Misconduct by researchers and authors
Harvey Marcovitch
Syndication editor, BMJ Publishing Group, Chairman, Committee on Publication Ethics, London, United Kingdom.

Abstract
Most scientific research is conducted properly and reported honestly but a few authors invent or manipulate data to reach fraudulent conclusions. Other types of misconduct include deliberately providing incomplete or improperly processed data, failure to follow ethical procedures, failure to obtain informed consent, breach of patient confidentiality, improper award or denial of authorship, failure to declare competing interests, duplicate submission and plagiarism. Editors, peer reviewers and publishers may also act wrongly. Good practice guidelines are available from the International Committee of Medical Journal Editors (The Vancouver Group) and the Council of Science Editors, amongst others. The Committee on Publication Ethics provides flowcharts to assist editors deal with authorial misconduct. Examples are provided of cases involving epidemiological or public health research, reported to COPE over the last 9 years. Suggestions are offered as to how misconduct might be handled in future.

Key words: Scientific misconduct. Ethics. Journals. Research.

Revisiónes

Resumen
Aunque la mayor parte de la investigación científica se realiza y comunica de manera honesta, algunos pocos autores inventan o manipulan los datos para obtener conclusiones fraudulentas. Hay, además, otros tipos de malos comportamientos, como proporcionar deliberadamente información incompleta o mal procesada, vulnerar la confidencialidad de los pacientes, atribuir o denegar improcedentemente la autoría, no declarar algún conflicto de interés, publicar de forma duplicada y el plagio. Los editores y revisores externos también pueden actuar erradamente. El Comité Internacional de Directores de Revistas Médicas (el Grupo de Vancouver) y el Consejo de Editores Científicos han elaborado guías de buena práctica. El Comité de Ética en Publicación proporciona diagramas para ayudar a los editores a afrontar los casos de mal comportamiento. En este trabajo se comentan algunos casos prácticos de mala práctica en investigación en epidemiología y salud pública de entre los abordados por el Comité de Ética de publicación durante los últimos 9 años. Se presentan además sugerencias para tratar estas situaciones en el futuro.

Palabras clave: Malas prácticas. Ética. Publicaciones. Investigación.

Introduction
Rightly, the public expects scientists, researchers, clinicians and journal editors to be honest and trustworthy. Failure to live up to these ideals can result in science being corrupted, patients harmed and financial sponsors deceived. While the majority of research is conducted properly and reported honestly, a depressing series of scandals shows that there is a dishonest minority. In the worst cases, data have been invented or manipulated to reach fraudulent conclusions. But there are also lesser or more subtle degrees of scientific and publication misconduct. Those most frequently encountered are listed in table 1.

Misconduct by editors, publishers and peer-reviewers

Authors are not the only ones who may be guilty of misconduct. Editors, publishers and peer reviewers also have responsibilities: for example, peer reviewers have a duty of confidentiality pre-publication; they have a duty not to allow professional or personal jealousy or rivalry to influence or determine the advice they offer editors; and they have a duty not to cause undue delay to the processing of a submitted paper


Correspondence: Harvey Marcovitch.
Syndication editor, BMJ Publishing Group.
Chairman, Committee on Publication Ethics.
E-mail: h.marcovitch@btinternet.com

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Table 1. Categories of scientific and publication misconduct reported to the Committee on Publication Ethics (COPE) from 1998 to date

- Carelessly or deliberately permitting basic faults in study design, performance or documentation which may prejudice the findings
- Failure to follow accepted ethical procedures when involving live subjects (animal as well as humans), such as conducting experiments on human subjects without properly informed consent or on animals without regard to national regulations
- Breaches of patient confidentiality or failure to obtain informed consent to take part in research (or for permission to submit case reports)
- Inadequate or partial disclosure of how data were obtained and analysed with explanation for any exclusions
- Electronic manipulation of images in such a way as to significantly change how they are interpreted
- Improper award of authorship: all authors should have made significant contributions to the conception, design, analysis or reporting of the study and no such author may be excluded from final attribution
- Failure to declare any competing interest, especially financial, which might bias a study's conclusions or lead readers to doubt the conclusions
- Attempts at redundant or duplicate publication
- Breach of copyright and plagiarism

