Review

The Royal Society of Medicine

Journal of the Royal Society of Medicine; 2014, Vol. 107(2) 61–65
DOI: 10.1177/0141076813511452

Fraud in scientific research – birth of the Concordat to uphold research integrity in the United Kingdom

Ankur Khajuria[1] and Riaz Agha[2]
[1]Imperial College London School of Medicine, London, SW7 2AZ, UK
[2]Department of Plastic Surgery, Stoke Mandeville Hospital, Aylesbury, HP21 8AL, UK
Corresponding author: Ankur Khajuria Email: ankur.khajuria09@imperial.ac.uk

Summary

Fraud in research has risen exponentially and recent high profile cases may just be the tip of the iceberg. This threatens to have a major impact on public health, with policy makers and clinicians acting on erroneous data. To address this, the new research "Concordat", a consensus statement on research misconduct, has been published. Can it hold the key to rebuilding public confidence in scientific research in the United Kingdom? This review focuses on the concept of research misconduct, highlighting prominent cases and discussing strategies in order to restore confidence in the validity of scientific research.

Keywords

fraud, misconduct, public health, research, Concordat

Introduction

Commitments to transparency and rigour are principal cornerstones of modern research. However, there has been a long and discreditable history of fraud in research.[1] Recent high-profile cases may just be the tip of the iceberg, threatening to have a major impact on public health.[2] Misinformation can risk policymakers and clinicians acting on inaccurate or nonexistent data, risking harm to people. Furthermore, public trust in future research can be undermined, resulting in patients risking emotional and financial harm. Recent misconduct scandals have haunted the research community, putting a dark shadow over integrity in the past decade. However, unless more scrutiny is given to this field, we may not be ready to face the consequences, if/when these occur again. Can the new research 'concordat', a published consensus statement on research misconduct, hold the key to rebuilding public confidence in scientific research in the United Kingdom? This paper focuses on the concept of research misconduct, highlighting prominent cases and discussing strategies in order to restore confidence in the validity of scientific research.

A dishonourable past

From William Summerlin's fake transplantation experiments, colouring dark patches with a pen on white mice,[3] to Hwang Woo-Suk falsely claiming to have produced stem cells from adult cells,[4] fraud in science has a long, dishonourable past. Research misconduct encompasses three main forms, as defined by the U.S. National Science Foundation[5]: (a) fabrication – making up data or results and reporting them; (b) falsification – omitting data or manipulating research processes without good cause; and (c) plagiarism – using another's ideas, results or words without giving appropriate credit. These modalities pose great risk to the general public as evident from high-profile cases, none more prominent than that of Andrew Wakefield in 1998.

His paper advocated a link between the MMR (measles, mumps and rubella) vaccine and subsequent development of autism.[6] Opponents highlighted that the study was a small case series that lacked controls and the conclusion relied upon parental beliefs and recall.[2] Subsequent media involvement resulted in a significant drop in MMR vaccination rates, from 92% in 1997 to below 85% in 2002, with a rise in associated caseload.[7] Later investigations revealed data manipulation and undeclared conflict of interest, with Wakefield having received £50,000 by a lawyer who headed a lawsuit against the MMR vaccine.[8] His paper was retracted and he was struck off by the General Medical Council in 2010. Brian Deer's *post-hoc* investigation revealed that patients' medical histories were altered, with Wakefield's institution further supporting his views.[2]

Unfortunately, the damage is 'still going on',[9] driven largely by an unequivocal response by researchers, government and journals.[10] Vaccination rates remain below 95%, the level recommended by the World Health Organization to maintain herd immunity, with a subsequent measles endemic declared in England and Wales in 2008.[7] Other consequences include the diversion of money and effort

away from research into actual causes of autism to provide therapeutic benefit to those patients.[11] Hence, this case evidently highlighted the need for more transparency in research; yet, numerous cases of fraud have since occurred. The cases of Scott Reuben and Joachim Boldt highlight this.[12–15] What is driving scientists to publish fraudulent research?

