International Journal of Surgery (2006) 4, 122–126

INTERNATIONAL JOURNAL OF SURGERY

www.int-journal-surgery.com

REVIEW

Deceit and fraud in medical research

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KEYWORDS
Fraud;
Deceit;
Medical Research;
Medical Ethics

Abstract Deceit and fraud in medical research is a serious problem for the credibility of published literature. Although estimating its prevalence is difficult, reported incidences are alarming. The spectrum of the problem ranges from what may seem as rather innocuous gift authorship to wholesale fabrication of data. Potential factors which may have promoted fraud and deceit include financial gain, personal fame, the competitive scientific environment and scientific hubris. Fraud and deceit are difficult to detect and are generally brought to the fore by whistleblowers. Although most cases may be dealt with at an institutional level, regulatory organisations such as the Committee on Publication Ethics (COPE) and Medical Research Ethics Committee (MREC) have been established to monitor and try to remedy the problem.

Introduction

Fraud and deceit in medical research corrupts the scientific record and leads to false conclusions. It leads to a loss in public trust in medical research and doctors. Fraud in medical research affects all grades of investigator.

Perhaps the most famous case in Britain was that of Malcolm Pearce, a senior lecturer at St George's Hospital Medical School and Geoffrey Chamberlain, Professor and head of the department.[1] In 1994 they published a paper in the British Journal of Obstetrics and Gynaecology, of which Pearce was assistant editor and Chamberlain editor. The paper claimed success in re-implanting an ectopic pregnancy. In the same issue, Pearce had published a randomised controlled trial. A few months later, a junior researcher in their department alerted authorities that the re-implantation case was a work of fiction and that the patients randomised in the trial did not exist. The affair led to Chamberlain resigning and Pearce being struck off the medical register. The story warranted front page attention in the Daily Mail newspaper.

Although this was a rather sensational case, fraud and deceit in medical research has a 'pathogenesis' and manifests itself in a number of ways. In this paper the nature and causes of fraud and deceit in medical research are examined as well as potential solutions to the problem.

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doi:10.1016/j.ijsu.2006.02.004

Definitions of fraud and error

The committee on Public Ethics (COPE) holds that the principle underlying misconduct is intention to cause others to regard as true that which is not true.[2] Misconduct, therefore, not only involves a particular act or omission, but also the intention of the researcher, author, editor, reviewer or publisher involved.

Although an honest mistake is very different from deliberate fraud, it is not enough to say that all human activity including research is prone to error. The scientific record is equally at risk from honest mistakes as from deliberate fraud. Hence it is the responsibility of the authors to check their work and ensure accuracy.

Prevalence of fraud and deceit

It is difficult to estimate the prevalence of fraud and deceit in the medical literature directly, but an indirect insight can be gained from questionnaire surveys. One North American study reported that 36% of doctoral and post-doctoral students were aware of an instance of scientific misconduct; furthermore, 15% were willing to do whatever was necessary to get a grant or publish a paper.[3] Another survey of Biostatistician members of International Society for Clinical Biostatistics, who may be thought of as unbiased and in a prime position to observe fraud and deceit, revealed that 51% of respondents knew of fraudulent projects. Different forms of fraud such as fabrication and falsification of data, deceptive reporting of results, suppression of data, and deceptive design or analysis had been observed in fairly similar numbers.[4] This evidence fairly convincingly debunks the idea that fraud or deceit in medical research is a relatively minor and isolated activity. It is indeed widespread.

Potentially dubious practices in medical research

Plagiarism

Plagiarism can range from the unreferenced use of others' published or unpublished ideas to submission under 'new' authorship of a complete paper, sometimes in a different language.[2]

Forging

Forging is the invention of some or all of the research data that are reported, including the description of experiments that were never performed.[5] Cases of forging have been well publicised in the past.[6,7] Although forging is the most obvious form of fraud and deceit in medical research, it is by no means the only type of misconduct.

'Cooking' and 'trimming'

Cooking refers to retaining and analysing only those results that support the hypothesis being investigated and ignoring data which may weaken the results. Trimming involves smoothing the irregularities in the data to make the results look more convincing for publication. These offences seem mild in comparison to plagiarism and forging however they provide a first step for the vulnerable researcher down the road of fraud and deceit.

Misuse of statistical techniques

Owing to the complexity of statistical analysis and the difficulty many researchers have with it, fraud and deceit can creep in unwittingly. With the ready availability of menu driven statistical software and lack of understanding of associated hypotheses and assumptions, improper techniques may be employed leading to misleading research.

Irresponsible authorship

Multi-authored papers have become increasingly common over the past 10 years with some having up to 40 authors. Often 'authorship' has been granted for the need to accord recognition rather than due to any direct scientific contribution to the endeavour.