Editors have a prime duty to their readers to maintain the integrity of the scientific record. This must take precedence over their other duties, for example, making sure their journal is readable and profitable (or, at least not a financial burden for the society, academic institution, governmental body or publisher to whom they are responsible). Therefore, they should follow good practice guidelines, such as those published by the International Committee of Medical Journal Editors (ICMJE) or the Council of Science Editors (CSE)\textsuperscript{1,2}. Important functions include correcting significant inaccuracies or misleading reports by publishing corrections; ensuring that proper ethical standards have been followed in the conduct of research or clinical practice forming part of submitted or published papers and paying strict regard to patient confidentiality.

Editors can access advise from the Committee on Publication Ethics (COPE) by way of flowcharts devised from the organisation’s experience over 8 years of handling allegations of misconduct\textsuperscript{5}. If a satisfactory explanation cannot be supplied by authors, then editors should normally report any reasonable concerns about research misconduct to their institution(s) or those who funded their study so that they can investigate and publish a notice of concern where the initial case looks strong, followed by retraction when there is a finding of fraud or a major error which, if left to stand, would significantly distort the scientific record.

Editors and their publishers must make sure that their journal is open and transparent in its instructions to authors (advice to contributors), especially with regard to describing the peer review process as well as its definitions for authorship and requirements for declaration of competing interests. They should have a well-defined appeals procedure and an independently supervised complaints process.

Publishers, themselves cannot escape responsibility, if only because they may be required to investigate and adjudicate on complaints against editors or editorial boards. Some publishers have accepted that responsibility. For example Wiley Blackwell provides a set of ethical guidelines which it expects its journal editors to follow. Additionally, publishers should not attempt to interfere with editorial freedom unless there are exceptional circumstances whereby an editorial board or other responsible body produces cogent evidence that an editor has misused that freedom.

Types of misconduct

Submission of fraudulent data

The extent of fraudulent research data is not known, although many experienced editors believe that undiscovered fraud is much more common than is supposed. It is rarely easy to detect. An editor or associate editor processing a paper may be suspicious that the results are «too good to be true» but without specific expertise in the topic, he or she cannot be certain. Statistical analysis of a paper will sometimes demonstrate that data must have been manipulated. Likewise, reviewers sometimes express concerns about the honesty of a paper.

There have been numerous high profile cases of fraudulent data being presented. Most dramatic, perhaps, was the claim of Professor Hwang Woo-suk of Seoul National University that his team had created a cloned human embryo from which it had extracted stem cells.

A major scandal involved Schön, whose research on molecular scale electronic devices and induced superconductivity in carbon «buckyballs» led to a series of papers in Nature and Science which are now known to contain data which were fabricated and misrepresented.

Fraudulent papers may corrupt future research by others as they continue to be cited (sometimes even after they have been exposed). For example, a randomised controlled trial concluding that a year of a low fat, fibre-rich diet almost halved the risk of death from all causes\textsuperscript{4} had been cited 225 times by 2005 and included in various guidelines, according to White\textsuperscript{5}. In her paper, she detailed the doubts expressed repeatedly by reviewers and editors. These led to mounting concerns over other publications by the senior author, followed by various inconclusive investigations and the ultimate decision by the then editor of the BMJ, Richard Smith, to publicise the entire history of the matter.
Incomplete or improperly processed data

The reliability of the scientific record can be disturbed by conduct far short of fraud. For example, it is commonplace that inconvenient data are sometimes excluded from a study or that the most advantageous statistical analysis is performed, especially if the results can be used, for example, to increase prescribing rates or enhance the chance of further research funding).