Fraud on the rise

Scientific misconduct is on the rise. Since 1975, there has been a 10-fold increase in scientific articles retracted due to fraud.[9] Fang *et al.*[9] reviewed 2047 articles indexed in PubMed that were retracted by 3 May 2012 and demonstrated that error was attributable to only 21.3% of cases. 67.4% were attributable to research misconduct, including fraud (43.4%), plagiarism (9.8%) and duplicate publication (14.2%).[9] Japan, China and the United States made up 75% of retractions due to fraud, while China and India collectively accounted for a higher number of plagiarised cases than the United States alone.[9] Furthermore, journal impact factor also showed a statistically significant correlation with retractions due to fraud.[9] Of concern is the discovery of multiple fraudulent cases, committed by the same laboratory or individual, when investigating a single fraud instance. Sawada *et al.*[16] was retracted from the journal, *Blood*. Consequently, 30 additional articles were retracted originating from the same laboratory.[9]

Researchers are under tremendous pressure to publish, emphasising the culture of 'publish or perish', a major contributor to the rise in research misconduct.[11,17] The phrase describes the academic pressure on scientists to continuously publish work for career advancement and promotion. Publication productivity and impact are often major deciders for distribution of professorships, research funding and admission to competitive doctoral programs.[18] With this disproportionate system of rewards in place, is the temptation to bend the rules inevitable?

The pharmaceutical industry has also been shown to influence research integrity.[19] A prime example is the diabetes drug 'Avandia'. Its market success led to annual revenue of $3.2 billion by 2006.[20] This crashed after a study in the *New England Journal of Medicine* associated the drug to a 43% increased risk of having a myocardial infarction.[21] Subsequent investigations revealed that GlaxoSmithKline, the drug's manufacturer, had masked the drug's safety profile to protect sales.[22,23] Thus, drug development, if driven by financial gains, has grave implications for the future of research and patient safety. To avoid such cases in the future, what measures are being taken to tackle misconduct?

Tackling research misconduct

A two-day conference at the Royal College of Physicians of Edinburgh was held in 1999 to address research misconduct.[24] The consensus from the meeting was that the UK lagged approximately 20 years behind the United States and Western Europe in addressing the issue, bourn largely due to high-profile cases in the UK as well as lack of strict, stringent protocols for dealing with misconduct allegations.[25] Furthermore, a national panel was needed to provide direction on dealing with misconduct.[25] The situation in 2012 was that a body to spearhead the work in research misconduct in the UK was still lacking.[26] However, there had been progress in dealing with publication misconduct. The Committee on Publication Ethics (COPE) was founded in 1997 and had since reviewed some suspected cases of publication fraud, with an attempt to give advice to editors grappling with these issues while publishing guidelines for authors, reviewers and editors on best practice.[27]

Following accumulating analyses, national policies for setting standards for responsible research conduct as well as investigations of misconduct allegations are being supported by governments in Western Europe, the United States and elsewhere.[26] However, for the UK to maintain its reputation for honest and sound research, it must also support such policies and diminish the lag behind the other nations.[1] British academics have voiced a concern over research misconduct. Leading experts have commented and warned of the fundamental failing of British scientists to deal with research misconduct.[28] A recent *British Medical Journal* (*BMJ*) survey showed that 13% of doctors claimed to have knowledge of data fabrication, with 6% claiming of being aware of cases of possible research misconduct at their institutions that had not been properly investigated.[28]

Concordat

COPE and the *BMJ* held a meeting in January 2012 to discuss issues surrounding research misconduct. Delegates agreed on the lack of robustness of UK's current methods to deal with this issue.[24,29] Consequently, Universities UK and Research Councils UK, two bodies that represent universities and funders, published the concordat in July 2012.[30] This is a consensus statement on research misconduct with the aim to provide reassurance to the international scientific community, wider public and the government that all fields of research in the UK are underpinned by integrity and highest standards of rigour.[31] It provides 'a comprehensive national framework' for research governance while ensuring openness and transparency.[32] The concordat's

role was highlighted by the following points[31]:

1. Maximising the integration of current approaches to research integrity.
2. Ensuring that integrity and rigour continue to underpin all research.
3. Encourage transparency at both sector and institutional levels.
4. Promoting reflection to identify areas for improvement.