There is as yet no universally accepted definition of authorship. COPE guidelines state that the award of authorship should balance intellectual contributions to the conception, design, analysis and writing against the collection of data and other routine work. The guidelines go on to state that if there is no task that can be reasonably attributed to a particular individual then the individual should not be credited with authorship.

Authorship carries important implications for responsibility for the published material. All authors carry the responsibility to check data and ensure its honesty. Most journals now require authors to provide a signed statement that they have read the manuscript prior to submission and are thus aware of its contents. In cases where certain aspects of a paper are beyond an individual's capabilities, the relevant section should be checked by someone with the appropriate expertise who has not written the particular contribution.

Redundant publication

Redundant publication occurs when two or more papers, without cross reference, share the same hypothesis, data, discussion points or conclusions.[2] Although previous publication of an abstract during the proceedings of meetings does not preclude subsequent submission for publication, full disclosure should be made at the time of submission. A somewhat similar practice, known as ''salami slicing'' allows the production of multiple papers by fragmentation of the same data-set.

The consequences of fraud and deceit

Fraud and deceit in medical research may lead to two major problems for science in general. Firstly, there will be an erosion in trust in the overall validity of scientific discoveries which may lead to a slowing of the pace of research as investigators spend more and more time trying to confirm the work of others rather than building on it. And secondly, fraud or deceit may lead to patient management being instituted on evidence with a less than firm base in scientific fact and hence may not have the expected benefit and possibly cause harm to patients.

A prominent case which highlights both of these aspects is that of Mark Williams and Cameron Bowie.[8] Drs Bowie and Williams instituted a survey of need of severely handicapped patients in the community. The results were fascinating. Those severely disabled people who were being seen only by their GP and community nurse had far more unmet needs than those who were also being seen by a social worker or who were in contact with a patient organisation. The results provided empirical evidence of inadequate medicosocial assessment, coincidentally reported at just the right time to back the government's community care proposals. Later, Williams was investigated for fraudulent behaviour (including lying about his qualifications) and struck off the medical register which resulted in all the research he was involved in being withdrawn including this survey.

Dr Bowie lamented later at the time of retraction that the paper had been 'seminal' in community care reform and had done much good. Unfortunately he personally had not looked at the raw data and thus could not vouch for the honesty of the paper and so had no alternative but to withdraw it.

This case aptly demonstrates that any degree of deceit and fraud may have a disastrous effect on medical research in general owing to erosion of confidence and mistrust in the scientific literature.

Potential causes of fraud and deceit in medical research

There may be a variety of causes of fraud and deceit in medical research. In generously funded, industry supported research, clearly financial gain may be an incentive. In centres of clinical research, the motives may be more complex. Competition, discussed below, or simply the desire for fame may be contributing factors.

Angell argues that the highly pressurised environment in which medical research is carried out has given rise to fraud and deceit.[9] He points out that because promotion and funding of physicians in academic medicine are closely linked to the number of their publications, investigators feel impelled to publish as frequently as possible. This pressure leads to, for instance, trivial studies being undertaken because they yield rapid results, needlessly reporting the same study in instalments, reporting a study more than once, and listing as authors people only marginally involved in the study or even to outright forging.

Hubris, where a researcher just 'knows' what the result of a study ought to be and manipulates or fabricates the data to confirm this belief, may lead to fraud. The most celebrated case is that of William McBride who gained worldwide acclaim for discovering that thalidomide caused birth defects but his subsequent studies showing the same for the drug debendox were falsified. He subsequently admitted forging the data ''in the interests of humanity''.

Angell further proposes that an effective way to reduce these offences and affirm the supremacy of substance over volume in scientific research would be to place a ceiling on the number of publications that can be considered in evaluating a candidate for promotion or funding. Each publication would then receive commensurately more attention, both from the researcher and from those judging the work.

In the US setting, Petesdorf describes a ''premed syndrome'' in the pathogenesis of fraud and deception.[10] He argues that the extraordinary size of science (which makes supervision of young investigators difficult), and competition, both professional and economic, has lead to fertile soil for fraud. Petersdoft suggests that solutions include more careful selection of personnel, reduction of excessively large research groups, and closer examination of work at all levels—the

laboratory, the academic department, and the institution. He also suggests that institutions should have in place mechanisms to investigate research fraud when it is uncovered.

Statistical methods for the detection of data fabrication

Various statistical methods are available to investigate whether data is likely to be fabricated or not.[11] The techniques detect 'strange' patterns in the data including studying outliers, inliers, overdispersion, underdispersion and correlations or lack thereof. These techniques all rest upon the premise that it is quite difficult to invent plausible data, particularly highly dimensional multivariate data. The multicentric nature of clinical trials also offers an opportunity to check the plausibility of the data submitted by one centre by comparing them with the data from all other centres.

