Research misconduct: can Australia learn from the UK's stuttering system?

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ABSTRACT

- Research and publication misconduct is commoner than many believe, hard to detect and difficult to investigate, with institutions often being reluctant to take action.
- The first countries to set up formal systems for policing research misconduct were the United States and some Scandinavian countries.
- The US Office of Research Integrity (ORI) is a useful model for other countries; rather than conduct investigations, the ORI supervises the investigation by the respondent's institution.
- The United Kingdom has taken more than 10 years to set up a national supervisory body — the UK Panel for Research Integrity in Health and Biomedical Sciences. Unlike the ORI, it has no statutory basis. It is too early to tell whether the procedures set up in the UK will work.
- The present trend for governments to encourage universities to link up with industry may lead to a culture of secrecy and confused accountability.
- In any country, including Australia, intent on policing research, it is only possible for editors, reviewers or readers to initiate investigations, not undertake them, as power lies in the hands of employers, research funders and regulatory bodies.

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Throughout the 1940s, the eminent British botanist John William Heslop Harrison made his reputation by developing a theory that, contrary to accepted belief, plant species of certain islands off the coast of Scotland had survived the last ice age. Because of rumours circulating in academic herbaria and arboreta, a Cambridge scientist, John Raven, undertook an investigation. His thorough (and damning) report was deposited in the library of Trinity College, Cambridge in 1954, but never published. In 1980, 17 years after Raven died, the science writer Karl Sabbagh gained access to the report and revealed — after 50 years of gossip and whispers — the true extent of Harrison's fraudulent activity, namely secretly planting Swiss alpine plants in remote valleys on the island of Rùm and then allowing his research student to "discover" them.[1]

In 2005, Jon Sudbø, a researcher at the Radium Hospital in Oslo, Norway, was lead author of a study published in the *Lancet* that concluded that long-term use of non-steroidal anti-inflammatory drugs (NSAIDs) was associated with a reduced risk of oral cancer. Eight months later, after learning of doubts about the existence of many of the patients described, the *Lancet* published an "expression of concern" and, in January 2006, when the hospital confirmed the allegations, a retraction of the article.[2] Currently, an independent review commission chaired by Anders Ekbom from the Karolinska Institute in Sweden is investigating the research underlying 38 previous publications by Sudbø dating back to 1997, having secured all the available data.

In between the quiet burying of botanical transplants and the immediate effective action of Norwegian oncologists, an army of fraudsters, plagiarists, and data manipulators have gone about their business, largely unscathed. They have been joined by battalions of gift and ghost authors, and often left undisturbed by trusting, naïve, overstretched or acquiescent editors, while academic and research institutions have fallen over themselves not to get involved.

By virtue of the underhand methods used by these miscreants, there are no reliable quantitative data on the frequency of scientific misconduct. Some disturbing statistics were uncovered in a recent survey of scientists in the United States: a third admitted to engaging in one or more types of unethical research behaviour, and 15.5% admitted to changing trial design, methodology and results in response to pressure from research funders.[3]

In the United Kingdom, the issue of research misconduct began to be treated seriously in the late 1980s, after investigations by the Royal College of Physicians of London and the Association of the British Pharmaceutical Industry.[4,5] The Association collected the evidence required for 16 doctors, mostly general practitioners, to be found guilty by the General Medical Council of serious professional misconduct. Most cases involved insertion of fraudulent data in drug trials, in which doctors were paid a fee for recruiting, supervising and documenting the patients concerned. In general, these cases did not shift the opinions of many doctors in the UK, who adhered to the "bad apple" theory or were incredulous when they were apprised of what was alleged.[6]

The turning point came with the case of Malcolm Pearce, a senior lecturer in obstetrics and gynaecology at St George's Hospital Medical School, London, who in 1994 had two articles published in the *British Journal of Obstetrics and Gynaecology* (of which he was an assistant editor) describing work that was entirely fictitious. He claimed to have reimplanted, successfully, an embryo from an ectopic pregnancy, and to have conducted a trial of treating recurrent miscarriage in polycystic ovary syndrome.[7] He was exposed by a whistleblower at the medical school and erased from the medical register by the General Medical Council within the space of 9 months. The affair was investigated by his university and the journal owners, but the prevailing ambience of clinical research was such that an editorial in the *British Medical Journal* noted sardonically: "In most other medical institutions in Britain nothing would have happened; the affair would have been brushed under the carpet and the whistleblower would probably have been hounded out of her job."[8]

In 1997, a group of frustrated journal editors set up the Committee on Publication Ethics (COPE) as a discussion forum to determine the best methods of dealing with publication misconduct (Box).