The concordat advocates that institutions must have strict and robust protocols in place for investigating misconduct allegations. It is the employers' responsibility to orchestrate confidential investigations, while ensuring that the people in charge have the suitable authority, experience and skills.[31] Furthermore, subsequent steps must be handled appropriately, involving imposing of sanctions and reporting to regulatory and statutory bodies, funders and researchers.[31] Where there is no evident intention to commit fraud, support, mentoring and guidance should be provided to the researchers involved.[31] Moreover, the concordat mandates that institutions provide yearly and publically available reports that outline any formal investigations of suspected misconduct as well as reports on activity promoting good research conduct.[32] These should provide assurance that transparent and robust processes are in place to combat misconduct.

Major grant-giving bodies such as the Wellcome Trust, National Institute for Health Research (NIHR), the Higher Education Funding Council (HEFCE) and Research Councils UK have also confirmed that they would be incorporating the concordat's principles into their funding conditions.[32] The funders would require research institutions to appoint a research integrity officer, usually a senior member of the research group, as well as register with a national advisory and oversight body, such as UK Research Integrity Office (UKRIO).[24] Furthermore, the funders have stipulated that employers of researchers must have well-defined and confidential mechanisms for reporting misconduct allegations with a transparent method for tackling them.[28] The annual summaries, as described above, would also form part of grant applications and used by bodies such as UKRIO for surveillance of research misconduct. These being made publically available with concomitant summaries from the signatories of the concordat, like the Wellcome Trust, will reinforce the dogma of transparency, highlighting the efforts of the research sector in cultivating upmost research integrity.[31] Thus, the concordat promotes cooperation and identifies the roles of the key participants, i.e. researchers, employers and funders, facilitating a collaborative effort in maintaining the highest standards of integrity.[31]

The concordat emphasises that researchers should also take responsibility of their own personal development, further fostering research integrity.[31] Researchers' activity must be underpinned by core principles of integrity including honesty in presentation of aims and findings, accurate methodology, acknowledgement of work of other researchers and adhering to agreed protocols.[31] Any conflict of interests must be declared in reporting of methods, analysis and interpretation with presentation of also negative results available to other researchers and the general public.[31] Researchers must comply with ethical guidelines. It is also the role of employers to ensure that clear policies are in place and that the researchers are both aware and understand these with resources which they can access for advice and guidance.[31] A further responsibility of employers is to provide adequate mentoring and training opportunities to facilitate researchers' development.[31] The overarching premise of the concordat is to act as a tool for promoting reflection on whether the measures above remain fit for purpose.[30]

The concordat has also stressed the importance of protecting whistleblowers.[24] Employers must appoint a confidential third party or contact, acting as liaisons for whistleblowers or others who wish to highlight potential misconduct.[31] Its importance is typified by the recent case of the University of Tokyo's Dr Shigeaki Kato, who was exposed by a whistleblower though the video-sharing website, 'YouTube', for data falsification.[33,34] This included 60 apparently duplicate and manipulated images in 24 papers published in high-impact journals such as *Nature*, *Cell* and the *Proceedings of the National Academy of Sciences*.[33]

It is important to note that the concordat's aim is not to replace existing regulatory standards underpinning research activity in the UK but to set the guidance and advice that is already available to researchers in a broader national framework.[31] Medicine has been a key driver for the research integrity movement and the concordat. Most of the funding of the UKRIO is from the Department of Health.[24] It is recommended that all organisations with a stake in UK research, sign up to the concordat. A further recommendation is that representatives from the signatories organise an annual integrity forum to evaluate progress and plan for the future.[31]

