

Research fraud — where to from here?

Given the nexus between published research, medical practice and public health policy, the veracity of published medical research is vital. Melbourne newspaper *The Age* recently reported on an “explosion of medical research fraud” (12 May 2011), and Myburgh's editorial in this issue of the Journal (*page 621*) examines a specific incident of fraud.

Trust in the ethical behaviour of researchers is the cornerstone of medical science and publication. The Guideline for Good Clinical Practice, to which Australia adheres, provides some regulation but not enough to protect against fraud.

It is up to medical journals to take a primary role in the prevention of research fraud, and many already have policies in place. These include requirements for ethics approval and registration of all trials before publication will even be considered. Authors should state their contribution to the study and manuscript and must declare all financial conflicts of interest. Finally, articles must be skilfully peer reviewed before publication. Despite all this, as described in Myburgh's editorial, it is clear that current policies are inadequate and we must ask — what else can be done?

The role of thorough audits is well established to improve regulation by funding bodies and ethics committees.

There is a push to make raw trial data available to reviewers and readers. Already, some agencies such as the United States Food and Drug Administration mandate that raw data be made available to them for their own independent analysis.

In principle, making raw datasets available at or before the time of publication has many potential advantages, with deterrence of fraud being only one important benefit. Facilitating data sharing among researchers, allowing other researchers and peer reviewers to test

published conclusions, testing of secondary hypotheses, simplifying data acquisition for meta-analyses, and preventing selective reporting are all important advantages. It may even reduce unnecessary research duplication and facilitate research progress.

In comparison, the case against the publication of raw datasets seems flimsy. Issues of confidentiality are easily overcome, and issues of data dredging and invalid analyses are no different to those already confronted by ethics committees and the peer-review process.

However, the practical difficulties of data sharing cannot be understated. The vast quantity of data collected in large clinical trials would require the provision of the data dictionary and statistical code to make the data intelligible. Further, it is unlikely that peer reviewers would be able to make sense of the data in a timely way.

But practical issues are not the only obstacle. Clearly, there is resistance to the publication of raw data; researchers have a natural tendency to view the collected data as their own. However, there is a compelling argument to maximise the utility of data collected when research has been funded by the public purse. The Wellcome Trust has already stated its aspiration to share data (*BMJ* 2011; 342: d2323).

For now, however, to prevent research fraud, we need to ensure that we seek out smart, proactive peer reviewers, and the research community needs to ensure that audits are carried out so that history does not repeat itself and researchers are called to account early in their careers. Change is inevitable, but what shape it takes is yet to be defined.

Annette Kataris

Editor, *Medical Journal of Australia*
akataris@ampco.com.au