Authors and Publication Practices

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ABSTRACT: *Although authors are usually considered to be the main perpetrators of research and publication misconduct, any person involved in the process has the potential to offend. Editors may breach ethical standards particularly with respect to conflicts of interest. In the same way that authors are now required to declare competing interests, notably commercial affiliations, financial interests and personal connections, so must editors. Editors can influence the chances of acceptance or rejection of a paper by reviewer selection. Reviewers should also be ready to disclose conflicts of interest. They must ensure that their reviews are evidence based and free from destructive criticism driven by self interest. It seems likely that ultimately we will progressively move towards 'open' peer review in which both the authors and the reviewers are known to each other.*

There is an urgent need for increased transparency of the relationship between editors and owners. The events of the last few years indicate that unless this interface is fully understood by all parties, conflicts may arise. There is also a need for a radical overhaul in the relationship between journals, journal editors and the biomedical industry. It is now increasingly accepted that all clinical trials should be registered in a centrally held database and that protocols should include the primary and secondary outcome measures and the intended approach to data analysis thereby avoiding opportunistic post hoc analyses. However, the even more radical proposal that journals should cease to publish clinical trials sponsored by industry deserves wider debate.

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Introduction

The discovery of new knowledge, the delivery of that new knowledge to the wider community and, ultimately, the translation of those discoveries into tangible benefits for mankind are at the heart of the main mission of the world of science. However, this process is totally dependent on the integrity of those involved in all aspects of the journey. As an editor of a specialist journal I became aware very rapidly that this was not always the case and I was soon exposed to a variety of breaches of publication ethics.[1-3] These ranged from relatively minor misdemeanors such as dual submission, redundant publication and failure to disclose conflicts of interest, through to the more serious breaches of research integrity, namely plagiarism and research fraud. Thus, I was concerned at an early stage that not all investigators were observing the basic rules for the responsible conduct of research.

As a new, inexperienced editor, I found it difficult to know exactly how to handle these episodes of dishonesty, since they were individuals working within my own part of the biomedical community, were often known to me through their scientific reputation and through interactions at scientific meetings and, occasionally, were known to me personally. These issues raised important questions for me as an editor and, I hope, for the individuals concerned when their actions were discovered. I found it difficult, for instance, to know how far to go in investigating the alleged misconduct. When a reviewer drew my attention to serious plagiarism in an article submitted to the journal, it was not immediately clear as to whether I should carry out an extensive examination of the author's other publications to determine whether this was a habit or a one-off? Should I report this to anyone? Should I have discussed the problem with another editor or the appropriate regulatory agency for the country concerned (this was not a paper from the UK)? Should I punish the authors in some way, such as by refusing to consider further papers for the journal, say for a period of 1-3 years? Or should I just reject the paper, forget about it, and do nothing more? Reject and forget!

It was at this point that I and a group of other editors got together and informally set up in 1997 the Committee on Publication Ethics, 'COPE'.[4] Although it is not clear as to whether there has been a true increase in the number of breaches in research and publication ethics, there is no doubt that the climate has changed. The days are gone when an editor can ignore such breaches and just rejecting the questionable paper is no longer acceptable. Editors must fully engage with the world of biomedical science by ensuring they fulfill their duties at all levels of editorship. In 1999 COPE published the first version of its guidelines,[5] *Good Publication Practice* and has continued to revise them on a regular basis (latest version may be accessed at www.publicationethics.org.uk).

Although the title of this paper indicates that the predominant focus will be authors and their potential to fail in achieving high standards of conduct in the publication process, I intend to extend the scope of the discussion further, as I believe other players, such as editors and reviewers, also have a role in maintaining the integrity of the publication process and can, indeed, themselves be guilty of misconduct. I will take

one further step and go beyond the traditional "publication triangle", and discuss the important influence that the publisher or owner of a journal can have in the publication process. This is particularly relevant in the era of electronic publishing and open access journals, since the financial pressures on the traditional major biomedical publishers are now substantial, and the need to maintain profitability is greater than it has ever been.

Finally, there is a 5th player, particularly in biomedical publishing, namely the biomedical industry. Pharmaceutical companies and instrument manufacturers rely heavily on biomedical journals to publish the results of drug evaluation in clinical trials and new developments and uses of biomedical equipment. It is now widely acknowledged that there is inter-dependency between medical journals and the pharmaceutical industry which may not always be healthy.[6]

Authors and Publication Ethics

Who is an author? This remains a key question, as with authorship comes responsibility for both the data contained in a scientific paper and its interpretation. This question has been debated extensively during the past ten years following which there has been a substantial evolution of our ideas as to what constitutes authorship.[7] The International Committee of Medical Journal Editors have published strict criteria as to what an author needs to have contributed to a publication to justify appearing in the list of authors (Table 1).[8] A substantial contribution is demanded during all phases of planning and performance of the research and in the preparation of any research paper that emanates from the work.