However, is the concordat the answer to restoring confidence in scientific research? Fang *et al.*[9] reported a 10-fold increase in retracted scientific papers, due to fraud, since the 1970s. But the overall proportion is still small, from 0.00096% in 1977 to 0.0096% in 2012.[9] Is this significant enough to warrant a major change in research policy? Conversely, as

demonstrated by Wakefield's case,[6] it takes just one fraudulent paper to harm public health and undermine public trust. As Professor Arturo Casadevall, from Albert Einstein College of Medicine in New York, emphasises that 'Very few people are doing it (fraud), but doing it in important areas. When this comes out, the public loses faith in science'.[35] Yet, there are several unanswered questions. Who will fund the concordat? Estimates are in the region of £500,000 per year. And, who will be responsible for implementing changes? Achieving the concordat's goals is unlikely to be easy. What does the future hold for UK research and the public's trust in it?

The future

The concordat may or may not be the answer to solving rising misconduct. Nevertheless, institutions needing to adopt the concordat statement to obtain funding is a positive and crucial stepping stone for research integrity in the UK. Indeed, it was only when the Declaration of Helsinki made trial registration mandatory from an ethical point of view that trial registration increased in significant numbers, despite earlier calls from the International Committee on Medical Journal Editors and Food and Drug Administration.[36] One hopes that concordat compliance and collaboration between funders, employers, researchers and organisations like COPE and the UKRIO, with activities underpinned by integrity and transparency, will be a powerful driver towards greater confidence in UK research, for the scientific as well as the broader scholarly community. This may allow the UK to lead the way internationally in tackling research misconduct.

Declarations

Competing interests: Riaz Agha is a former Committee on Publication Ethics (COPE) Council member

Funding: None declared

Guarantor: AK

Ethical approval: Not applicable

Contributorship: AK: conception and design, drafting and final approval and review of literature; RA: conception and design, final approval

Acknowledgements: None

Provenance: Not commissioned; peer-reviewed by Timothy Coats

References

1. Farthing M, Horton R and Smith R. Research misconduct: Britain's failure to act. *BMJ* 2000; 321: 1485–6.
2. Godlee F, Smith J and Marcovitch H. Wakefield's article linking MMR vaccine and autism was fraudulent. *BMJ* 2011; 342: c7452.
3. Weissmann G. Science fraud: from patchwork mouse to patchwork data. *FASEB J* 2006; 20: 587–90.
4. Saunders R and Savulescu J. Research ethics and lessons from Hwanggate: what can we learn from the Korean cloning fraud? *J Med Ethics* 2008; 34: 214–21.
5. Martyn C. Fabrication, falsification and plagiarism. *QJM* 2003; 96: 243–4.
6. Wakefield AJ, Murch SH, Anthony A, et al. Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. *Lancet* 1998; 351: 637–41.
7. Fitzpatrick M. MMR: risk, choice, chance. *Br Med Bull* 2004; 69: 143–53.
8. Deer B. How the case against the MMR vaccine was fixed. *BMJ* 2011; 342: c5347.
9. Fang FC, Steen RG and Casadevall A. Misconduct accounts for the majority of retracted scientific publications. *Proc Natl Acad Sci USA* 2012; 109: 17028–33.
10. Hilton S, Hunt K, Langan M, Hamilton V and Petticrew M. Reporting of MMR evidence in professional publications: 1988–2007. *Arch Dis Child* 2009; 94: 831–3.
11. Oakley GP Jr and Johnston RB Jr. Balancing benefits and harms in public health prevention programmes mandated by governments. *BMJ* 2004; 329: 41–3; discussion 43–4.
12. Harsoor S and Gangadhar S. Fraud in anaesthetic research and publication. *Indian J Anaesth* 2012; 56: 1–3.
13. Boldt J, Suttner S, Brosch C, Lehmann A, Rohm K and Mengistu A. Cardiopulmonary bypass priming using a high dose of a balanced hydroxyethyl starch versus an albumin-based priming strategy. *Anesth Analg* 2009; 109: 1752–62.
14. Perel P and Roberts I. Colloids versus crystalloids for fluid resuscitation in critically ill patients. *Cochrane Database Syst Rev* 2007; 4: CD000567.
15. Zarychanski R, Abou-Setta AM, Turgeon AF, et al. Association of hydroxyethyl starch administration with mortality and acute kidney injury in critically ill patients requiring volume resuscitation: a systematic review and meta-analysis. *JAMA* 2013; 309: 678–88.
16. Retraction. Sawada S, Ishikawa C, Tanji H, et al. Overexpression of caveolin-1 in adult T-cell leukemia. *Blood* 2010; 115: 2220–30. (Retraction in *Blood* 2010; 116: 1386).
17. Neill US. Publish or perish, but at what cost? *J Clin Invest* 2008; 118: 2368.
18. Agha R. Annals of Medicine and Surgery – educating and developing leading physicians and surgeons. *AMS* 2012; 1: 1.
19. Lexchin J, Bero LA, Djulbegovic B and Clark O. Pharmaceutical industry sponsorship and research outcome and quality: systematic review. *BMJ* 2003; 326: 1167–70.

