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Failure to Confront Research Fraud

R. Smith

Abstract: Fraud in medical research makes researchers and their institutions feel extremely uncomfortable. Everybody would like to think that it never happens and that if it does happen it is extremely rare and usually caused by some sort of mental illness in the researcher who commits the fraud. Unfortunately, growing evidence shows not only that it does happen, perhaps commonly, but also that the scientific community is poor at both preventing and managing misconduct.

The idea of research fraud causes even more discomfort than financial fraud because we like to believe that scientists have a higher calling than financiers and also that science is somehow objective, above human failing. But science is of course a human activity carried out by fallible human beings, and so research fraud is as inevitable as financial fraud. Indeed, it may be commoner than financial fraud because science operates on trust in a way that is not true of finance. If a researcher says that 50 patients were included in a study we do not ask to see names,

photos, and signatures – rather we assume that there were 50 patients. Similarly we see combined and analysed data not raw data – because we trust the researchers. It is thus easier for a researcher than a financier to deceive.

Kurzfassung: Das Versagen, dem Forschungsbetrug ins Auge zu sehen. Betrug in der medizinischen Forschung löst bei Forschern und deren Einrichtungen sehr großes Unbehagen aus. Jedermann möchte gerne glauben, dass er nie vorkommt und dass, falls es doch passiert, es ein extrem seltenes Ereignis ist und normalerweise durch die eine oder andere Art von Geisteskrankheit bei dem fälschenden Wissenschaftler hervorgerufen wurde. Unglücklicherweise beweist die steigende Anzahl von Fällen, dass Betrug nicht nur passiert, vielleicht sogar häufig, sondern dass die Scientific Community schlecht darin ist, dieses Fehlverhalten zu verhindern bzw. damit umzugehen.

Die Vorstellung von Betrug in der Forschung löst noch mehr Unbehagen aus als finanzieller

Betrug, da wir glauben möchten, dass Wissenschaftler eine höhere Berufung haben als Bankiers und auch, dass die Wissenschaft in gewisser Weise objektiv ist, über menschlichem Versagen steht. Aber die Wissenschaft ist selbstverständlich eine menschliche Aktivität und wird von fehlbaren Menschen durchgeführt, damit ist der Betrug in der Forschung so unvermeidbar wie in der Finanzwelt. Ja, er mag sogar noch häufiger vorkommen als der finanzielle Betrug, da die Wissenschaft auf Vertrauen aufbaut, das die Finanzwelt nicht genießt. Wenn ein Wissenschaftler behauptet, dass 50 Patienten in eine Studie eingeschlossen waren, fragen wir nicht deren Namen, Fotos und Unterschriften – wir gehen davon aus, dass 50 Patienten eingeschlossen waren. Ähnlich sehen wir kombinierte und analysierte Daten und keine Rohdaten – weil wir den Forschern vertrauen. Es ist somit für einen Forscher einfacher als für einen Bankier zu betrügen. **J Gastroenterol Hepatol Erkr 2009; 7 (3): 41–4.**

■ Defining Research Fraud

I should at this point probably stop using the phrase research fraud even though those new to the subject prefer it for its directness. Those who have an established interest in the subject prefer the phrase research misconduct – to avoid confusion with financial fraud, reflect the diversity of forms of misconduct, and acknowledge that some misconduct is relatively minor.

There has been something of an Atlantic divide in defining research misconduct. The Americans, who have more experience than anybody else with some shocking cases going back to the early 1970s, prefer an operational definition that potentially will allow researchers to know exactly what counts as misconduct. After various definitions the federal government in 2000 produced a comparatively short definition (only with long footnotes) together with requirements for a finding of misconduct [1]. The definition states:

“Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

Fabrication is making up data or results and recording or reporting them.

Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

Plagiarism is the appropriation of another person’s ideas, processes, results or words without giving appropriate credit.”

The definition continues by making clear that “research misconduct does not include honest error or differences of opinion”.

A finding of research misconduct depends on three requirements. Firstly, there must be “a significant departure from accepted practices of the relevant research community”. Secondly, the misconduct must be “committed intentionally or knowingly, or recklessly”. Thirdly, the allegations must be proved “by a preponderance of evidence”.

The Nordic countries and Britain have taken a different line from the Americans and opted for broad definitions [2, 3]. The Norwegian Committee on Scientific Dishonesty defines research misconduct as “all serious deviation from accepted ethical research practice in proposing, performing, and reporting research” [2]. A British consensus conference held in Edinburgh in 2000 went for something still broader: “Behaviour by a researcher, intentional or not, that falls short of good ethical and scientific standards” [3]. This definition includes nothing about falling “seriously” or “significantly” short of good standards and does not depend on intention.

The problem with the European definitions from an American point of view is that they do not allow researchers to know what is unacceptable, but – perhaps because I am a European – I think that the forms of misconduct are too varied to capture simply. Plus expectations change over time.