TABLE 1: Authorship

Authorship credit should be based only on substantial contributions to

(a) Conception and design or analysis and interpretation of data; and to

(b) Drafting the article or revising it critically for important intellectual content; and on

(c) Final approval of the version to be published

Conditions (a), (b) and (c) must all be met.

Participation solely in the acquisition of funding or the collection of data does not justify authorship

General supervision of the research group is also not sufficient for authorship

From reference 8

'Gift authorship': Merely providing funding or overall supervision of a department or research laboratory is insufficient. The long established tradition of a senior figure expecting 'gift authorship' because of his or her position in the organization, should now be dispensed with.

The vast majority of high quality peer reviewed biomedical journals have signed up to these uniform requirements. With authorship comes responsibility for the data and opinions contained in the paper. Someone who has not been directly involved in the work is unable to take on this responsibility. This is particularly, but not exclusively, relevant to the authors of large multi-centre clinical trials sponsored by the pharmaceutical industry. The selection of authors for these papers is generally in the hands of the sponsor. Because of the size of the datasets, most of these authors will not have been directly involved in the data analysis or in the selection of data that are included (and excluded) from the paper. Thus it may be difficult for these 'authors' to take responsibility for the final published work. In addition, trials or parts of trials may be combined, sometimes in a selective way, which may not always be transparent to the varying pool of investigator/authors.

'Ghost authorship': Finally, professional medical writers sometimes called 'ghost authors', are invited to draft these reports, which selected investigators review and revise and then append their name as authors. The professional writer's name does not usually appear in the list of authors nor is there commonly a disclosure that such an individual has been involved in the process. There is nothing intrinsically wrong about using professional writers in biomedical publications but disclosure of their involvement is essential. Recently *Good Publication Practice for Pharmaceutical Companies* has been published which gives clear guidance on how professional medical writers should be used by the industry and their relationship to the other medical authors.[9]

There is now increasing support for a move beyond the concept of *authorship* to one of 'contributorship'.[10,11] The *Lancet*, *British Medical Journal* and an increasing number of other journals, now publish a list of contributors at the end of the paper, making it entirely clear as to what specific task each has undertaken, both with respect to the planning and conduct of the research, data analysis and preparation of the paper. It is important, under these circumstances, to identify the individual who will act as "guarantor" of the published work and thus ensure its reliability and veracity.

Although there have been a number of guidelines published on the ethical standards required for the entire research process, few have focused specifically on publication ethics. COPE first published its *Guidelines on Good Publication Practice* in 1999.[5] These focus predominantly on guidance for authors, although, there are also sections that are relevant to both editors and reviewers. The guidelines stress the importance of ensuring that the study design is sound and goes on to make recommendations about data analysis and the importance of full disclosure about the methods used, conflicts of interest and authorship. There are also sections on misconduct, specifically covering redundant publication and plagiarism and some recommendations as to how alleged breaches of research and publication ethics should

be dealt with, should an editor discover possible misconduct during the editorial process.

Despite many excellent guidelines on what constitutes good research and publication practice, authors still do not always get it right. Some of the main areas of difficulty are listed in Table 2.

Authors are not always totally transparent with each other while the research is conducted or during the preparation of the final paper and any subsequent revisions requested by a journal editor. Strictly speaking these disputes are of no material concern to an editor, but they often come to light during the editorial process. The authorship of any anticipated publications should ideally be decided before the work starts and this should be based on the projected contributions from each individual involved in the project. All authors should approve the final draft that is submitted to a journal and any subsequent revisions. This will avoid editors receiving complaints such as the order of the authors has changed during revisions of the paper. Following publication of a paper, editors are sometimes approached by investigators who are aggrieved because they feel they should have been included in the list of authors. This is an issue for the lead author and their institution and is not something that an editor could or should resolve.

TABLE 2: Authors and publication misdemeanors or misconduct

'Gift' authorship
'Ghost' authorship
Disputes between authors
Dual submission
'Salami slicing'
Conflicts of interest
Redundant publication

Dual submission: Some authors still submit their work to more than one journal at a time. This irritates editors and wastes editorial and reviewer time and if discovered, as in my experience it often is, it can result in both journals rejecting the paper.

