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# 1-4.4: Conflict of interest: declaring more or less?

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Conflicts of interest are complex and some of the main problems have been extensively described in the literature. They were described in the Bible and during the Middle Ages, and they exist in all aspects of our lives. Scandals in the corporate world have shown that mixing consulting and auditing is a common practice that leads to odd situations. Every day we are exposed to bias: how does my banker behave when I seek advice for a loan? Is the advice based on my interests or on a potential bonus?

It has also been clearly shown that conflicts of interest have impacts on science and many investigations have been conducted on this in the fields of biomedical research. A review article from 2003 concludes [1]: "Financial relationships among industry, scientific investigators, and academic institutions are widespread. Conflicts of interest arising from these ties can influence biomedical research in important ways". In another example [2] from studies of the health effects of passive smoking, analysis of 106 reviews led to the following observation: "In multiple logistic regression analysis controlling for article quality, peer review status, article topic, and year of publication, the only factor associated with concluding that passive smoking is not harmful was whether an author was affiliated with the tobacco industry."

The field of conflicts of interest (or competing interests) is of concern in many disciplines, among them law, sociology, philosophy, economics, fundamental research, medicine, publishing and editing. Presenting a broad overview is impossible and this chapter written by a physician has a biomedical bias.

## Definition

Dictionaries give short definitions of conflict of interest, such as: "a conflict between the private interests and the official responsibilities of a person in a position of trust (as a government official)" (Webster's Third New International Dictionary, 1993).

When the International Committee of Medical Journal Editors revised its uniform requirements and statements in 2001 [3] it issued the following statement:

> Public trust in the peer review process and the credibility of published articles depend in part on how well conflict of interest is handled during writing, peer review, and editorial decision making. Conflict of interest exists when an author (or the author's institution), reviewer, or editor has financial or personal relationships with other persons or organizations that inappropriately influence (bias) his or her actions. The potential for such relationships to create bias varies from negligible to extremely great; the existence of such relationships does not necessarily represent true conflict of interest therefore. (Relationships that do not bias judgment are sometimes known as dual commitments, competing interests, or competing loyalties). The potential for conflict of interest can exist whether or not an individual believes that the relationship affects his or her scientific judgment. Financial relationships (such as employment, consultancies, stock ownership, honoraria, paid expert testimony, patents) are the most easily identifiable conflicts of interest and the most likely to undermine the credibility of the journal, the authors, and of science itself. Conflicts can occur for other reasons, however, such as personal and family relationships, academic competition, and intellectual passion.

## Variations between disciplines and countries

Concern about conflict of interest has increased considerably in recent years. Although publications on conflicts of interest were limited to the Anglo-Saxon world 20 years ago, in the last 5 to 10 years we have seen debates arising in other European countries and Asia. In most of these countries, conflicts of interest were first identified within committees advising governmental bodies. Recent publications in Latin Europe (e.g. Spain, Italy, France) have shown that definition and concepts are not yet clearly identified and admitted. There is confusion about who is involved, and some opinion leaders do not accept that any deviant behaviour occurs. Their position is clear, as quoted in a French report [4]: "Fundamental research as such already is ethics; hence, it cannot be questioned".

It is interesting to cite the international conference held in Warsaw, Poland (5–6 April 2002), on the theme: "Conflict of interest and its significance in science and medicine" [5]. This conference was

organized by the Commission for Ethics in Science and the State Committee for Scientific Research, Poland, and held under the auspices of the Secretary General of the Council of Europe. Introduced by a message from Pope John Paul II, the conference recognized all concerns about conflicts of interest. Thirty speakers are listed in the proceedings, and a wide range of views were presented [5]:

- The disciplines represented were medicine (12 speakers), ethics–health policy (5), law (4), fundamental research (4) drug industry (2), agricultural science (1), philosophy (1), economy (1);
- The countries represented were the USA (9 speakers), Germany (3), France (3), UK (2), Armenia (1), Canada (1), Croatia (1), Estonia (1), Italy (1), Latvia (1), Lithuania (1), Pakistan (1), Poland (1), Romania (1), Russia (1), Switzerland (1), Ukraine (1).

