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Title:
Australia needs an Ombudsman or Office for Research Integrity

Date:
2016-10-01

Citation:
Brooks, P. M., Vaux, D. L. & Williamson, R. (2016). Australia needs an Ombudsman or Office for Research Integrity. Internal Medicine Journal, 46 (10), pp.1233-1235. https://doi.org/10.1111/imj.13211.

Persistent Link:
https://hdl.handle.net/11343/291791

Australia needs an Ombudsman or Office for Research Integrity

We are greatly encouraged by Kerry Breen's important article, "Research misconduct: time for a re-think?" and suggest that all those interested in the future of health research in Australia consider it.[1] As Dr Breen points out, at present Australia lacks a national body, such as an Office of Research Integrity, to promote responsible research conduct and manage allegations of misconduct. Instead, cases are handled by host institutions that typically lack experience and suffer from conflicts of interest when investigating their own staff.

This is particularly important, because it is not just the reputation of the institution and the accused person that is at stake; research misconduct can threaten the careers of students and other researchers, waste scarce funding resources (usually from the public purse), delay life-saving discoveries, and directly threaten the safety of patients in clinical trials and the welfare of experimental animals.

For all of those taking part, whether it is the panel members, the whistle-blower, or the person accused, a research integrity investigation is one of the most unpleasant situations people will experience. It is stressful, difficult, time-consuming and thankless, and in Australia there is little guidance or support for any of the participants, for most of whom it will be their first and (hopefully) only experience. Unless those involved are indemnified, they also risk legal suits from disgruntled protagonists, yet once lawyers become involved, costs spiral.

There are growing numbers of examples where the governance of medical research has gone badly wrong. In the US, anaesthetist Scott Reuben was found to have faked data in 25 studies. In 2009 he was sentenced to prison. The editor of the journal Anesthesia & Analgesia, Paul White, said Reuben's studies affected the way millions of people were treated for pain during and after orthopaedic surgery, and led to the sale of billions of dollars worth of the COX2 inhibitors celecoxib and rofecoxib for applications whose benefits/risks are now in question.[2]

In France, the trial of the drug BIA 10-2474 led to the death of one volunteer and the hospitalization of five others. After the first volunteer was hospitalized with headaches and blurred vision, the other participants were not informed, but were given another dose of the drug. The critical mistake was the failure to inform participants in the trial that one of the volunteers had suffered severe side effects. Because they were not fully informed, they could not re-assess their willingness to continue.[3] As outlined in the Declaration of Helsinki, providing informed consent is a cornerstone of ethics in clinical trials, and yet the governance of human research ethics is even weaker in Australia than in France prior to the Biotrial disaster.

In one Australian clinical trial, where there was an ongoing independent investigation into *prima facie* evidence that the preclinical data had been falsified, and concerns about patient safety were raised, the trial was not suspended pending the outcome of

the investigation, and none of the patients were informed at any stage. When concerns were raised about patient safety with the NHMRC, these were referred to the "Business Support Branch", which provided assurances that "the NHMRC is monitoring the situation" and "the NHMRC takes its responsibilities for the development of ethical standards relating to the conduct of research extremely seriously," but there was no evidence of any action, such as halting the trial pending the outcome of the ongoing research integrity investigation.

According to Professor Ian Olver, Chair of the Australian Health Ethics Committee (AHEC), this NHMRC committee has no regulatory role, and can only provide guidance of a general nature. It does not provide advice on specific matters relating to decisions taken by individual ethics committees, or decisions taken by individuals at particular research institutions.

As Breen says, the role of the Australian Research Integrity Committee (ARIC) is also limited. It can only review whether an institution has followed the procedures laid down in the Australian Code for the Responsible Conduct of Research. It cannot consider the merits of a case, or take rapid (potentially life-saving) action, because it will not consider cases while institutional processes are still underway.

A national body, such as the Office of Research Integrity in the United States, the Research Integrity Office in the UK, or the LOWI in the Netherlands would not be a panacea, but could fulfil several functions. It could provide advice to whistle-blowers, institutions, and those accused; offer education and training; collect data; update the Australian Code for the Responsible Conduct of Research; keep lists of experienced, independent investigators and panel members; provide oversight; provide an avenue for appeal; and ensure that the literature is corrected.

The integrity of research conduct is the cornerstone of good research practice. The recent Lancet Commission on waste in medical research[4] highlights some of the issues relating to reproducibility of research results and the importance of transparency of data collection and evaluation. In the discipline of medicine we have made great strides with the issue of patient safety through careful development of quality systems, checklists and protocols. Similarly, we need to ensure that ALL researchers ensure that the integrity of data is the best it can be, collected appropriately, transformed carefully to ensure no manipulation, interrogated carefully and transparently and subject to internal and external audit if required.

We must ensure this level of integrity if we are to maintain our confidence in medical research, and to continue to use research as the basis for change in practice. Australia needs a national office or ombudsman with overarching responsibility for issues related to research integrity. Such a body would support institutional governance, enhance reproducibility and hence efficiency, and maintain and enhance public confidence in research.

1 Breen KJ. Research misconduct: time for a re-think? *Int Med J* 2016; **46**: 728-33.

2 White PF, Rosow CE, Shafer SL. The Scott Reuben saga: one last retraction. *Anesth Analg*. 2011; **112**:512-5.

3 Enserink M. France tightens rules in wake of fatal clinical trial. *ScienceInsider* 2016; DOI: 10.1126/science.aaf5742

4 Kleinert S, Horton R. How should medical science change? *Lancet* 2014; **383**: 197-8

Unlike the US, Canada, the UK, the Netherlands, Denmark, Germany and many other leaders in health and medical research, Australia lacks a national body to promote responsible research conduct and to handle allegations of research misconduct. It is time one was established.

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Word count abstract 42

Word count main text 941