Even with full disclosure, publication bias can distort the record when it results in a greater likelihood that positive studies will be published and negative studies rejected. Of course, this form of misconduct is as much the responsibility of editors as it is that of authors. One systematic review of studies comparing methodological quality and outcome according to the source of funding showed that research sponsored by pharmaceutical companies is less likely to be published than that funded otherwise, that company sponsored research is of lower quality and that findings are more likely to be favourable to the product investigated (OR = 4.05; CI, 2.98-5.51).

Publication of fraudulent research, apart from being intrinsically dishonest, may distort the scientific record, divert resources to projects doomed to failure as they are predicated on the false data and, ultimately harm patients. Countries have various systems to deal with fraud: formal governmental mechanisms exist or are being developed in Australia, Canada, Denmark, Finland, Germany, Norway, Sweden and the USA. In other countries individual institutions may assume responsibility. Regulatory bodies may become involved, not as primary investigators but to decide upon sanctions. For example, in the UK, over the last 10 years, the regulatory body for medical practitioners, the General Medical Council has charged 20 doctors with fraud when conducting research – often related to inserting non-existent patient data in a medication trial.

For example, in 1997 a former secretary of the Royal College of Physicians in Edinburgh was erased from the medical register (thus removing his right to practice medicine in the UK) for conducting a 15 month long sham drug trial (case report 1).

A reviewer informed a journal editor that the design of a population-based survey was flawed and he was convinced the survey could not have been carried out as reported because the follow-up rate was impossibly high and he doubted the authors had the financial resources to have undertaken a study that involved collecting data in several countries. He had scanned Medline and found 3 other studies with similar authorship, each with a similar protocol but different populations, which seemed to him equally unlikely. Neither the authors nor the head of their institutions responded to letters of enquiry from the editor.

Incomplete or improperly processed data

In February 2005, the editor of Nutrition retracted a paper by the Canadian researcher RK Chandra that it published in 2001. This randomised controlled trial declared that cognitive function in elderly people was improved by provision of certain vitamins and trace elements in their diet. Grave doubts were then expressed about a similar paper published in The Lancet more than 10 years earlier which had been cited over 300 times.

It is likely that many similar frauds are perpetrated, often as part of a research project of lesser significance so that suspicions are not aroused. For example, one editor was surprised to receive a paper detailing a population survey in which data were collected 18 months apart from the same 15,000 patients living in a particular area. Almost 100% follow-up was achieved despite his knowledge that natural turnover by death, moving to another address or simple failure to cooperate with a trial not funded to seek out non-respondents was unlikely to reach a follow-up rate greater than 60%.

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An editor was told that a series of papers from a high profile researcher might be fraudulent and that the subjects described might not have existed. An independent epidemiologist and a statistical adviser were asked to review the published papers and two awaiting publication. Both experts doubted the truth of the work and the author was asked to provide the original data. This arrived in a large box, written in pencil: entering them into a computer proved time-consuming and expensive. The statistician had other work to do but eventually reported that the data in the one paper he had analysed was probably fraudulent. The author appeared to be head of the institution where he worked. He did not reply to the editor’s questions. The national body in his country which seemed to be the regulatory authority stated that it did not have jurisdiction and referred the editor back to the institution. Little progress was made over several years.

Source: Committee on Publication Ethics (http://www.publicationethics.org.uk/cases)

Medicinal consent. It adds that identifying details should be omitted if inessential. Journal editors vary in how closely they follow this guidance. For example, the BMJ group of journals states that consent must have been obtained to publish material about a patient if there is any chance they might be identifiable. An exception may be made if the author has attempted to contact the patient but found it impossible, for example if either has moved or if the former can no longer access case notes. Even then the journals demand that the public interest in publishing the study must outweigh any possible harm that might befall patients if they are identified.

This can pose problems, such as how to disguise photographs to make them unidentifiable. Many journals are now placing their historic archives on-line; in previous years, sensitivities were not so great so patient identification was common. Should publishers remove identifying data that is, for example over 50 years old?

