

Obstacles to honesty in science: the case of medical research

Peter Wilmschurst has worked in the medical sciences for over 30 years. His focus has become the investigation of research misconduct which, he argues, is far more common than is publicly acknowledged, and largely due to the power of corporate interests.

Medical research relies on the integrity of investigators, because we accept on trust what they submit for publication. The trust placed on medical researchers by society is founded on the naïve belief that those who gain advancement through publication of medical research are more honest than those who gain advancement in other occupations. This belief flies in the face of evidence – often from investigations by universities, regulators or journalists – that much of what medical researchers publish cannot be trusted.^{1,2,3,4}

Industry conceals negative research

Dishonesty in research is not only a matter of publishing false data. It can also involve concealing the truth. We know that much research goes unreported, particularly when industry sponsors consider the results commercially damaging.⁵ Industry sponsors are able to prevent publication of commercially damaging findings because their contracts with research institutions often contain clauses that ensure that the sponsors 'own' the data and have all rights over its publication, rather than it belonging to the patients who took the risk of participating in the research, the investigators or society at large. Academic institutions accept these legal clauses because the research contracts are lucrative for institutions and investigators. The latter are often retained as industry consultants and are paid handsomely to lecture provided they continue to propagate the corporate message.⁶ Commercial sponsors take legal actions for breach of contract to ensure that damaging findings are kept secret.

12 Early in my career I was threatened with litigation if I revealed that a new drug for heart failure was ineffective and caused life-threatening side effects.⁷ On that occasion I went to The Guardian newspaper to expose the actions of the pharmaceutical company after three major journals had refused to publish the details because of fear that they might be sued for libel by the company.⁸ I also know from experience that the libel laws are used in attempts to silence investigators who are prepared to raise concerns about research.^{9,10} As a

result, the best evidence required for a systematic review of the medical literature, the keystone of evidence-based medicine, may have been deliberately concealed. If one is fortunate, the process known as 'critical appraisal' may provide hints about some of the research that has been performed but has not been published. Critical appraisal is the process of careful, transparent and systematic examination of research to judge its trustworthiness, and its value and relevance in a particular situation.

Journals reject negative research

Editors and researchers also deserve some of the blame for failure to publish research. 'Negative trials' are those that show that a treatment is ineffective. These are valuable for patients, who do not want to take treatment that does not work, and healthcare providers, who do not want to pay for it. Editors, acting in the commercial interests of their publishers, are reluctant to devote space to 'negative trials' when the space in a journal could be given to trials of drugs or medical devices that show products in a favourable light. Such 'positive trials' guarantee that the product's manufacturer will purchase advertising space to accompany the article and buy reprints to give to doctors.¹¹ For the most prestigious medical journals, an article reporting commercially favourable findings may earn the journal over \$500,000 from reprint sales to the sponsoring company.¹¹ This is a good reason for editors to reject 'negative' research and to ask no questions about whether the claims in 'positive' commercial trials are true.

Reluctance to highlight flawed research

Editors can also be reluctant to publish reports of failed attempts to replicate earlier research, as it might lead to criticism of their earlier decision to publish. On their part, researchers may not try to publish such failure out of concern that critics will say that they cannot do the experiments properly, particularly when there is a large amount of contradictory data already published or even when there is a small amount of contrary data published many times. We think of science as self-correcting, but in practice human frailty and the conflicting interests of those involved means that once a flawed idea becomes established it is difficult to dislodge.

Critical appraisal should detect duplicate publication of data from a single research study. There are some

acceptable reasons for re-publication, such as in a different language for a different readership, but it must always be stated explicitly. More often duplicate publication is misconduct because it is performed to give an unwarranted impression of high research output.¹² To achieve the deception it is necessary to ensure that readers do not realise easily that it is a duplicate publication.

Some journals actively encourage duplicate publication by republishing articles in industry-sponsored supplements, sometimes changing the title of an article and the order of the authors, which gives the impression that it is an entirely different research study.¹¹ Industry pays journals handsomely for these supplements because they allow their sales representatives to supply doctors with a single document containing a number of favourable articles about their product from their chosen opinion leaders without the recipients seeing any unfavourable data or counter opinions. Duplicate publications bias the evidence by suggesting larger numbers of observations than were obtained. One hopes that this type of research misconduct will be recognised during critical appraisal of studies identified, but duplicate publication often goes undetected.

Positive spin

Besides concealing commercially damaging data, industry also ensures that what is published has a positive spin. There are many ways of doing this. Drug studies are often designed to compare a product with a competitor's, but with a dose of the competing drug that is so high that it produces side effects or so low that it is ineffective. If such bias in design does not produce the desired outcome, the predefined endpoints may be altered and the data may be reanalysed until some marketable result is found. Industry employs eminent doctors to add credibility to their message.⁶ The most eminent doctors may have had no involvement in industry sponsored research, but are paid large consultancy fees to act as gift authors of research articles and editorials written by company employees. The names of the real authors never appear in the publication: they are 'ghost authors'. This practice allows industry to misrepresent product advertising and corporate messages as the research and views of the opinion leaders, who many readers will believe to be objective scientists rather than members of a corporation's advertising department.



Critical appraisal may sometimes reveal such major inconsistencies in research that they are difficult to explain except by gross carelessness on the part of investigators or by fabrication of data. In either case the research cannot be relied upon. However when misconduct is brought to the attention of a journal that published the research, the editor often refuses to take any action. I accept that an editor of a journal in one country may have difficulty compelling an author in another country to explain their actions. If that happens editors could say that they will never publish work from those authors again. I also accept that editors may not have training or funding to mount their own full investigations. However they should ask authors for an explanation, report the concerns to responsible bodies in the country of origin of the research and publish a notice of concern about the publication. Editors have a moral obligation to patients who might be harmed by flawed data and to the scientific community to do something other than claim that any problem with research that they published is nothing to do with them. Unfortunately editors often refuse to take any action.

Commercial interests before patients' interests

Even when official investigations confirm that there was data fabrication, many journals fail to retract dishonest research, which continues to pollute the literature, bias systematic reviews and harm patients.¹³ The reluctance of journals to correct the scientific record is in part because they wish to deny any involvement in misconduct, but more often it is because of fear of being sued for libel by authors whose fraudulent work they retract.

I am a cardiologist and I have published research with implications for the health and survival of patients. No editor of a medical journal has ever asked me to provide evidence for any claim made in a scientific paper. I am also invited to write about research misconduct and when I do the journals' editors require that every statement can be confirmed by supporting documents to the satisfaction of the journals' lawyers to avoid the risk of a libel claim.^{11,14} Clearly, for the editors of many medical journals, the finances of the journal are more important than the lives of patients who might be harmed by publication of research that cannot be substantiated.

When I have reported concerns about research articles, journal editors have almost invariably refused initially to consider my concerns. It is a long, hard and thankless task to get concerns about research published. Editors, authors and research institutions usually try to dismiss concerns because they have a conflicting interest in continuing the pretence that what is published in medical journals is honest and accurate. If those involved in research publication admit that much of what is published is neither honest nor accurate, they would have to put in place better measures for scrutiny. That would be costly for them, but it would be cheaper than the cost to society of allowing patients to suffer from ineffective or dangerous treatments and of diverting other researchers up blind alleys.

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