20. Harris G. *Research Ties Diabetes Drug to Heart Woes* (online). See http://www.nytimes.com/2010/02/20/health/policy/20avandia.html?pagewanted=all&_r=0 (last checked 2 July 2013).
21. Nissen SE and Wolski K. Effect of rosiglitazone on the risk of myocardial infarction and death from cardiovascular causes. *N Engl J Med* 2007; 356: 2457–71.
22. Hawkes N. GlaxoSmithKline pays $3bn to settle dispute over rosiglitazone and other drugs. *BMJ* 2011; 343: d7234.
23. GlaxoSmithKline to Pay $3bn in US Drug Fraud Scandal (online). See http://www.bbc.co.uk/news/world-us-canada-18673220 (last checked 2 July 2013).
24. Tavare A and Godlee F. Helping institutions tackle research misconduct. *BMJ* 2012; 345: e5402.
25. Christie B. Panel needed to combat research fraud. *BMJ* 1999; 319: 1222.
26. Farthing M. *Keep it Real* (online). See http://www.timeshighereducation.co.uk/420565.article (last checked 2 July 2013).
27. Kleinert S. Committee on Publication Ethics (COPE). COPE's retraction guidelines. *Lancet* 2009; 374: 1876–77.
28. Cressey D. *British Science Needs 'Integrity Overhaul'* (online). See http://www.nature.com/news/british-science-needs-integrity-overhaul-1.9803 (last checked 2 July 2013).
29. Tavare A. Institutions must do more to eliminate research misconduct, meeting hears. *BMJ* 2012; 344: e446.
30. A consensus statement on research misconduct in the UK. *BMJ* 2012; 344: e1111.
31. UK U. *The Concordat to Support Research Integrity* (online). See http://www.universitiesuk.ac.uk/highereducation/Documents/2012/TheConcordatToSupportResearchIntegrity.pdf (last checked 2 July 2013).
32. Torjesen I. Strategy for boosting integrity of research is launched in UK. *BMJ* 2012; 345: e4747.
33. Normile D. *Whistleblower Uses YouTube to Assert Claims of Scientific Misconduct* (online). See http://news.sciencemag.org/scienceinsider/2012/01/whistle-blower-uses-youtube-to-assert.html (last checked 2 July 2013).
34. *Alleged Image Fraud by Shigeaki Kato lab at the University of Tokyo (Alleged Research Misconduct)* (online). See http://www.youtube.com/watch?v=FXaOqwanWnU (last checked 2 July 2013).
35. Borenstein S. *Study: Fraud Growing in Scientific Research Papers* (online). See http://www.guardian.co.uk/world/feedarticle/10464024 (last checked 2 July 2013).
36. Bian ZX and Wu TX. Legislation for trial registration and data transparency. *Trials* 2010; 11: 64.