

SECTION EDITOR



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Failure to disclose conflicts of interest: Research misconduct

There is a growing debate in journals and articles on financial and non-financial conflicts of interest (COIs). This debate exists in scientific journals and also in the mainstream media. I provide two examples: the *New York Times* (NYT) and *JAMA*.

In September 2018, the NYT published a long article on Dr José Baselga, the chief medical officer at Memorial Sloan Kettering Cancer Center, New York, accusing him of failing to disclose important ties to the topics of his research articles.¹ The NYT accused the editors of scientific journals of being lax because they did not control the COIs.

One of the world's top breast cancer doctors failed to disclose millions of dollars in payments from drug and health care companies in recent years, omitting his financial ties from dozens of research articles in prestigious publications like The New England Journal of Medicine and The Lancet.

Medical journals have said they don't routinely fact-check authors' disclosures. Dr Baselga sent corrections to the journals to declare his many conflicts; he resigned from his position. In December 2018, the NYT revealed further cases of non-reporting of COIs in the cancer field:²

Dr. Howard A. "Skip" Burris III, the president-elect of the American Society of Clinical Oncology, for instance, declared that he had no conflicts of interest in more than 50 journal articles in recent years, including in the prestigious New England Journal of Medicine. However, drug companies have paid his employer nearly \$114,000 for consulting and speaking, and nearly \$8

million for his research during the period for which disclosure was required.

These articles forced the journal editors to react.

An editorial signed by the *JAMA* chief editor had the following conclusion:³

COIs are likely to become more challenging in the years to come. As more investigators and their institutions have and enter into financial relationships from which they benefit, it is critical that authors report COI information accurately, completely, and transparently so readers can evaluate whether the information in the article could be biased because of authors' potential COIs. Equally as important, if not more important, are the responsibilities of editors to ensure that published information is accurate and objective and to maintain the integrity of the scientific record. Ultimately, physicians, other health care professionals, and other readers must assess the information available to them, determine the value and importance of an article, and make decisions about its applicability to clinical care and contribution to health.

In the same issue, a viewpoint proposed to redefine research misconduct:⁴

If leaders don't follow the rules, then we don't really have rules. It is time to strengthen institutional COI policies by considering the intentional or negligent failure to disclose significant financial relationships relevant to the conduct of research to be research misconduct.

In December 2018, the ICMJE issued updated recommendations.⁵ They added the failure to disclose COIs in the paragraph defining scientific misconduct (page 8, IIIB):

Scientific misconduct in research and non-research publications includes but is not necessarily limited to data fabrication; data falsification, including deceptive manipulation of images; purposeful failure to disclose conflicts of interest; and plagiarism.

References

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Should journal editors consider potential harms of publishing certain research findings?

An article in the *Journal of Medical Ethics* addresses a general question in the context of biomedical journals: "Is there research that it is permissible to conduct but that ought not to be published?"¹ There is a concept referred to as *dual use research*. A simple example is in the field of terrorism. It is recognised that research whose results could provide ideas to terrorists cannot be published. If they are published, key points must be hidden, or only partially disclosed in order to avoid reproducibility. The *Journal of Medical Ethics* article describes two similar situations:

- A Danish team has shown that antibiotics reduce the symptoms of a widespread chronic disease. One reviewer noted that these data could change practices and contribute to an increase in antibiotic resistance, thus inadvertently resulting in deleterious health effects (the name of the disease is not given in the article).
- A *BMJ* article suggested that the adverse effects of statins were more important than the beneficial effects in patients at low and

moderate risk of cardiovascular disease. The subject has launched a rather heated debate, particularly in the mainstream media. An estimate has been made: about 200,000 people would have stopped their treatment, and probably 2000 cardiovascular events would be observed in the future. Finally, *The BMJ* and authors withdrew statements suggesting that adverse events occur in 18% to 20% of patients.²

The main messages are:

1. The publication of Danish and British studies can cause significant harm to individuals.
2. Editors of medical journals have a moral responsibility for the potential adverse effects of publishing research.
3. The refusal to publish is not an adequate instrument to fulfil this moral responsibility.
4. Internationally recognised codes of ethics should provide a solid basis for assessing and mitigating the potential effects of the publication of medical research in general.



The article deals only with the publication of medical research, simply because it is a field of research that is already regulated by a number of international codes. However, the points raised certainly also apply to other areas of research.

References

1. Ploug T. Should all medical research results be published? The moral responsibility of medical journal editors. *J Med Ethics*. 2018;44:690–4.
2. Godlee F. Adverse effects of statins. *BMJ* 2014;348:g3306.

How to explain away negative tests: the Panellists' Playbook

The *BMJ* Christmas issue contains 25 articles, some of which are very humorous, others more serious.¹ One article in particular is worth remembering.² The second paragraph sets the scene:

When key opinion leaders are asked to comment on disappointing trial results in news reports or at conferences, we have observed that they seem curiously unable to recognise that the treatment doesn't work. They prefer to argue that the trial design was wrong, drawing from a set of stereotyped criticisms. Using cardiology as an example, we have systematically analysed the excuses they provide to compose the Panellists' Playbook, an anthropological classification that will be useful not only for readers but for key opinion leaders in need of inspiration (or backbone).