Let me use the example of appearing as the author of a scientific study when you have not actually participated in the study and may not even have read the final version of the submitted manuscript. It used to be routine for heads of department to do this – almost like countersigning a cheque – and still is in many cultures and institutions. We know from stud-

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ies that as many as a fifth of authors of scientific papers fall into this category [4], and yet for me and many others, particularly editors, this is research misconduct.

■ How Common Is Research Misconduct?

The frequency of research misconduct obviously depends on how it is defined, and it is hard to study because most cases are probably not publicised. They are simply not recognised, covered up altogether, or the guilty researcher is urged to retrain, move to another institution, or retire from research.

We do, however, have many high profile cases of research fraud dating back decades. In January 2006, for example, Seoul National University concluded that Hwang Woo-suk, a pioneer in stem cell research and a national hero in Korea, had fabricated much of his research. His claim in 2005 to have produced stem cells from adult cells had reverberated around the world because it opened up new ways to treat Parkinson's disease and other degenerative diseases. His disgrace was equally high profile, providing one of the most dramatic cases ever of scientific fraud.

This was one of the first cases to emerge from Korea or, indeed, East Asia, but the United States, which conducts far more research than any other country, has had a steady stream of cases since 1974 [5]. For example, William Summerlin from the Sloan-Kettering Institute in New York, one of the world's leading biomedical research centres, claimed to have transplanted human corneas into rabbits. He also faked transplantation experiments in white mice by blackening patches of their skin with a pen, an extraordinarily crude form of forgery. Eventually, Summerlin's misconduct could no longer be ignored, but his behaviour was attributed to a mental health problem. This is a response that is seen repeatedly. It is a form of scientific denial.

John Darsee worked in the department of cardiology at Harvard and was observed falsifying data. His boss, Eugene Braunwald, an eminent cardiologist, decided that this misconduct was an isolated incident and so did not fire him. A few months later, however, it became clear that results he had obtained in a study being conducted in several places were very different from those of the others. An investigation was started and went back to when he was an undergraduate. Many of his more than a 100 studies proved to be fraudulent and had to be retracted.

Britain has had perhaps 50 cases, and the most celebrated is that of Malcolm Pearce, an obstetrician and gynaecologist with an international reputation from his work on ultrasonography [6]. He published a case report in the August 1994 issue of the *British Journal of Obstetrics and Gynaecology* that described an ectopic pregnancy being reimplanted into the womb and a baby being born [7]. This was something doctors had been trying to do for decades, and the case received worldwide publicity. Unfortunately, the patient did not exist. Equally unfortunately, another author on the paper was Geoffrey Chamberlain, the editor of the journal, the head of Pearce's department, and the president of the Royal College

of Obstetricians and Gynaecologists. He was a "guest author", and the mistake cost him his reputation and career.

Pearce was the author of a second paper in that same issue of the journal that described a trial of treating recurrent miscarriage in nearly 200 women with polycystic ovary syndrome [8]. This too proved to be fraudulent – as did several other studies that Pearce had published in various journals, including the *BMJ*.

Germany has had some high-profile cases of misconduct, and Austrian authorities are investigating a study published in *The Lancet*.

I have spoken perhaps a dozen times on research misconduct in several countries and often to audiences where people come from many countries. I usually ask the members of these audiences how many know of a case of misconduct (I consciously do not offer a definition). Usually, half to two thirds of the audience put up their hands. I then ask whether those cases were fully investigated, people punished if necessary, lessons learnt, and the published record corrected. Hardly any hands go up.

Stephen Lock, my predecessor as editor of the *BMJ* who became interested in research misconduct in the 1980s, long before most people in Britain, got a similar result from a postal survey he did of friends who were professors of medicine [9].

These "cover-ups" explain why it is so hard to get good data on the prevalence of serious research misconduct, but some countries and disciplines have more cases not, I suspect, because misconduct is commoner but because they have begun to face up to the problem.

Nicholas H. Steneck, one of the world's leading authorities on research misconduct and a consultant to the Office of Research Integrity in the US, estimates from a series of studies that we might expect to see one case of serious misconduct a year for every 1000 researchers. He uses a more conservative estimate of one case for every 10,000 researchers and then calculates that the US would thus see about 1500 cases a year and the European Union about 1000. In fact, the US records about 20 cases a year and the European Union 10. So cases are not being identified or reported.

As some support for this thinking, I have been involved with exploring the work of two researchers – R. B. Singh from India and R. K. Chandra from Canada – who between them have published dozens of trials about which the most serious questions have been raised [10–17]. We do not know for sure how many of their studies may have serious deficiencies, but many people suspect that it is dozens. Yet all but two of these studies remain in PubMed without any indication of these doubts.

