

COMMENTARY

The Lancet's policy on conflicts of interest

As a signatory journal to the *Uniform requirements for manuscripts submitted to biomedical journals*,¹ how we manage conflicts of interest at *The Lancet* is largely based on ICMJE recommendations (ICMJE is the International Committee of Medical Journal Editors). On Sept 10, 2001, with the publication of a joint statement² by members of ICMJE, these recommendations were substantially revised, which led us to change how we put these guidelines into practice.

For any journal, a conflict of interest exists when an author, reviewer, or editor has ties to activities that could inappropriately influence judgment. Conflicts of interest can affect the individual or be relevant to the individual's institution; they can be personal, professional, or financial; and they can be actual (do influence judgment) or potential (could affect judgment). With the increasing links between academia and industry, medical research is becoming more dependent on commercial sponsorship to fund it and on contract research organisations to do it. The primary goal of medical research—to improve health—may be subjugated to commercial opportunities for profit or to personal gain. Conflicts are ubiquitous but what we can do is limit their effects.

Conflicts of interest matter because they can bias the research record and undermine its integrity. Conflicts can prevent results from being submitted, in total or in part. Contracts that restrict the freedom of investigators to submit findings for publication can lead to the suppression of data and limitation of academic freedom.³ That freedom is important to investigators, but even more so to patients who take part in research, exposing themselves to unknown risks or benefits, assuming that their data will contribute to medical science and will be published and available for public scrutiny. Medical research depends on volunteers who may, rightly, lose faith in a process that allows those with vested interests to suppress results. *The Lancet* therefore invites submission of protocols before a study has begun and we publish selected protocols on our website. Protocol publication encourages submission of clinically important negative findings and allows readers to check that what was done is what was planned. We support attempts to set up clinical trial registers, but such registers should either be linked, or one international, comprehensive, and accessible register is needed.

Since the beginning of 2002 we have asked for protocols to be submitted with reports of all randomised trials. The editors check that the report as submitted is an accurate reflection of the protocol. For those trials that survive clinical peer review, protocols go for statistical review with the submitted manuscripts. Since the beginning of 2002 we have consistently published conflict of interest statements from authors, together with details of the role of the funding source, as recommended by the new ICMJE guidelines (panel). We ask for these details to be included with submissions. From now on, we will ask the corresponding author to state that he or she had full access to all the data in the study and had final responsibility for the decision to submit for publication.

About 70% of submitted original research to *The Lancet* is rejected without external peer review. It is editors who are making these judgments and so wielding considerable power. Recognising that power, we introduced (on Nov 8) guidelines to manage editors' conflicts of interest. After much internal discussion, we have agreed six principles (panel) that we will test in practice and modify as needed.

First, we have agreed that *Lancet* editors (employees who make decisions on content of the journal, which includes those involved in peer review, commissioning, writing, and subediting) should have no direct personal, professional, or financial conflict with any manuscript they might judge, edit, or commission. In practice, editors exclude themselves from any part of the decision-making process (including the alteration of content that is part of subediting) if they have any conflict of interest. For example, if an editor has collaborated with an author, is a friend of an author, or the editor's partner has direct shareholdings in the company that makes the drug under trial, it is wise for another editor to take responsibility for the paper. Second, editors must not use information gained through working with manuscripts for private financial or personal gain. Third, editors should avoid submitting to *The Lancet* their own reports of original research (articles, mechanisms, or research letters). This policy differs from that of some other journals. If an editor, especially the editor-in-chief, submits a research paper to his or her own journal, it seems to us to be difficult for colleagues to make an unbiased decision about that paper, even if editors exclude themselves from decision making. Contributing editors, and other regular attendees at our weekly meeting where decisions on manuscripts are made, are not excluded from submitting original research, but should exclude themselves from meetings at which their paper is discussed. Household members of editors can submit original research, but the relevant editor should take no part in the decision-making process. Fourth, editors should avoid commissioning commentaries, seminars, reviews, or series from any member of a current editor's household. We consider that these sections, which may be especially influential to prescribers, may also carry weight with tenure or appointment committees, and we recognise the need to avoid perceived or real favouritism. Fifth, *Lancet* editors should avoid accepting payment for travel, accommodation, hospitality, or gifts from anyone other than their employer. Finally, annual financial disclosure statements will be submitted to the Editor to include all honoraria, payment for travel or expenses, research funding, company ownership, direct shareholdings, or gifts.

For those papers that survive internal review, external peer review is the next stage. Our general policy is to avoid choosing reviewers from the same institution as an author, or those who are known collaborators. We consider whether it is wise, and it usually is not, to seek review from a known antagonist or supporter of the author's work. We also rely on reviewers to tell us whether they have a conflict

How *The Lancet* manages conflicts of interest

Authors

Conflict of interest statement (published at end of text) includes:

Any financial arrangement (employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications, travel grants) that could bias your submitted work

Any personal relationship with other people or organisations that could bias your submitted work

Statement that you had full access to all data

Statement that you took final responsibility for decision to submit

Role of funding source (published in methods section) describes role of sponsor in: study design; data collection, analysis, and interpretation; writing report; and decision to submit