'Salami slicing': Sadly some authors are still searching for the 'minimal publishable unit'! They divide their work up, like 'slicing a salami' into smallest publishable components, with the intention of building their curriculum vitae on the basis of *quantity* while perhaps reducing or indeed neglecting *quality*. In the UK I have a sense that this practice may be on the decline because of the increasing pressure through the national Research Assessment Exercise which financially rewards institutions on research excellence not on research quantity. The influence of journal impact factors, while detested by many, may also have assisted change in the right direction since the

high impact factor journals are much less likely to accept fragmented work and thus if investigators wish to increase in esteem through their research they must aim to publish their work in these journals.

Conflict of interest: The importance of declaring conflicting or competing interests remains a high priority for most journals. It has been said that 'disclosure is almost a panacea'! However some authors and even some editors still do not appear to understand the relevance of making such a declaration. During my time as an editor I once received a paper describing a new diagnostic test. The paper was very positively received by both reviewers, but one who obviously knew the senior author well, pointed out that the author held patents relating to the test and was the owner of the company that was now marketing this test widely. He clearly had more than just a scientific interest in the test. There is absolutely nothing wrong with this, indeed scientists and clinical investigators are being strongly encouraged to seek commercial exploitation of their discoveries. However, as a reader I think it would be important to know of this competing interest when evaluating the results and any subsequent recommendations in the discussion section. The basic message would seem to be '….if in doubt, disclose'.

Redundant publication: There continues to be a desire to publish data on more than one occasion, so called duplicate or redundant publication.[12] When I challenged some authors once on this issue, they merely replied that 'it was such a good paper that it deserved a wider audience'. In general it is not helpful to re-publish data in more than one journal. It can be particularly dangerous in the case of clinical trials as it can falsely bias the literature towards a particular form of therapy if it is not apparent that two papers are describing the same dataset. This is relevant in meta-analyses which will produce erroneous results if it is not apparent that two papers are reporting the same study.[13,14]

There are instances when it is perfectly acceptable to re-publish material particularly if the original publication was in a language that is not widely understood and the paper has global relevance. The authors just need to obtain permission from the editor of the journal in which the paper was first published, and fully disclose the paper's history to the new editor. It is then up to this editor and the reviewers to decide whether there is a case for re-publication and a clear disclosure in the second paper describing its history.

Editors and their responsibilities

Editors have an extensive range of responsibilities to many individuals in the publishing process. They clearly have a responsibility to provide their readers with the high quality original and non-original material that they require to inform their research and their own professional development. In addition there are responsibilities to authors with whom editors have a confidential relationship, not so different from the

doctor-patient relationship; they have a similar relationship with the reviewers they commission to evaluate papers before publication.

Editors also have an important relationship with the publisher or owner of their journal and in view of some of the high profile difficulties that editors of major journals have encountered in recent years, it is desirable that editors should have a written statement or contract with the publisher on the nature of that relationship. An area that increasingly requires clarity is the editor's independence to publish material which is considered appropriate to the journal and of relevance to the readership. Tensions can arise when journal owners wish to prioritise income generation through advertising or by having a publication policy aimed at targeting articles that are more likely to generate income because of their commercial value and their ability to attract large numbers of reprints.

George Lundberg, former editor of the *Journal of the American Medical Association* (*JAMA*) was sacked by the chief executive of the American Medical Association because in his words, "through his recent actions, [Lundberg] has threatened the historic tradition and integrity of *JAMA* by inappropriately and in-exclusively interjecting [it] into a major political debate which has nothing to do with science or medicine". Lundberg had opted to carry an article which showed that '59% of college students did not consider oro-genital contact constituted "having sex" ….'. Lundberg had chosen to publish this article at a particularly sensitive time in Bill Clinton's presidency. Lundberg however protested the mantra of editorial freedom stating that 'no matter who owns a primary source, peer-reviewed medical or scientific journal, the editor must have absolute freedom to publish what he or she chooses…'. Editors around the world threw up their hands in disgust at the action of the American Medical Association but George Lundberg still lost his job.[15,16]

Editors however do not always get it right. When Jan Hendrik Schon was found to have committed serious research misconduct necessitating the retraction of several papers from *Nature* and *Science,* the journals were heavily criticized in the Wall Street Journal ; '*Nature* and *Science* are locked in such fierce competition for prestige and publicity that they may be cutting corners to get "hot" papers'.[17] The Nobel Laureate, Robert Laughlin spoke even more forcibly stating 'in this case the editors are definitely culpable …. They chose reviewers they knew would be positive …'. Similarly the editorial policy of the *Lancet* has also been criticized for publishing Andrew Wakefield's paper in 1998 which suggested that the measles, mumps, rubella (MMR) vaccine might be responsible for a form of autism and an associated inflammatory disorder of the bowel. Clearly this was another 'hot topic' but it was soon apparent that the science was not robust and there followed a multitude of studies which failed to confirm this association.[18] Nevertheless considerable damage has been done to the MMR vaccination programme in the UK because of what would now appear to be a premature publication whose importance had been over-estimated.

