



For Over 40 Years BMJ Editors Have Been Concerned About Scientific Research Fraud

Description



Richard Smith, editor of *The British Medical Journal* (“BMJ”) until 2004, has been concerned about research fraud for 40 years. “Stephen Lock, my predecessor as editor of *The BMJ*, became worried about research fraud in the 1980s, but people thought his concerns eccentric,” Smith wrote.

In an article he wrote, published in *The BMJ Opinion* a little over a year ago, Smith addresses the question: is it time to assume that health research is fraudulent until proven otherwise?

Health research is based on trust, Smith wrote. “Health professionals and journal editors reading the results of a clinical trial assume that the trial happened and that the results were honestly reported.” But according to Ben Mol, professor of obstetrics and gynaecology at Monash Health, about 20% of the time they would be wrong.

Mol’s 20% estimation came as no surprise to Smith but it did lead him to think that the time may have come to stop assuming that research actually happened and is honestly reported. In other words, the time had come to assume that the research is fraudulent until there is some evidence to support it has happened and been honestly reported.

Smith cites the example of a recent webinar during which Ian Roberts, professor of epidemiology at the London School of Hygiene & Tropical Medicine, began to have doubts about the honest reporting of trials. A colleague asked if Roberts knew that his systematic review showing the mannitol halved death from head injury was based on trials that had never happened. He didn’t, but he set about investigating the trials and confirmed that they hadn’t ever happened.

All had a lead author who purported to come from an institution that didn’t exist ... The trials were all published in prestigious neurosurgery journals and had multiple co-authors. None of the co-authors had contributed patients to the trials, and some didn’t know that they were co-authors until after the trials were published. When Roberts contacted one of the journals

the editor responded that 'I wouldn't trust the data'. Why, Roberts wondered, did he publish the trial? None of the trials have been retracted.

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Smith cited a second set of trials that Roberts investigated. This time, Roberts did a systematic review of colloids versus crystalloids only to discover again that many of the trials that were included in the review could not be trusted.

Roberts wrote about the problem of the many untrustworthy and zombie trials in *The BMJ* 7 years ago with the provocative title: '*The knowledge system underpinning healthcare is not fit for purpose and must change*'. Roberts' aim was to get the Cochrane Collaboration and anybody conducting systematic reviews to take the problem of fraud very seriously.

"Mol, like Roberts, has conducted systematic reviews only to realise that most of the trials included either were zombie trials that were fatally flawed or were untrustworthy," Smith wrote.

The anaesthetist John Carlisle analysed 526 trials submitted to *Anaesthesia* and found that 73 (14%) had false data, and 43 (8%) he categorised as zombie. When he was able to examine individual patient data in 153 studies, 67 (44%) had untrustworthy data and 40 (26%) were zombie trials. Many of the trials came from the same countries (Egypt, China, India, Iran, Japan, South Korea, and Turkey).

And when John Ioannidis, a professor at Stanford University, examined individual patient data from trials submitted from those countries to *Anaesthesia* during a year he found that many were false: 100% (7/7) in Egypt; 75% (3/4) in Iran; 54% (7/13) in India; 46% (22/48) in China; 40% (2/5) in Turkey; 25% (5/20) in South Korea; and 18% (2/11) in Japan. Most of the trials were zombies. Ioannidis concluded that there are hundreds of thousands of zombie trials published from those countries alone.

Very few of these papers are retracted.

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"We have long known that peer review is ineffective at detecting fraud, especially if the reviewers start, as most have until now, by assuming that the research is honestly reported," Smith wrote and recalls a case in the 1990s when Smith was part of a panel investigating "one of Britain's most outrageous cases of fraud."

The statistical reviewer of the study told the investigation panel that he had found multiple problems with the study and only hoped that it was better done than it was reported. "We asked if he had ever considered that the study might be fraudulent, and he told us that he hadn't."

In her book titled '*Research Misconduct Policy in Biomedicine: Beyond the Bad-Apple Approach*', Barbara K Redman, argued that research misconduct is a systems problem—the system provides incentives to publish fraudulent research and does not have adequate regulatory processes.

Researchers progress by publishing research, and because the publication system is built on trust and peer review is not designed to detect fraud it is easy to publish fraudulent research.

As noted by Smith:

- Journals and publishers' business models depend on publishing, preferably lots of studies as cheaply as possible. There is little incentive to check for fraud and a positive disincentive to experience reputational damage—and possibly legal risk—from retracting studies.
- Funders, universities, and other research institutions similarly have incentives to fund and publish studies and disincentives to make a fuss about fraudulent research they may have funded or had undertaken in their institution—perhaps by one of their star researchers.
- Regulators often lack the legal standing and the resources to respond to what is clearly extensive fraud, recognising that proving a study to be fraudulent (as opposed to suspecting it of being fraudulent) is a skilled, complex, and time-consuming process.
- Another problem is that research is increasingly international with participants from many institutions in many countries: who then takes on the unenviable task of investigating fraud?

Research authorities insisted that fraud was rare, didn't matter because science was self-correcting and that no patients had suffered because of scientific fraud.

All those reasons for not taking research fraud seriously have proved to be false, and, 40 years on from Lock's concerns, we are realising that the problem is huge, the system encourages fraud, and we have no adequate way to respond.

It may be time to move from assuming that research has been honestly conducted and reported to assuming it to be untrustworthy until there is some evidence to the contrary.

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