An even more difficult question is how many patients may be in a case series for there to be a real risk of identification. For example, an author submitted a paper detailing the histories of nine babies whom he believed had been suffocated by an abusive parent. The text showed that only 3 had been found guilty in a court of law so their actions were on public record. Unsurprisingly the author had not sought permission for publication from the other 6 whom he suspected. Since the author had an appointment at just one hospital, any reader could identify the area of the country where the subjects lived, while from the text he could impute the children’s ages, the period of time when the events occurred and certain unusual features in their personal information. One journal editor to whom the paper was submitted decided there was a risk of identification; an editor of the next journal approached agreed but decided the public interest in the information being made available outweighed any harm that might accrue to the families involved. It must be doubtful, however, whether he took into account the legal risks involved in potentially defaming the individuals concerned.

Editors and peer reviewers should understand also that submitted papers remain confidential until published. Reviewers should not pass on papers to others to read without the editor’s permission, reveal details, use information in lectures nor use the pre-publication data to inform their own research. Editors are in the same position and must make sure that their instructions to peer reviewers are clear about these matters.

Perhaps the most expensive example of a reviewer’s breach of confidentiality was when Cistron Biotechnology of New Jersey, USA alleged that a reviewer chosen by Nature, who was an employee of Immunex Corporation of Seattle, purloined a valuable DNA sequence from the unpublished paper he had been asked to review. Both companies sought patent rights to the sequence. The case was settled on the Courthouse steps when Immunex agreed to pay US$ 21 million to Cistron and transfer its patents.

Authors and editors must also take care that proper consent was given for the original study. In general, this task is undertaken by the authors stating that local ethical committee or institutional review board (IRB) consent was applied for and given. Problems may arise for editors when considering papers from countries which may not yet have high-quality IRBs. Many editors will decline to process such papers but others may be less restrictive. Once again, it is the responsibility of editors and publishers to make sure potential authors are informed of the journal’s policy in this respect.

Authors will sometimes claim that IRB approval was unnecessary because the study in question represented a report or audit of normal clinical practice. The question may then arise as to where the boundary lies between research and practice, especially when considering studies from tertiary or quaternary specialist centres.

Even where IRB approval has been granted, editors may reserve the right to make their own decision as to the ethics of the research presented. After all, IRBs themselves may not behave ethically (case report 3).

Source: Committee on Publication Ethics (http://www.publicationethics.org.uk/cases)
Authorship issues

The ICMJE criteria for authorship state that all persons designated as authors should qualify and each should have participated sufficiently to take public responsibility for the contents\(^1\). An individual cannot be included if he or she has not made a substantial contribution to the conception or design of the trial; or to the analysis and interpretation of the data; or to drafting the article or revising it for intellectual content as well as final approval. Again, journals should make clear in their instructions to authors what criteria they will apply when assessing authorship (or contributorship, as some journals prefer) (case report 4).

Where an editor is made aware of disputes between authors or groups of authors pre-publication, it is best not to accept the paper until the protagonists have settled their dispute. An exception might be when it is alleged that a particular author is deliberately refusing to co-operate in order to prevent or delay publication, perhaps because of personal antipathy to one or more colleagues.

The practice of honorary authorship has a long history, with authors named who do not meet the criteria for authorship, for example heads of department who have had no involvement in the particular research study other than as an employer. A less frequent but still unacceptable practice is that of ghost authorship, where an individual who has qualified for authorship does not appear on the list of authors. One survey of corresponding authors of papers published in 3 large-circulation general journals and 3 specialist journals showed that 19% of articles had honorary authors and 11% ghost authors\(^1\).

Many researchers and clinicians, however competent and distinguished, do not have literary or journalistic skills so may employ a staff writer, particularly common in large pharmaceutical company trials. Where a medical writer has assisted they should be mentioned in the paper’s contributorship statement and whether or not he or she was paid should be mentioned in the statement on funding. The European Medical Writers Association (EMWA) has published guidelines which include a statement on such writers professional responsibilities in ensuring that papers they write are scientifically valid and produced in accordance with generally acceptable ethical standards\(^1\).

