Fraud in medical research

Stephen Lock

Introduction

With fraud and sleaze so visible all over the world in politics, finance and public life, finding that these also exist in medical research should come as no surprise. Yet it does, and medical scientists still react as if a case were unique. And they manage it so badly, with the whistleblower often more penalised than the miscreant.[1] Seemingly, fraud has a brief history. I argue that scientists should be aware of the problem, try to deal fairly with any suspected case on well-recognised lines and, crucially, aim at preventing it by following good standards of research practice.

A brief historical account

Most accounts of fraud start in 1974, when William Summerlin purported to show that skin taken from a black mouse could be transplanted into a white one. In fact, Summerlin had used a black-tip felt pen to colour in an ordinary graft of white skin.[2]

Nevertheless, fraud has probably always been a feature of scientific work. Some commentators have even accused workers as distinguished as Newton, Mendel and Pasteur of fudging their results[3], while the fact that fraud has featured in at least four novels (from Dorothy L. Sayers' *Gaudy Night* [1936] to Carl Djerassi's *Cantor's Dilemma* [1989]), suggests that at the very least it has always been part of the tittle-tattle of senior common rooms.

Definition

Should the term be confined to the acknowledged major categories - forgery (the invention of data), plagiarism (stealing the data of others), and piracy (stealing ideas) - or should it include other abuses such as gift authorship, undeclared conflicts of interest and multiple publication? Some - especially the Nordic countries - see the topic as a spectrum (or a slippery slope) of practices and prefer to talk about 'scientific dishonesty' rather than fraud or misconduct, given that there is still no internationally agreed term for the abuse.

In the USA, the central body, first the Office of Scientific Integrity (OSI), now the Office of Research Integrity (ORI), wrestled with the problem of definition. Its original statement was unexceptionable until its latter part, which clever defence lawyers could (and did) drive a coach and horses through. This spoke of 'other practices that seriously deviate from those that are commonly accepted within the scientific community'. What, in particular, were those practices? Did they include, for example, sexual harassment of the supervised by the supervisor? For this reason the ORI set up a special commission to produce a special definition. To many of us the result was a great improvement on the old one, defining misconduct as 'significant misbehaviour that improperly appropriates the intellectual property or contribution of others, that intentionally impedes the progress of research, or that risks corrupting the scientific record or compromising the integrity of scientific practices'. But the US government rejected this new proposal and hence currently we are stuck with the old one or variations on the theme.

Extent of fraud

The next question - and one that is inevitably raised - is how prevalent is fraud in research? Almost certainly, the cases in the public domain are the tip of an iceberg, but any higher estimates are also likely to be inaccurate. These are derived from two sources: first, surveys of academics for their private knowledge of possible, probable or definite cases and, second, audits of research projects. The first show that anything between a quarter and a half of medical research workers have come across one or more cases, and the second that around 0.25% of research projects are tainted. Furthermore, the list of cases published each quarter by the ORI for one aspect of research alone - that funded by the US National Institutes of Health (NIH) - shows that in each period a consistent five or six scientists are being found guilty of malpractice. The background to such cases has usually been prestigious; few of these are lowly workers doing research in minor institutions on mundane topics; instead, the last have 'comprised the usual range of disciplines and particularly 'hot' fast-moving subjects such as molecular biology, immunology and cancer research. Thus, despite all the publicity, clearly some scientists think that they can get away with fraud. (And perhaps many of them do; we just don't know.)

Causes of fraud

Of the six causes of fraud usually quoted, the first is the pressure on scientists for large-scale publication of positive results to obtain research grants, tenure and promotion. Second comes greed: in some drug trials, particularly, pharmaceutical firms have paid £750 or even more for every patient enrolled into a study, and the temptation to invent data for non-existent patients has overwhelmed some less-than-honest doctors. The third cause is vanity - the desire to keep in the swim - and the fourth, though rare, frank mental illness. The fifth is deviancy. As Nobel Laureate Sir Peter Medawar pointed out, every section of the community has a small proportion of crooks and there is no reason why research should be any different.[4]

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Nevertheless, the most important is what Medawar called the 'Messianic complex'. In this, the scientist's own conviction that he knows the cause of schizophrenia or cancer overwhelms the normal imperative to do research and obtain the data - which he (and it has usually been a he) then proceeds to invent. This seems to be the reason for the prominent Australian obstetrician, William McBride, falsifying data showing that emetics given to pregnant animals were teratogenic: one of the first to describe the harm thalidomide did to the human foetus. McBride became convinced that most, if not all drugs, had a similar effect under similar circumstances[3].