The presentations showed that conflicts of interest concern all scientific disciplines, as well as both developing and developed countries.

**Which parties are involved in conflicts of interest?**

Ed Huth [6] has identified six parties with interests in the results of biomedical research:

- The investigator, whose successful research leads to career advancement, academic promotion, future research funding, and personal financing gains;
- The investigator's institution or employer, whose reputation and financial standing or profitability can be enhanced by the success of the investigator's research;
- The commercial sponsor of the research, who relies on positive research results to enhance return on investment and corporate profits;
- The patient, who desires personal benefit;
- The scientific community, which needs reliable information and public respectability, and
- The public, which pays for biomedical research through taxes and charitable donations.

The interests of each of these parties may conflict with the interests of any of the other parties.

All those working in the editing and publishing process are also concerned: authors, editors, reviewers, and journal owners. Most of the authors are the investigators named as responsible for articles, but ghost authorship and gift authorship are frequent, and their impact on conflicts of interest is unknown. Editors are scientists and their own interests can influence the decision to accept or refuse a paper. For reviewers, conflicts of interest are usually non-financial: rivalry, academic competition, philosophic values and beliefs. Publication owners have their say, as they can name and dismiss editors. Stakeholders of journals are for-profit companies or non-profit organizations (academic societies), but non-profit status, which is apparently more common in non-biomedical fields, does not preclude a conflict of interest.

**Financial conflicts of interests are more common**

The origins of conflict of interest are numerous. Listings of financial interests have been published by many organizations, though none are complete. Once such interests are recognized, the situation of conflict of interest exists. The existence of biases caused by this situation is more difficult to assess. Financial interests in biomedical research include the following [7]: salary and benefits of employment; consultancies; payment for service on boards of directors, advisory boards, review panels, and consensus groups; sponsored research agreements; donations of research-related funds, materials, or equipment; payment for recruitment or referral of study subjects; stock ownership and other forms of commercial equity; current and pending research grants; current and pending patents; licensing agreements; royalties paid; paid-for expert testimony; honoraria; financial support for education and meeting attendance; paid travel and accommodation.

Non-financial conflicts of interest are less obvious and include the desire for professional recognition and advancement, the need to compete successfully for research funding, and competition between academic institutions. Positive decisions are more easily taken when there are no financial interests: a reviewer might refuse to review because an author has recently become a post-doc at the reviewer's institute, for example.

**Variation between policies**

A US survey [8] analysed the policies of 127 medical schools and 170 other research institutions that received more than $5 million in total grants from the National Institutes of Health or the National Science Foundation. The main outcomes of this survey, which had 235 responding participants, are reproduced in Table 1.

The same study [8] investigated the basic science policies of 25 top-ranking clinical journals, as listed by the Institute for Scientific Information in 1997. Of the 47 with documentation, 20 reported that they had policies for the disclosure of conflicts of interest. Of these, ten required disclosure of income and equity interests, but only seven considered intellectual property rights reportable, and only one required apparent conflicts to be reported. Although all 20 journals required that each author disclose conflicts of interest, only five required

**Table 1. Policies of 235 medical schools and other research institutions on disclosure and management of conflicts of interest[a]**