Competing interests

We all have competing interests of some sort. By having their papers published, authors enhance their curriculum vitae (résumé), become stronger candidates for appointments and consequently increase their income. Editors may favour certain topics over others because of belief they might catch the eye of the public media and so lead to the editor’s name being better known to the profession and the public. Reviewers may be tempted to allow personal grievances or favours to affect their judgement. Good practice demands that, as far as possible, competing interests are subsumed by the need to be objective and fair.

In defining what might be a significant competing interest, one suggestion is that if it were later revealed, readers might feel misled or deceived. The most serious is likely to be financial or commercial but personal and political conflicts can affect judgement. Financial interests may include being paid by the sponsor of a research project to undertake the work, or receiving reimbursement for lecture or travel. Holding stock or share ownership, consultancies and holding or seeking patent rights in any product or device can also be regarded as a competing interest.

In 2001, Hussain and Smith\(^1\) sampled 3632 research papers published in *Annals of Internal Medicine*, *Lancet*, *JAMA*, *New England Journal of Medicine* and *BMJ* between 1989 and 1999. They found that only 52 (1.4%) included a declaration of competing interest although the situation had improved in the later years of the survey. Nonetheless, such conflicts are common: Belkeman\(^1\) reported that 1 in 4 US researchers received pharmaceutical company funding, and half disclosed related gifts. In his review of 789 papers in major medical journals, he found that 1 in 3 lead authors held shares, patents, directorships or paid membership of advisory boards.

The solution is straightforward: journals should require all authors to sign a declaration on submission of any competing interest (and if they have none). It will then be a decision of the editor as to whether this affects the chances of acceptance and of the readers as to whether it alters their view of a published paper’s conclusions. Editors and reviewers should also make it clear if a competing interest may affect their work; it is bet-

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**Case report 4**

A paper was accepted subject to revision. The authors had interrogated a national data set recording certain patients’ deaths and medicine prescriptions. The revised version did not contain the names of 2 original authors from a government body holding the data but only the other 2, from a university. The editor was contacted by a senior government official and the head of a regulatory board, concerned about possible adverse results on public health if the paper was misinterpreted by the national media as suggesting certain drugs were dangerous. The editor persuaded the remaining authors to modify their conclusions. He remained unsure as to whether he should have rejected the revision as two authors were now ‘ghosts’ and whether he had improperly succumbed to pressure and thereby improperly pressured the remaining authors to alter their paper.

Source: Committee on Publication Ethics (http://www.publicationethics.org.uk/cases)
Case report 5

A journal published a paper on passive smoking in which the authors failed to declare financial support from the tobacco industry. Although the authors responded to the editor’s enquiry by admitting funding from one source, he considered this insufficient and wrote an editorial detailing the extensive involvement of the research group with the industry. He was reluctant to publish their letter of response without further disclosure and refused to consider a second submitted paper. Eventually it became clear that the senior author had a consultancy with a tobacco company, for which he had lobbied outside his home country. COPE advised the editor to publish the entire history of the case and report the author to his country’s research integrity body. Subsequently the editor gave evidence at the author’s action for libel against another research group. During the hearing evidence of data tampering came to light and the Court decided the author had been involved in “unprecedented fraud.”

Source: Committee on Publication Ethics (http://www.publicationethics.org.uk/cases)

Redundant and duplicate publication

Because of the professional necessity or importance of having one’s research published, authors may be tempted to produce several papers from one dataset. There may be good reasons for this, which do not represent publication misconduct in any way. The results of a study may have different implications for differing professional or specialist groups: for example, a study on the long-term outcome of treatment of, say, myocardial infarction may contain material relevant to cardiologists, pharmacologists, intensivists, nurses and psychologists. In such circumstances it may be acceptable to divide the data where some may be relevant only to a particular readership because of the message it conveys. What matters is full disclosure, both at submission and in citations. Authors should always make clear if a contribution is part of a wider study and should include with their submission any other published or submitted paper depending on the same data set or patient group.

A study may, of course, be redundant before it starts. Where a subject has been thoroughly and convincingly elucidated, some find it questionable whether resources and, more importantly, the contribution of patients or subjects, might be misused by repeating the study. Researchers need to consider this before designing their trial.