At about the same time, the Royal College of Physicians of London called a meeting with a view to setting up a central investigative body. Richard Smith, the editor of the *BMJ* who attended the meeting, described representatives of the Royal Society, the Medical Research Council and the General Medical Council as "scornful of the proposal", and the initiative stalled.[10] In contrast, by this time the US had passed legislation regarding the

The Committee on Publication Ethics (COPE)

- COPE has over 300 members (including eight whose journal title includes "Australian" or "Australasian"), the majority from Europe, who agree to abide by COPE's code of conduct
- Its guidelines, code of conduct for editors and a repository of all cases discussed to date can be found at: http://www.publicationethics.org.uk
- Recent analyses of the first 79 cases where there was prima facie evidence of misconduct showed:[9]
  - In 23 cases (29%) the author's explanation was not accepted and his or her institution was contacted
  - Forty cases (50%) took more than a year to resolve
  - In four of 11 cases where dangerous treatment or lack of patient consent was suspected, neither employer nor regulatory body took action ◆

conduct of research sponsored by the US Public Health Service and had defined what it meant by misconduct — namely fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. Honest error or honest differences in interpretation or judgements of data were not included. The Office of Scientific (later Research) Integrity (ORI) was set up to supervise and ensure compliance by institutions where research was conducted.

At that time, four other countries had proposed or were operating a formal system for tackling research misconduct: Denmark, Norway, Finland and Austria.

The UK Panel for Research Integrity in Health and Biomedical Sciences and the UK Research Integrity Office (UKRIO) were finally established in March 2006, with support from the government, the National Health Service Executive, the major research councils, the universities, the General Medical Council, the Royal Society, and a raft of other stakeholders — including COPE. Unlike the ORI, UKRIO has no statutory basis, so it will have to work by consensus and agreement. Its remit is to develop a code of good conduct, including robust case-handling systems; to set up a register of expert advisers available to investigating bodies (generally employers or funders); and to maintain frequency data on cases. It will also provide an ear for whistleblowers and offer training in research integrity. UKRIO estimates its annual running costs at £250 000 (AU$627 000). At its launch, the chairman, Sir Ian Kennedy (an Australian expatriate), said:

> The issue has not been taken seriously enough. There has been a theory that researchers are generally good chaps who couldn't possibly do anything improper and a sense that all is well. But that degree of complacency fails to take into account the pressure of academic life, where the rewards for making breakthroughs and getting published bring real pressures.[11]

UKRIO's lack of mandatory powers has disappointed some, as success will depend on the enthusiasm and willingness of all stakeholders. In many cases their past record does not give cause for hope. However, in the past 5 years there has been a greater emphasis on clinical governance in the UK, so the same may prove true of academic governance. Fallout from a series of medical scandals has produced a clear chain of command within the National Health Service (which employs most of the UK's doctors) and, when suspicious that a colleague's or employee's fitness to practise may be impaired, failure to take appropriate action can lead to disciplinary procedures. The General Medical Council has made it clear what is expected of researchers, starting with an injunction that all research must be conducted with honesty and integrity, and that protecting study participants' interests must always come first.[12]

It is essential that those enjoined with the task of investigation do so in a way that is fair, thorough and transparent. In Scandinavia, national investigative bodies have been set up. The Danish Committees on Scientific Dishonesty (DCSD) consist of eight-member committees chaired by a High Court judge sitting with seven senior medical researchers. Denmark is not a large country and, in 2004, only 11 cases were reported, with one found proved. In line with that country's principle of resocialising the guilty, the DCSD does not publish the names of those on whom it has made findings. Decisions can be appealed to the Danish Agency for Science, Technology and Innovation. Its annual reports (with English translation) are available online.[13] Similar national committees operate in Norway, Sweden and Finland.

For larger countries, the US model may be more acceptable, with procedures based on those tried and tested by the ORI[14] and the National Science Foundation (the latter being responsible for US federal funding of non-medical scientific research). Rather than conduct investigations, the ORI supervises processes carried out by the respondent's institution. In summary, the regulations require that each institution appoints a research integrity officer to supervise the process. Respondents are shown allegations at the earliest stage and have the opportunity to respond by presenting evidence at a preliminary inquiry. The inquiry team must obtain all necessary records, and its members must have no competing interests and have appropriate expertise. The aim is not to determine whether there has been misconduct, but rather to summarise the evidence and determine whether a full investigation is needed — all within 60 days. The respondent can review and comment on the draft report and, at most institutions, may be legally represented throughout.