Corrective *steps*

The official approach to misconduct has varied- according to the country. The phase of shock/horror/denial was succeeded, initially in the USA, by a flurry of reports and recommendations ` from the professional bodies, and eventually, after a series of Congressional hearings, by the formation of the OSI. Despite some success, however, this was perceived as ineffectual and liable to frequent legal challenge, and only two years after its creation, it was superseded in May 1992 by the ORI. This reports to a different government department, has a different method of working, and, crucially, sees prevention as equally important as dealing with established cases reported to it (as required for any institution funded by the NIH). Thus it holds regular courses on the ethics of good scientific research, such as the recording and storage of data, the need for regular presentation and audit of data, and good publication practices (including a policy on who is and who is not an author in any individual case).

Such preventive measures are also a feature of the special organisations in the four Nordic countries. Each of these has a central committee on scientific dishonesty, which sees its role as much as for maintaining a high profile for good research practice as for advising on sanctions and instigating investigations with 'due process' - the American term covering speed, confidentiality and respect for the rights of the accused and particularly of the whistle-blower.

The USA, the Nordic countries and Austria are unique in having permanent committees devoted to the problem. Other countries - including Australia, Canada and Britain - have produced official reports but have done little to implement them in the way of establishing tangible and long-lasting procedures. Britain, in particular, has relied on its General Medical Council (GMC) to discipline its doctors found guilty of research fraud. The Council has considered the cases of over a dozen general practitioners (though only 'two consultants), mostly involved in forging data on multi-centre drug trials. They have been admonished, suspended from practice or had their names removed from the medical register altogether. Though such sanctions are severe, the procedure for bringing a case before the GMC is elaborate, while the fact that the case is heard in public on the adversarial basis of English law is enough to deter all but the most committed whistleblower.

Nevertheless, it would be unfortunate if whistleblowers were discouraged from carrying out their moral duty in bringing any legitimate suspicions to official notice. After all, most cases have come to light in this way (with a very few also being disclosed by editorial peer review - though we know that this cannot be relied upon to detect fraudulent work). The OR1 commission, which reported on the definition of fraud, also recommended that the whistleblower's bill of rights should be introduced, similar to that already in operation for Civil Services disclosures.

Lesson for research workers

They should practice research ethics, not only for their intrinsic goodness but also as an example to others. They should report suspicious conduct to the appropriate authority, insisting that any suspicions be followed to a satisfactory closure. They should ensure that whistleblowers who raise any questions in good faith are not penalised in any way. They should believe that however rare, misconduct may occur in their own laboratories and that rather than brushing allegations under the carpet, a full and fair inquiry must eventuate.

Those countries that do not have a central committee on research misconduct are, in my view, considerably disadvantaged. Apart from disclosing a cowardice that is usually alien to science, such countries lack several important features of the scientific life: the high profile which a committee gives to good scientific practice (including holding regular courses for trainee researchers); a method for giving the advice and support that both whistleblowers and local investigating committees need; and a mechanism for collating all the cases in any years, monitoring the action taken and enshrining the details in an annual published report.

Finally, of course, by no means all medical fraud is committed by doctors - in which case, other disciplinary mechanisms will have to be devised. At present this is largely limited to dismissal of a non-medical researcher by an employer, but with a code of sanctions laid down by a central body, this would become easier and fairer.

Difficulties there are bound to be, to be sure, in creating some sort of statutory authority which yet has a sure but light-handed touch. But in failing to do so - and, worse, in pretending that either the problem does not exist or can be dealt with on the old-boy network - any establishment is not only selling short its scientific community but also its population in general, who, through their taxes and contributions to charity, are the true paymasters.

Thus, India, which has a notable tradition of scientific research, should consider what mechanism(s) would best suit its own circumstances. A preliminary attempt might be, as has recently happened in Britain, for funding bodies to give research grants only if they are assured that the

institution has in place a mechanism for handling whistleblowers complaints with due process.

Note: Most of this text originally appeared as an editorial in *Nursing Times Research* 1997;2: 16 1- 163.

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Suggested additional reading

Broad W, Wade N: ***Betrayers of truth. New*** York: Simon & Schuster, ***1982.***

ORI Reports. Available from the Office of Research Integrity, Rockville, Maryland 20852, USA.

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