For instance in a randomised blinded trial comparing two groups, means and variances between baseline values can be compared between the two groups. Values which differ greatly would suggest that the two groups could not have been formed by random allocation. Digit preference has been described as a test, although is not itself evidence of misconduct. It is conceivable that if two individuals were given the task to record data for the treatment group and another the data from the control group that digit preference may occur. This could not happen if blinding had taken place.

Although statistical methods have been described, few examples of their application have been published. Also, statistical methods alone are not proof of data fabrication. Statistical methods can however be used in the setting of randomised trials where raw data is available.

Whistleblowing

Most fraud is probably detected by the suspicions of a colleague in the relevant department. In the context of witnessing fraudulent behaviour by a colleague, one should first try to assess whether this is likely to be deliberate or accidental. In the latter case, all that would be necessary would be to inform the colleague involved.

In the case of clearly deliberately fraudulent work, a letter could be sent to the editor of the journal in which the paper appeared which could later be published as an erratum, ideally with the consent of the offending author as a public admission of culpability. If it becomes clear that this is a pattern of behaviour and clearly negligent in nature, one would most likely wish to discuss the matter with an experienced colleague whom one trusts. If it seems that the matter should be pursued, the next step would be to initiate the institution's formal procedures or consult COPE for advice as to how to proceed. This is a particularly thorny issue for junior members of a team and could have serious personal consequences.

The 1998 Public Interest Disclosure Act gives whistleblowers the right to claim against wrongful dismissal, provided the correct procedures have been followed, but otherwise does not protect employment. A system where employment is protected under these circumstances would be difficult to implement owing to the intimacy of working relations in a research institution.

Guidelines and watchdogs

Kassirer[12] argues that lack of effective accountability and regulatory programs will result in draconian measures being instituted by governmental organisations which will limit our ability to perform research. He advocates adequate and stringent self regulation to rectify matters before responsibility is taken out of the hands of scientists.

The US moved in the 1980s to establish acceptability limits to medical research,[13] however it was thought that the prevalence of fraud and deceit in Britain was low enough not to require explicit guidance. Subsequent headline stories and other initiatives which produced the Uniform Requirements for Manuscripts Submitted to Biomedical Journals, commonly known as the Vancouver guidelines[14] led to the more recent establishment of COPE, founded in 1997 by editors of British biomedical journals, including those of the BMJ, Gut and the Lancet.[2]

COPE has five stated aims: (1) to advise on cases brought by editors; (2) to hold meetings and publish an annual report in which its members or invited speakers discuss current issues of publication ethics and describe cases brought to its attention; (3) to produce guidance on good practice; (4) to encourage research; (5) to offer teaching and training. It does not have a legal standing but aims to cause change by shaming the British establishment into mounting a proper response to inappropriate behaviour. Whether this will be successful is dubious; from the US experience Rennie[15] comments that a legal rather than scientific method is necessary to deal with fraud as scientists are not trained in conflict resolution. In an editorial in the British Medical Journal

(which had been affected by the Williams and Bowie case amongst others) Smith[16] stated that ''our experience with COPE makes it clear that once editors begin to pay serious attention to misconduct it is there before their eyes'', and called for a national body to oversee all scientific research. The same issue of the journal devoted several articles to the subject of research fraud, indicating the seriousness of the problem.

Research governance

Efforts to provide a national framework to monitor and regulate standards of behaviour by medical researchers has led to the establishment of Research Governance for NHS and joint projects with partners (http://www.doh.gov.uk/research/whatsnew.htm;). The governance framework was published by the Department of Health. This provides a register of research activity in each institution, sets out standards, delivery mechanisms, and monitoring arrangements. Research governance links in with mandatory submission to the Medical Research Ethics Committees.[17]

Conclusions

Fraud and deceit in medical research is of significant prevalence and potentially widespread. Its scale can range from what may seem like a relatively innocuous gift authorship for a head of department or senior colleague to wholesale fabrication of data. Through Research Governance, investigators must maintain vigilance to the dangers of deceit and fraud and should take reparative steps when necessary. Proof of serious misconduct is often difficult to establish without 'eye-witness' evidence as statistical tests cannot provide definitive proof in themselves. The research community should discourage the environment where publication at any cost is acceptable. Perhaps the principles of ethical behaviour should be introduced into the curricula of doctors and medical scientists.

Fraud, whether intentional or accidental, is deceitful and concealed so it will be difficult to predict whether the new guidelines and regulatory bodies will be effective; as in so many other area of life, the trust extended to authors will always be open to abuse.

Acknowledgement

This paper was originally submitted as an essay towards completion of the MSc course in Surgical Sciences at the Imperial College, London.

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