Sources of funding declared in acknowledgments

We avoid commissioning (commentaries, seminars, reviews, rapid reviews, series) from those with substantial financial interests (employment, stock ownership) in relevant company or competitor

Editors

Should have no direct personal, professional, or financial conflict with any manuscript they might judge, edit, or commission

Shall not use information gained from manuscripts for financial or personal gain

Shall not submit original research to *The Lancet*

Should not commission from member of current editor's household

Should not accept offers for travel, accommodation, hospitality, or gifts

Submit annual financial disclosure statements to *Lancet's* Editor

Reviewers

Decline to review a paper if substantial conflict

Consult with editor if in doubt

State whether do or do not have conflicts

Describe conflicts on reviewer form if do proceed with review

Editors avoid choosing reviewers from same institution as author or if known collaborator; and consider whether wise to ask known antagonist or supporter

Editors judge whether to use review or seek another

of interest of any type with the submitted paper (panel). We expect reviewers to decline to review any paper with which they have a substantial conflict. For example, close personal friends or past collaborators may find it difficult to give an objective opinion. If reviewers do choose to do the review, we expect them to declare such relationships. If reviewers are unsure, we suggest that they contact the editor to discuss the nature of the conflict. If conflicts are declared, editors then decide whether to use the review or whether another review should be sought. For those 30% or so of research manuscripts that are sent for external review, three clinical reviews are commonly sought, which protects authors from undeclared reviewers' conflicts. Manuscripts and their reviews are then discussed by the editors involved in peer review (about 12 editors), statistical advice is sought, and a decision made. The editor checks that the paper is a fair representation of what was actually done (with the protocol and CONSORT guidelines to hand for randomised controlled trials) and checks that the discussion of the findings is balanced.

Is all this enough to prevent the suppression or distortion of the research record from bias due to conflicts of interest? No, but as a journal, unless we see the protocol before the trial has started, by the time the research findings reach us it is too late to alter how the trial was done and by whom. We can set standards for the future, alter the presentation of studies, and we can reject studies that do not meet our

current standards, but we cannot alter what has been done. It is also for individual researchers, their institutions, and the sponsors of research to consider how to prevent or manage conflicts of interest in the early stages of the research process. What we can do is publish what we judge to be conflicts for authors or their institutions that readers should know about because they affect how the results may be perceived.⁴ We can also promote debate about conflicts of interest,⁵⁻⁷ especially where our policy may have failed to highlight important conflicts for readers.

Commissioning for *The Lancet* throws up additional challenges since it may be more difficult to detect bias in review papers or in commentaries than in reports of original research. We avoid commissioning from those with substantial financial interests (industry employees or those with stock ownership) in a company that makes a product or competitor to be discussed in the review. We point out to readers if a book is published by *The Lancet's* owner, Elsevier, since a favourable review in *The Lancet* could lead to increased sales of the book, and increased profits for Elsevier. Who owns a journal such as *The Lancet* can lead to other conflicts if the firewall between the editorial (content decisions) and commercial (revenue decisions) is breached. Research findings continue to be disseminated via advertisements and reprint distribution, both of which generate large revenues for *The Lancet* but should not and do not influence what we publish. We guard our editorial independence fiercely, and recognise that the integrity of the journal depends on it. This independence is increasingly important as medicine becomes more commercially minded and influenced. Some journal editors experience covert as well as explicit pressure to be more pro-pharma in their work. For example, editors might be encouraged to avoid criticising industry in their pages, to publish more drug-company trials, or to avoid public comment about aspects of medicine that might adversely affect the publisher. These limitations of independence are to be deplored.

What more can *The Lancet* do to minimise the influences conflicts of interest can have on the research record? We, in conjunction with ICMJE, could insist that the data are analysed independently of the funding source, at least for industry-sponsored studies. We should ask authors to state that their study is as specified in the protocol (or if not, why not). And we could even ask for the paper to be written by the authors as stated, or to ensure that those who wrote the paper are listed as authors. If we, and other journals, consistently ask authors, reviewers, and ourselves about conflicts, and do what we can to judge and present the research findings as honestly and fairly as possible, we can do more to protect the integrity of the research record and keep the trust of the public and the profession.

Astrid James, Richard Horton

The Lancet, London NW1 7BY, UK

- 1 International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals. 2001: <http://www.icmje.org> (accessed Dec 17, 2002).
- 2 Davidoff F, DeAngelis CD, Drazen JM, et al. Sponsorship, authorship, and accountability. *Lancet* 2001; **358**: 854-56.
- 3 Nathan DG, Weatherall DJ. Academic freedom in clinical research. *N Engl J Med* 2002; **347**: 1368-71.
- 4 Chaudhry S, Schroter S, Smith R, Morris J. Does declaration of competing interests affect readers' perceptions? A randomised trial. *BMJ* 2002; **325**: 1391-92.
- 5 Vandenbroucke JP. Was the LIFE study independent? *Lancet* 2002; **360**: 1171.
- 6 Vandenbroucke JP. Do editors live up to the Sept 10, 2001, expectations? *Lancet* 2002; **360**: 1605-06.
- 7 Horton R. Do editors live up to the Sept 10, 2001, expectations? *Lancet* 2002; **360**: 1606.