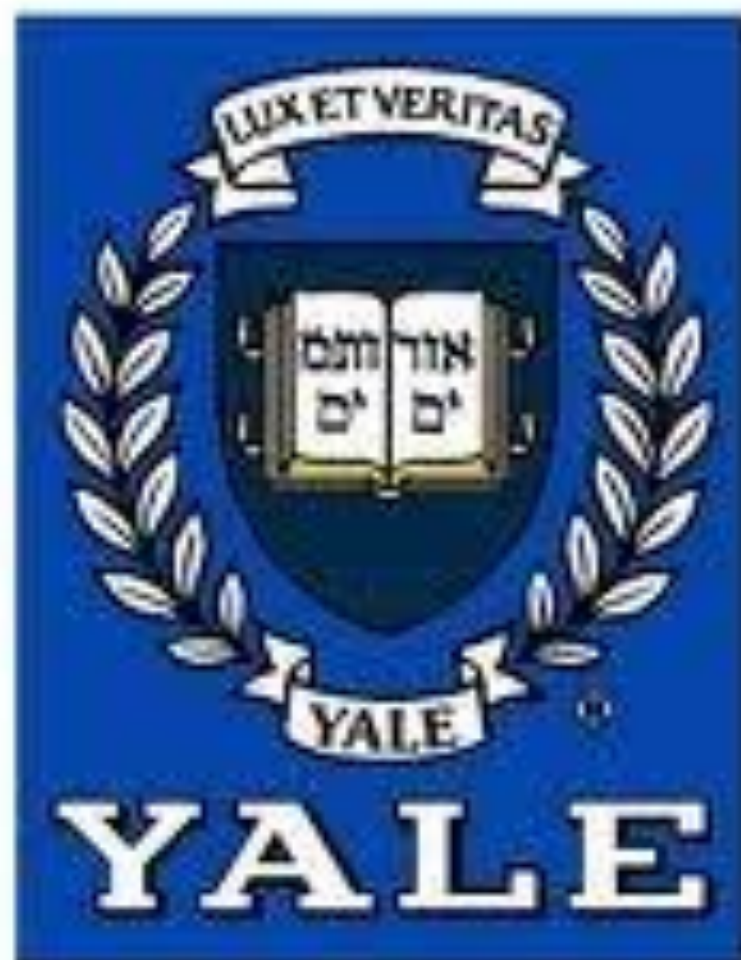
Non-financial conflicts of interest

3. **political or religious beliefs** (the tendency to favor or reject positions because it affirms or challenges one's political or religious beliefs);
4. **institutional affiliations** (the tendency to favor or reject results of research because of one's institutional affiliations).



WAME statement on conflict of interest in peer-reviewed medical journals <http://www.wame.org/conflict-of-interest-in-peer-reviewed-medical-journals>







Element aspects	Key	Comments
<p>Types of Competing Interests</p>	<p>A clear statement of examples of the types of competing interests (and their definitions) the journal says must be declared.</p> <p>Should include the following as examples but there could be others:</p> <ul style="list-style-type: none"> (a) Financial ties (b) Academic commitments (c) Personal relationships (d) Political or religious beliefs (e) Institutional affiliations 	<p>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.</p> <p>Examples and definitions of what competing interests should be declared needs to be articulated with Journals moving beyond just financial conflict of interest.</p>

Conflict of Interest and Disclosure



How does this Statement differ from earlier conflict-of-interest statements?

SECOND, WAME does not prescribe a universal standard for when meaningful conflict of interest exists.

Rather, it defines and recommends elements of conflict of interest policies and encourages journals to establish their own standards



WAME statement on conflict of interest in peer-reviewed medical journals <http://www.wame.org/conflict-of-interest-in-peer-reviewed-medical-journals>

Element aspects	Key	Comments
Definition and Scope	A clear definition the journal uses as to what is conflict of interest and who is captured in the definition.	<p>Sample definition: Conflict of interest exists when a participant in the publication process (author, peer reviewer or editor)</p> <p>has a competing interest that could unduly influence (or be reasonably seen to do so)</p> <p>his or her responsibilities in the publication process (submission of manuscripts, peer review, editorial decisions, and communication between authors, reviewers and editors).</p>

submission and peer-review system available at <http://philjol.info/index.php/PJOHNS/about/submissions#onlineSubmissions> *Philipp J Otolaryngol Head Neck Surg* can no longer accept hard-copy manuscripts or those sent via e-mail. Authors must first register to use the site.