■ „Questionable Research Practices“

Steneck and others have come to believe that the body of research may be more damaged by „questionable research practices“ than by fabrication, falsification, and plagiarism – because these practices seem to be common and may systematically distort the scientific record.

Important evidence on the level of “questionable research practices” comes from a US study in which the researchers surveyed 7760 researchers funded by the National Institutes of Health about a range of practices [18, 19]. Some 3247 responded (42 % response rate), and 0.3 % admitted having committed a major offence. But many more had been guilty of “questionable research practices”. A quarter, for example, had misused data in some way by either falsifying them, dropping observations because of a gut feeling that they were inaccurate, overlooking other’s use of flawed data, or failing to present data that contradicted their research. Around 16 % had abused the academic credit system by using another person’s work without giving credit, publishing the same study more than once, inappropriately assigning authorship, or getting by on the work of others. From other types of studies we know that around 40 % of authors do not meet the criteria for authorship of the International Committee of Medical Journal Editors and that around a fifth have not even taken part in the research [4]. We know, too, that around a fifth of studies are published more than once [20].

The US survey looked at a wide range of “questionable research practices”, but particularly disturbing was the high percentage (40 %) who had succumbed to outside influence, including failing to declare involvement of firms whose products were based on their research or changing the design, methodology, or results of a study in response to pressure from a funding source. These results fit with studies showing that the majority of US researchers have conflicts of interest and that until recently most were not disclosed [21]. Unfortunately we have expanding evidence that conflicts of interest have a profound effect on studies: for example, clinical trials funded by industry are at least four times more likely to get results favourable to the sponsor than studies publicly funded [21].

The anxiety that medical research may be seriously corrupted by financial influence is reaching a crescendo in the US, where several professors of psychiatry have had to step down after failing to disclose having received large sums of money from pharmaceutical companies. There is a worry that much of the research on new antidepressants and antipsychotic drugs may be seriously misleading, suggesting that these drugs have a much more positive balance of benefit against harm than is truly the case.

In April 2009, the Institute of Medicine published a report on conflicts of interest in medicine and saw considerable evidence of harm [22]. “It is time to end a number of long-accepted practices that create unacceptable conflicts of interest, threaten the integrity of the medical profession, and erode public trust while providing no meaningful benefits to patients or society”, said Bernard Lo, the chair of the committee that produced the report.

■ Responding to Research Misconduct

The evidence is strong, I judge, that these “questionable research practices” may cause even more damage to medical research than the major problems of falsification, fabrication, and plagiarism, but at the same time it seems likely that we are

failing to respond adequately to the major problems. When my predecessor as editor of the *BMJ*, Stephen Lock, became concerned about research misconduct in the early 1980s, many people, including me, thought that he was making too much fuss about a minor problem. Now it looks as if even he did not grasp the full extent of the problem, and the response in most countries has been wholly inadequate. The fear must be that if researchers do not do a better job of regulating themselves then politicians will step in. This has already happened in the US despite it having a better response than perhaps any other country.

Rather as advocated by Alcoholics Anonymous, a response to a problem must begin with its recognition. The subsequent 11 steps to conquering alcohol are of no use to alcoholics if they cannot take the first step of admitting that they are powerless over alcohol, and similarly no country can mount an adequate response unless it accepts the reality and inevitability of research misconduct. Many alcoholics never manage the first step even though they think that they have, and similarly, I believe, many countries never manage the first step – because recognising research misconduct is too painful.

I know Britain best, and, although we have the UK Panel on Research Integrity in Health and Biomedical Sciences (of which I am a member), I am unconvinced that we have truly taken the first step. The UK panel has the legal status of a “cricket club” and can operate only by persuasion.

A full response to the problem of research misconduct does require a national body to provide leadership. It needs to raise consciousness about the problem, provide guidelines on good practice, encourage research and teaching, offer help with investigations of misconduct, and probably provide a place for whistleblowers to report anxieties and for the hearing of major cases or appeals against local judgements. One problem with local bodies – universities or hospitals – dealing with cases is that they often lack competence and sometimes commitment. They also face a deep conflict of interest in that they fear that openly investigating and reporting a case will damage the institution.

The main emphasis in responding to the problem of misconduct should be on raising the overall level of scientific integrity rather than on investigating suspected cases – although there have to be good systems for investigating, judging, and reporting cases. We need codes of good practice rather than simply lists of bad practices to be avoided, and we need to teach integrity rather than warn against dishonesty.

Once their consciousness is raised researchers will realise that they are constantly presented with ethically difficult questions around analysis of data, authorship, conflict of interest, informed consent, and a dozen other issues. There are usually not “right” answers that can be read from a rulebook. Rather researchers need to be able to think their way through the complexities to reach an ethically defensible answer. They may often need help and should not be afraid to ask for it.

This article contains material already published by Richard Smith in his book, *The Trouble with Medical Journals* [23], and in an article in the *Journal of the Royal Society of Medicine* [24].

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