If the first report recommends a full inquiry, it is conducted by three independent experts, with the respondent having the right to object to any of those appointed. All evidence is recorded and the final report submitted to the ORI together with any comments from the accuser and respondent, as well as details of the sanction or administrative action recommended.

If found not guilty, the institution must act to restore the respondent's reputation, while whistleblowers are protected, provided their allegations were made in good faith. The regulations include advice on confidentiality and on how widely the final report should be distributed. During the early stages, confidentiality is the norm unless patient care or public health dictates otherwise. However, the ORI publicises widely the names of those found guilty, although the National Science Foundation does not include names in its reports. There is, of course, an appeals process. The obvious disadvantage is that the ORI has no aegis when federal funds are not involved.

The importance of this due process cannot be overestimated. In the past, many inquiries in different countries have fallen into a quagmire of legal argument and institutional confusion. Loopholes, such as resigning, retiring or making secret agreements with employers to avoid a full investigation, must not be allowed.

Any system can be subverted. Some university authorities may continue to feel that it is in their best interests not to pursue allegations, thus increasing the need to keep up public, profes-

sional and, vitally, editorial pressure. The media have a role in reminding citizens that what goes on in university research departments is everyone's business. Sudbø's papers could have led unsuspecting clinicians to prescribe NSAIDs unnecessarily, which may have caused harm. The discredited Canadian nutritionist RK Chandra's flawed work might have resulted in babies being fed an inappropriate formula, or older people spending their diminishing capital on unnecessary supplements.[15]

Will the UK procedures work? It is obviously far too early to know, as UKRIO is only at the stage of defining its functions. One person who is probably sceptical is the UK's most prolific whistleblower on misconduct by clinicians and researchers, cardiologist Peter Wilmshurst. The introduction to his recent discussion piece in the *BMJ* talks of "corruption at a senior level in academic institutions".[16] Readers of the *MJA* will have to find the paper version in their libraries, as the electronic version has been replaced on the *BMJ*'s website (http://bmj.bmjjournals.com/cgi/content/full/325/7374/1232) with the bald statement that it has been removed for legal reasons. His article was not about pharmaceutical companies, but others are concerned about the enormous pressures placed on universities by governments to link up with industry, which may be leading to a culture of secrecy and confused accountability, as scientists work on industry projects in university laboratories.[17] There are also risks of being at the wrong end of employment or defamation legislation.

One saga involving more than its fair share of problems is that of Aubrey Blumsohn, previously senior lecturer at Sheffield University in the UK. He pursued a long dispute with his employer, with the pharmaceutical company Procter & Gamble, and with the editor of the *Journal of Bone and Mineral Research* over his contention that certain published clinical trial data are misleading. After 2 years of campaigning, during which he was suspended from his post, the journal published a statement of concern on its website about the data analysis of research findings on the osteoporosis drug risedronate, the subject of Dr Blumsohn's campaign.[18] In his response to an inquiry from the Council for Academic Freedom and Academic Standards as to why the case had not been referred to UKRIO, the vice-chancellor of Sheffield University stated that the university welcomed that body, but added, "However, it is our understanding that the remit of this panel will not be to investigate specific misconduct allegations."[19]

Therein lies the problem for any country, including Australia, intent on policing research. As things stand, editors (and reviewers and readers) can only initiate investigations, not undertake them.[20] Power lies in the hands of employers, research funders or regulatory bodies. All may find reasons, cogent or dubious, as to why they should not investigate a particular complaint. Supervisory bodies along the lines of UKRIO, without statutory authority, can only apply moral authority. Time will tell if this is sufficient. If it is not, then it might prove necessary to protect science by resorting to criminal proceedings. Once again, the US is in the vanguard: in June 2006, Eric Poehlman, a tenured researcher at the University of Vermont pleaded guilty before the US District Court in Burlington to lying on a federal grant application. He admitted to fabricating scientific data on obesity, menopause and ageing, over a period of 10 years. The Court handed down a sentence of 1 year and 1 day in federal prison followed by 2 years' probation.[21]

Competing interests

I am Chair of the Committee on Publication Ethics, a member of the board of the UK Panel for Research Integrity in Health and Biomedical Science and an associate (Chair of Fitness to Practise Panels) of the General Medical Council. None of these bodies has been involved in this submission and the views expressed here are entirely my own. I have received speaker fees and/or educational grants and travel assistance to attend meetings addressing research integrity from academic and governmental institutions.

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