| *Item[b]* | *Institutions with policies that address item: No. (%)* |
|---|---|
| **Type of conflict** | |
| Income | 215 (91) |
| Equity interest | 218 (93) |
| Intellectual property | 171 (73) |
| Finder's fees | 2 (1) |
| Fiduciary interest only | 134 (57) |
| Appearance of conflict | 156 (66) |
| Support of research | 79 (34) |
| Other in-kind support | 104 (44) |
| Policy meets federal guidelines | 215 (91) |
| Policy exceeds federal guidelines | 20 (9)[c] |
| **Person (or entity) with interesting requiring initial disclosure** | |
| Investigator | 235 (100) |
| Spouse or partner | 210 (89) |
| Minor or dependent child | 208 (89) |
| Another household member | 75 (32) |
| Adult child | 53 (23) |
| Parent | 51 (22) |
| Grandchild | 15 (6) |
| Another relative | 36 (15) |
| Family (unspecified) | 5 (2) |
| Trust | 15 (6) |
| **Party to which initial disclosure must be made** | |
| Party within institution | 235 (100) |
| IRB | 3 (1) |
| Funding agency or sponsor | 18 (8) |
| Research subjects | 3 (1) |
| Journals | 16 (7) |
| Collaborating researchers | 1 (<1) |
| **When disclosure is required** | |
| Annually or semi-annually | 193 (82) |
| On material change creating new potential for conflicts | 178 (76) |
| **When disclosure is required (continued)** | |
| When conflict is anticipated | 133 (53) |
| On application for funding | 149 (63) |
| On award of funding | 20 (9) |
| **How disclosure should be managed** | |
| Divestment of interest | 146 (62) |
| Withdrawal of investigator from project | 143 (61) |
| Disclosure to IRB | 0 |
| Disclosure to funding agency or sponsor | 102 (43) |
| Disclosure to research subjects | 0 |
| Disclosure to journals | 5 (2) |
| Disclosure to collaborating researchers | 2 (1) |
| Modification of research plan | 139 (59) |
| Monitoring of project | 156 (66) |
| Additional peer review | 16 (7) |
| Mandatory management method | 1 (<1) |
| Discretionary management method | 234 (>99) |
| **Penalty for nondisclosure** | |
| Termination | 109 (46) |
| Suspension | 47 (20) |
| Salary modification | 29 (12) |
| Non-financial modification (eg, research space) | 29 (12) |
| Reprimand | 65 (28) |
| Disqualification from future grant applications | 44 (19) |
| Notification of funding agency, journal, or both of non-disclosure | 98 (42) |
| Removal of investigator from project | 11 (5) |
| Unspecified or non-specified penalty | 108 (46) |
| Mandatory penalty | 0 |
| **Discretionary penalty** | 235 (100) |

[a]Table reprinted with permission from the *New England Journal of Medicine* [8].
[b]The items are not mutually exclusive. IRB denotes institutional review board.
[c]One institution applied criteria that were stricter than the federal guidelines to clinical research, but applied the federal criteria to basic-science research. This institution was considered to have exceeded the federal guidelines.

disclosure of interests involving spouses or partners and minor or dependent children.

The conclusions of this survey were: "There is a substantial variation among policies on conflicts of interest at medical schools and other research institutions. This variation, combined with the fact that many scientific journals and funding agencies do not require disclosure of conflicts of interest, suggests that the current standards may not be adequate to maintain a high level of scientific integrity." [8]

## How to handle conflicts of interest

Different policies exist to handle these situations. Variations are important between countries and disciplines and over time. The exclusion of scientists with a conflict of interest has some defendants. However, a conflict of interest does not mean that

judgement is necessarily biased. There is a tendency for institutions to support the disclosure of conflicts of interest in biomedical research.

Government bodies, academic societies, and international organizations have published codes of ethics and guidelines on scientific integrity and conflicts of interest. The recommendations included in an editorial policy statement [9] on conflict of interest and the peer review process are reproduced here (with permission):

The Council of Science Editors recommends that

- Journals require authors to state explicitly 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 either to include a description of all financial support with the published article or letter or to publish a footnote on the first page of the manuscript that reveals any conflict of interest that he or she feels the readers should know.
- Journals have a policy about the handling of undisclosed conflicts after they are identified by a third party and the means to provide some explanation to the readers.
- Journals 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 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.

However, compliance with these recommendations is probably poor. Implementing recommendations takes time, as all those involved interpret them differently.

## Conclusion

Conflicts of interest are ubiquitous. There is little hope that they will disappear. Many organizations in a growing number of countries and scientific domains are addressing these issues. Will global guidelines lead to a solution? Probably not, considering the cultural variation between countries and language areas. Will recommendations customized by domain and country be more effective? Possibly, but it will take years to implement all the guidelines. What will be the impact of the globalization of science and the internet? There are difficulties specific to disciplines (the patient plays a role in medicine, for example) and differences between the efforts in academia and industry. Transparency, openness and disclosure are positive trends, but may not be enough. Ethics and integrity in science and publication are not yet taught in most universities over the world.

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## Further reading


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