There is evidence that editors may attempt to manipulate the impact factor of their journals. COPE received a complaint from an associate editor indicating that the editor-in-chief had promoted a policy which, before papers were accepted for publication, authors were encouraged or possibly even coerced to cite, wherever possible, other

papers that had been published previously in the journal. Others have complained of similar practices.[19] Fassoulaki and colleagues have shown a relationship between the self-citing rate and the impact factor in six anesthesia journals.[20] This does not of course prove causation but it certainly raises an interesting hypothesis which perhaps should be tested prospectively.

Finally, editors and their journals need to have a responsible relationship with the media. One study has shown that of 127 press releases produced by nine prominent medical journals, only 23% of these releases noted any limitations in the papers that they covered; the inference being that journals have a tendency to 'hype' studied findings both to attract readers and with a view to increasing the citation rate of these articles. This may be particularly relevant for those papers that might be thought to have commercial value.

Richard Smith drew attention to editorial miscommunication and misconduct in an editorial in the *British Medical Journal* in 2003.[21] He referred to the spectrum of editorial misdemeanors and posed the question, 'do we need an international medical scientific press council?' similar to the UK Press Complaints Council that investigates complaints against the daily newspapers and other press activity. COPE has now published a *Code of conduct for editors of biomedical journals,* which stresses the unique responsibilities of a journal editor and outlines the key role that the individual plays in maintaining the quality of the scientific literature.[22] It stresses the importance of declaring clear processes for peer review, for correcting the record when errors have been made, of maintaining confidentiality and of disclosing any conflicts of interest. It is anticipated that this guidance will be of assistance to all interested parties in the publication process, will ensure greater transparency in all aspects of the publishing process and ultimately to improve its quality.

Reviewers and their responsibilities

The peer review process has undergone substantial critical appraisal during the past decade.[23,24] It is clearly not a perfect process and there are many opportunities for reviewers to abuse their position of privilege. They may fail to declare conflicts of interest when reviewing a manuscript or research proposal. COPE has considered a number of cases in which authors have complained about the quality of reviews and expressed concerns that the individual concerned may be using anonymity to hide behind an inappropriately destructive report because of an unhealthy wish to retard the progress of the manuscript and the author's research group. COPE has also seen examples where reviewers have abused the confidentiality entrusted to them and plagiarised the material or ideas contained within a paper or grant proposal. On more than one occasion I have heard someone at a scientific meeting comment on data that were contained in an unpublished paper that the individual had obtained access to through the peer-review process. The relationship between a reviewer and both editor and author is a confidential relationship and should not be used to take unpublished data into the public domain.

Publishers and owners: What has happened to editorial freedom?

COPE'S editors' code of conduct addresses the important role that editors have in acting as champions of freedom of expression. Many editors in the world of biomedical publishing were shocked by the sacking of George Lundberg and protested loudly.[15,16,25] Doctor Jerome Kassirer, former editor of the *New England Journal of Medicine* also demitted office around the same period because of what was described at the time as 'honest differences of opinion'.[26] However, it was quite clear that Kassirer had had difficulties with the owners of the journal for some time. Marcia Angell, former executive editor (and editor-in-chief following the departure of Dr Kassirer) of the journal stated that 'behind this oblique explanation, lay a long standing struggle between Kassirer and the society's leadership over the latter's ambitious plans to expand its role as the medical publisher, both in print and online, by launching and acquiring new publications, repackaging the journals content for consumers, and entering into joint arrangements ("co-branding") with various information-based commercial enterprises.'[27]

What happens when the vision of the owner and the editor are out of line? These recent events would suggest that the freedom that editors have enjoyed over the years may be being eroded. Although it must be recognized that for the majority of the large publishing houses, journal publishing is a business, not all journals are profitable but those that are, often support those that are not. Editors should ensure before taking up a post, that both the vision (where we want to get to) and the mission (how we're going to get there) are openly discussed and agreed with the journal owner and publisher. It could be argued that this should be part of the job description and explicitly stated in the contract between the parties.

Industry and biomedical publishing: Too close for comfort?