This work is serious and is based on analysing *Medscape* and *MedPage Today* articles on the three largest cardiology congresses over 5 years. A trial was considered negative if the primary endpoint was not met. Of 321 trials in 15 congresses, 127 were negative, and the authors analysed 438 comments from opinion leaders. They listed 40 excuses classified into 17 themes. Frequent excuses: sample too small, other studies are needed, follow-up too short (Figure 1).

References

1. *BMJ*. 2018;363(8180). Available from: <https://www.bmj.com/content/363/8180>.
2. Hartley A, Shah M, Nowbar AN, Raikumar C, Howard JP, Francis DP. Key opinion leaders' guide to spinning a disappointing clinical trial result. *BMJ*. 2018;363:k5207.

Figure 1. Panellists' Playbook. An efficient standardised framework for busy key opinion leaders asked to comment on trials with negative results. Reproduced from *Key opinion leaders' guide to spinning a disappointing clinical trial result*. Hartley A, et al. *BMJ* 2018;363:k5207. *BMJ*. with permission from *BMJ Publishing Group Ltd*.

Excuse	Frequency (%)
1 Too small	39 (31%)
2A Too wrong	0 (0%)
2B Too old	4 (3%)
3A Too male	3 (2%)
3B Too female	0 (0%)
4A Diseases too advanced / severe	7 (6%)
4B Disease too early or mild	11 (9%)
4C Clinical status evolving too quickly at enrolment	1 (1%)
5A Too inclusive	22 (17%)
5B Too exclusive	7 (6%)
6A Too many comorbidities	1 (1%)
6B Too few comorbidities	4 (3%)
7A Patients wrong race	7 (6%)
7B Wrong country / continent	9 (7%)
8A Intervention wrong drug / device	20 (16%)
8B Intervention wrong dose / device generation	3 (2%)
8C Intervention wrong manufacturer	15 (12%)
9A Intervention given unskillfully	2 (2%)
9B Intervention could not be directly measured	1 (1%)
9C Wrong access route	
10A Intervention too late	8 (6%)
10B Intervention too early	1 (1%)
11A Compliance too low	3 (2%)
11B Compliance too high	2 (2%)
12A Background medical therapy not good enough	0 (0%)
12B Background medical therapy too good	15 (12%)
12C Background therapy compliance unknown	1 (1%)
13A Follow-up too short	21 (17%)
13B Follow-up too long	1 (1%)
14A Endpoint blinded	0 (0%)
14B Endpoint unblinded	1 (1%)
14C Endpoint too difficult to blind	1 (1%)
14D Endpoint too subjective	7 (6%)
15A Endpoint not subjective enough	1 (1%)
15B Endpoint not subjective enough	3 (2%)
15C Not enough subgroup analyses	6 (5%)
15D Not enough endpoints	4 (3%)
15E Not enough endpoints	3 (2%)
16A Unspecified multiple reasons	6 (5%)
16B Unspecified need to understand procedure / drug better	
16C Unspecified better patient selection needed	5 (4%)
16D More studies needed	27 (21%)



Collaborating on multi-authored papers and resolving disputes

Every time I'm in discussion with researchers, the issue of teamwork – especially collaboration in writing – is a hot topic, even very hot. The most frequent practice is that of the first author to send a manuscript (without the order of authors) to his co-authors, with a vague request: What do you think? The troubles begin, and then the atomic war is triggered when trying to decide the order in which authors names should be listed. We do not have enough rules to decide the order of authors, or even to know which researchers can be authors. Existing rules (such as those of the International Committee of Medical Journal Editors ICMJE) are either not known to researchers or are ignored even when they are known. A new article suggests 10 rules for collaborating on multi-authored papers.¹

1. Build your writing team wisely

2. If you take the lead, provide leadership
3. Create a data management plan
4. Jointly decide on authorship guidelines
5. Decide on a writing strategy
6. Choose digital tools to suit your needs
7. Set clear timelines and adhere to them
8. Be transparent throughout the process
9. Cultivate equity, diversity, and inclusion
10. Consider the ethical implications of your co-authorship

Interestingly, this paper includes a footnote regarding the order of authors. "MAF is the lead author. All authors contributed equally to this work. Besides for MAF, author order was computed randomly."

Another paper on authorship disputes concludes:

Rather than viewing authorship disputes as rare events that must be handled on a

case by case basis, researchers and journals should view the potential for disputes as predictable, preventable, and soluble. Independent bodies that can offer alternative dispute resolution services to scientific collaborators and/or journals could quickly help research communities, particularly their most vulnerable members.²

References

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2. Faulkes Z. Resolving authorship disputes by mediation and arbitration. *Res Integr Peer Rev.* 2018;3:12.

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