Any attempt at duplicate publication, that is sending the same or very similar findings from the same study to more than one journal is misconduct. Firstly, the second submission may involve intellectual theft as the journal which first published the study may hold copyright or a license which only allows the author to use the material with permission. More importantly, duplicated papers may have a significant effect on systematic reviews and meta-analyses if the same data are counted twice.

This was well illustrated in a systematic review by Tramér et al18 of papers comparing the effectiveness of intravenous ondansetron in preventing vomiting. They found 16 unduplicated studies and 3 studies subject to duplication (with 6 duplicates of the 3 studies). The calculated number needed to treat (NNT) from the 16 unduplicated papers was 9.5 while, from the 3 papers where the data were published more than once, it was 3.9. Combining all 19, the NNT was 4.9. The true NNT was 6.4.

Table 2. Websites with advice and discussion of ethical issue in scientific publication

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<th>Institution</th>
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<td>International Committee of Medical Journal Editors</td>
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<td>World Association of Medical Editors</td>
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<td>Danish Committees on Scientific Dishonesty</td>
<td><a href="http://forsk.dk/">http://forsk.dk/</a></td>
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<tr>
<td>Deutsche Forschungsgemeinschaft (proposals for safeguarding good scientific practice, in English)</td>
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<td>Swedish Medical Research Council</td>
<td><a href="http://www.vr.se/english">http://www.vr.se/english</a></td>
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<td>Canadian Guidelines on Ethical Conduct for Biomedical Research Involving Humans</td>
<td><a href="http://www.nserc-crsng.gc.ca/">http://www.nserc-crsng.gc.ca/</a></td>
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<tr>
<td>Indian Council of Medical Research</td>
<td><a href="http://icmr.nic.in/">http://icmr.nic.in/</a></td>
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<td>UK Panel on Biomedical Research Integrity</td>
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<td>World Medical Association Declaration of Helsinki</td>
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Conclusions

There is little doubt that there is growing awareness that science needs policing. Much of the impetus has come from individual ‘whistleblowers’, often junior colleagues who may have to put their own careers at risk by laying information against a senior member of their department. Journal editors, with help from reviewers and readers, are gradually finding their voice. But it is not enough to leave the handling of publication misconduct in the hands of ad-hoc bodies such as ICJME and COPE. Governments, universities, research councils, the pharmaceutical industry and other funding bodies all have a duty to ensure the integrity of the scientific record. Some countries have formalised their response, for example the US Office of Research Integrity, albeit it can deal only with federally funded research, while national mechanisms exist or are in development in Canada, Denmark, Finland, Germany, Norway, Sweden, Australia and the UK. Many universities have sophisticated procedures to deal with allegations of research misconduct while others are accu-
see of not doing enough. There remains no agreed set of sanctions beyond rejecting suspect manuscripts or publishing retractions on those proved fraudulent. Science has no borders and journals admit papers from all over the world, often with co-authors attached to institutions in different countries. It is time for an international consensus on dealing with misconduct. A starting point might be the example of the speed and efficiency with which the Norwegian authorities dealt with the multiple fraudster, Jan Sudbo. In October 2005 he published a paper in *The Lancet*. Within weeks, the Cancer Registry of Norway alerted authorities that Sudbo could not have accessed data in their registry which formed a key part of his paper. In January 2006 an investigation commission was set up by the University of Oslo and the Rikshospitalet-Radiumhospitalet, under the chairmanship of the head of the clinical epidemiology unit at the Karolinska Institute, Stockholm, Professor Anders Ekbom. In June 2006 the commission produced its report, arising from which many of Sudbo’s papers were retracted, he resigned from his posts and had his licences to practice medicine and dentistry revoked by the Norwegian Board of Health. The report concludes thus: «The research community must make an all-out effort to make plain research’s traditional ideals of honesty, thoroughness, trustworthiness and openness.» And so it must, not just in Norway.

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