2. Manuscripts must be accompanied by accomplished author statements in the forms provided in each issue or available from <http://www.psohns.org.ph/pjohns>. The following information is contained:

- A full statement that the manuscript is **original material** that is not being considered for publication or has not been published or accepted for publication elsewhere, in full or in part, in print or electronic media. All previous reports that might be regarded as redundant publication of the same or very similar work should be referred to specifically and referenced in the new paper. Copies of such material should be included with the manuscript.
- A statement that the manuscript has been read and approved by all the authors, that the requirements for authorship have been met by each author, listing their specific contribution(s), and that each author believes that the manuscript represents honest work;
- A disclosure statement of financial or other (including personal) relationships, intellectual passion, political or religious beliefs, and institutional affiliations that might lead to a conflict of interest, if that information is not included in the manuscript itself;
- A copyright transfer form signed by all authors; and
- The acknowledgement by the corresponding author, who is responsible for communicating with the other authors about revisions and final approval of the proofs. Copies of any permission to reproduce published material, to use illustrations or report information about identifiable people, to name people for their contributions, and the completeness, validity and reliability of all manuscript data must be guaranteed by the corresponding author.

2. Manuscripts should be neatly prepared in correct English using Microsoft Word, RTF or Word Perfect software on A4 format in Times New Roman font size 12, double spaced, with a 1 inch margin on all sides. When necessary, the manuscript should employ italics, rather than underlining (except with URL addresses). A maximum of twenty (20) pages (for original articles) is allowed for the text, with one (1) additional page each for proposed algorithms, figures or tables. Generally, a maximum of twenty (20) references are allowed. If the MS

should be copied and pasted separately in the appropriate spaces under Step 2 (Entering the Submission's Metadata) of the 5-step submission process. Following this, Parts (1) to (7) should be fully uploaded under Step 3 (Upload Submission) portion. However, each figure (8) should be uploaded separately as a supplementary file. The author statement forms should also be uploaded separately as supplementary files.

4. Authors can check the progress of their submissions online and should respond to all requests from the editor in a timely manner.

REQUIREMENTS FOR AUTHORSHIP

Each author should have participated sufficiently in the work to take public responsibility for its content. He or she should have made substantial contributions to all three of the following conditions: (a) conception and design, or acquisition of data, or analysis and interpretation of data; (b) drafting or revising the manuscript critically for important intellectual content, and (c) final approval of the version to be published. General supervision of the research, collection of data, funding acquisition or statistical analysis do not constitute authorship.

CONFLICT OF INTEREST NOTIFICATION

To prevent information on potential conflict of interest for authors from being overlooked or misplaced, it is necessary for that information to be part of the manuscript. Each author is expected to disclose any type of financial or proprietary interest related to the manuscript, including (but not limited to) stock in or ownership of an entity connected to a product described in the paper, consultancy for the company or competing companies, honoraria, travel support or patent rights to a drug, instrument or equipment, or benefits derived from the use thereof. Conflict of Interest also includes "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). Where no conflict of interest exists, a written statement should be made to that effect.

Conflict of Interest and Disclosure



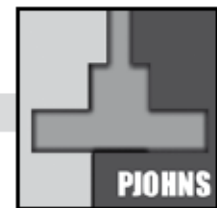
How does this Statement differ from earlier conflict-of-interest statements?

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.



WAME statement on conflict of interest in peer-reviewed medical journals <http://www.wame.org/conflict-of-interest-in-peer-reviewed-medical-journals>

Element aspects	Key	Comments
<p>Declaring Conflicts of interest</p>	<p>Clear statements on</p> <p>(a) What is to be declared, when and to whom;</p> <p>(b) format for declaration;</p> <p>(c) a journal's role in asking additional questions or seeking clarification about disclosures; and,</p> <p>(d) consequences for failing to disclose before or after publication.</p>	<p>Journals rely on disclosure about the facts because routine monitoring or investigation is not possible.</p> <p>This creates a particular onus on the declarer to report carefully and comprehensively.</p> <p>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.</p>



AUTHOR FORMS

Each author must read and sign (1) the authorship criteria and responsibility statement; (2) the conflict of interest disclosure statement; and (3) the copyright transfer statement. For additional co-authors, extra copies of this document should be accomplished. Author forms should be scanned and accompany your submitted manuscript. No manuscript will be reviewed or processed without author forms.