There is a mutual interdependency between a journal and the external commercial world. This is perhaps best exemplified in the field of biomedicine in which major pharmaceutical companies rely heavily on medical journals to disseminate the results of the clinical evaluations of their products and subsequently to use these journals as vehicles for advertising their products to the medical profession. For many journals, the income gained through advertising and contracts for large reprint runs for use by the pharmaceutical industry may constitute a substantial proportion of the income for that journal. It has been suggested that journal owners might even try to influence editorial policy by ensuring that major pivotal trials that are likely to attract large reprint orders, should be prioritized by the editor. Clearly such a policy is totally reprehensible and if proven would amount to a breach of COPE'S guidelines on editorial conduct.

In recent years a much broader issue has been debated, namely the desirability of publishing the results of large multi-centre clinical trials in medical journals.[6] At one level it seems the obvious thing to do but at another there is a concern that the final, relatively brief clinical report could represent a selected pastiche of the 'good news'

from an extensive data set, that may contain a large number of primary and secondary end points, neglecting those end points that fail to show a statistically significant benefit or may even have revealed a negative side to the new drug.

There is also a question of authorship of these large trials. Traditionally, it is often said, that the pharmaceutical industry regard authorship of major trials as a reward to investigators for having entered patients into the trial and perhaps in addition for having acted as an advisor during the planning phase of the trial. However many of these authors, perhaps most, will not have been closely involved with the data analysis because such analysis are usually carried out 'in house' by the sponsor and it is uncertain as to whether all eventual authors are totally aware of the rationale for selecting the data which ultimately appear in the final paper. A variety of initiatives have been proposed to improve the quality of the reporting of clinical trials. These include the Consort Guidelines, which encourage the use of a template to ensure that no vital data are excluded. *Good Publication Practice Guidelines for Pharmaceutical Companies* clarifies the role of professional medical writers and other issues including the responsibilities which accompany authorship.[9]

However it is now quite clear that the recent concerns about data concealment by the pharmaceutical industry have opened a new chapter in the history of clinical trial reporting.[28,29] It is now widely accepted that all major clinical trials should be entered onto a register prior to patient enrolment.[30] This goes part of the way in allaying fears that the results of all trials should be placed in the public domain irrespective of whether the results are positive or negative. There is still a major concern that the literature is biased towards trials that would support the registration of a new drug, while those that are negative remain unpublished and buried as "data on file". Industry sponsored trials are more likely to have a positive outcome than non-industry sponsored studies.[31] Registration would also include an outline protocol and the intended data analysis with respect to primary and secondary end points. It has also been suggested that because of the possible unhealthy interdependency between journals and industry, that clinical trials should no longer be reported in medical journals but should appear as a complete data set in a web based repository.[6] This would allow an independent analysis of the clinical impact of a new drug and perhaps produce a more balanced view as to its true impact in the clinical setting. Although this may not seem immediately attractive to all parts of the pharmaceutical industry, it may substantially reduce any future claims for damages against any adverse effects of the drug as these data will have been placed in the public domain at a very early stage thus allowing clinicians, statisticians, potential patients and their advocacy groups to make a full assessment of the potential benefits that drug may have for them.

Conclusions

Although investigators/authors are usually considered to be the main perpetrators of research and publication misconduct, any person involved in the process has the potential to offend. Editors may breach ethical standards particularly with respect to conflicts of interest. In the same way that authors are now required to declare competing interests, notably commercial affiliations, financial interests and personal connections, so must editors. Editors can influence the chances of acceptance or rejection of a paper by selecting 'hawks' or 'doves' to review the paper. Editors have also abused their position and published their own fabricated papers, sometimes by-passing the usual peer-review process.[32]

Reviewers should also be ready to disclose conflicts of interest. They must ensure that their reviews are evidence based and free from destructive criticism driven by self interest. It is my personal belief that ultimately we will progressively move towards 'open' peer review in which both the authors and the reviewers are known to each other.

There is an urgent need for increased transparency of the relationship between editors and owners. The events of the last few years indicate that unless this interface is fully understood by all parties, conflicts may arise. This relationship should ideally be made explicit in the editor's contract with the owner /publisher.

There is also a need for a radical overhaul in the relationship between journals, journal editors and the biomedical industry. The CONSORT guidelines,[33] *Good Publication Practice for Pharmaceutical Companies*[9] and the widely accepted concept that all clinical trials should be registered in a centrally held database[30] are major steps forward. These protocols should include the primary and secondary outcome measures and the intended approach to data analysis thereby avoiding opportunistic post hoc analyses. However, the even more radical proposal by Richard Smith that journals should cease to publish clinical trials sponsored by industry deserves wider debate.[6] It might be of greater value to clinicians, the wider biomedical community and to possible future users of a new drug if the complete data set was put up on an easily accessible website and journals published solicited or unsolicited reviews of the material. For me this argument has great force but there is obviously a need for this to receive wider debate by all stakeholders.

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