Manuscript title: _____

Authors in order of listing (last name followed by initials of first and middle names): _____

Authorship statement (all authors): I have participated sufficiently in the (1) a. conception and design of this work, or b. acquisition or c. analysis and interpretation of the data, as well as in (2) a. drafting or b. revising the manuscript critically for important intellectual content to take public responsibility for it and (3) have read and approved the final version submitted for publication. I believe the manuscript represents original, honest work and I assume responsibility for the completeness, validity and reliability of all manuscript data. Neither this manuscript nor one with substantially similar content has been published or is being considered for publication elsewhere, unless described in an attachment to this statement.

Author signature(s)	Printed name(s)	Date signed	Contribution (check all that apply)	Attachment
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Disclosure statement (all authors). I certify that this manuscript is not sponsored directly or indirectly by a pharmaceutical, medical equipment or instrument company, public relations firm or other commercial entity. I certify that neither I nor any immediate family member currently has a financial or other interest in or arrangement with any person or organization that may have a direct interest in the subject matter of this manuscript, or any product used or cited in this study, except as disclosed in an attachment to this statement [Financial interest or arrangement here includes but is not limited to the following: financial support, assistance with manuscript preparation, honoraria, consultancies, grant receipt, research support, stock holdings, speakers bureau listing, advisory board membership, employment or other material support. Other interests include intellectual passion, personal relationships, political or religious beliefs and institutional affiliation].

Author signature(s)	Printed name (s)	Date signed	Attachment
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Conflict of Interest and Disclosure



How does this Statement differ from earlier conflict-of-interest statements?

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

13. WAME policy on the relationship between journal editors-in-chief and owners (formerly titled Editorial Independence). <http://www.wame.org/resources/policies#independence>



Element aspects	Key	Comments
Managing conflict of interests	<p>A clear statement on how conflict of interest will be managed by the journal,</p> <p>including the position that all relevant conflict of interest disclosures (or the declaration of no conflict of interest) will be published with the article</p> <p>and clarity about what conflict of interest situations will result in a manuscript not being considered.</p>	<p>Journals use various rules about how they will deal with conflict of interest and conflict of interest disclosures</p> <p>And these need to be made known to all those involved in the publication process.</p>

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Disclosures: The HearCheck™ Navigator was complementarily provided by Siemens for research purposes. The authors signed disclosures that there are no financial or other (including personal) relationships, intellectual passion, political or religious beliefs, and institutional affiliations that might lead to a conflict of interest.

Presented at the Analytical Research Contest (1st Place), Philippine Society of Otolaryngology Head and Neck Surgery, Natrapharm Patriot Building, Paranaque City, Philippines, October 13, 2010

was treated as a separate subject. Results obtained from the HearCheck™ Navigator were designated as observed values and were classified as “no hearing loss” for green light, and “with hearing loss” for yellow or red lights. Results were compared with pure tone air conduction averages designated as gold standard values. Normal hearing acuity (0-25 dB) was classified as no hearing loss. Pure tone air conduction averages of 26dB and above were classified as “with hearing loss” and were further stratified as mild hearing loss (26-40dB) and moderate or worse hearing loss (≥ 41 dB). Observed and gold standard values were compared and tabulated in a 2x2 table for all levels of hearing loss, mild hearing loss, and moderate or worse hearing loss. Accuracy, sensitivity, specificity, positive and negative predictive values of the Siemens HearCheck™ Navigator inside a soundproof audiometry booth and in a quiet room were determined using pure tone audiometry as the gold standard.

Results: 100 patients (200 ears) were tested, with a median age of 43 years old (range 15-75), and an almost equal number of male and female participants (52 males, 48 females). Accuracy rate of the Siemens HearCheck™ Navigator inside the soundproof audiometry booth and in a quiet room were 82.5% and 84% respectively for all levels of hearing loss. Sensitivity, specificity, positive and negative predictive values were similar whether the examination was done inside the soundproof audiometry booth or in a quiet room. These values were notably higher in

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Conflict of Interest and Disclosure



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.



Conflict of Interest and Disclosure



No statement will solve the conflict of interest problem, nor will it ever be solved altogether.

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.

