

Fraud and deceit in medical research

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Publication of medical research is the cornerstone for the propagation and dissemination of medical knowledge, culminating in significant effects on the health of the world's population. However, instances of individuals and institutions subverting the ethos of honesty and integrity on which medical research is built in order to advance personal ambitions have been well documented. Many definitions to describe this unethical behavior have been postulated, although the most descriptive is the "FFP" (fabrication, falsification, and plagiarism) model put forward by the United States' Office of Research Integrity. Research misconduct has many ramifications of which the world's media are all too keen to demonstrate. Many high-profile cases the world over have demonstrated this lack of ethics when performing medical research. Many esteemed professionals and highly regarded world institutions have succumbed to the ambitions of a few, who for personal gains, have behaved unethically in pursuit of their own ideals. Although institutions have been set up to directly confront these issues, it would appear that a lot more is still required on the part of journals and their editors to combat this behavioral pattern. Individuals starting out at very junior positions in medical research ought to be taught the basics of medical research ethics so that populations are not failed by the very people they are turning to for assistance at times of need. This article provides a review of many of the issues of research misconduct and allows the reader to reflect and think through their own experiences of research. This hopefully will allow individuals to start asking questions on, what is an often, a poorly discussed topic in medical research.

Key words: Ethics, fraud, plagiarism, research, scientific misconduct, United States' office of Research Integrity

INTRODUCTION

Medical research is the cornerstone of scientific research. It has the potential to engender a better state of physical and psychological health. Therefore, it is imperative that medical research is genuine and free from bias. When conducting medical research, one must abide by the ethical and moral obligations as outlined by the Nuremberg code in 1947^[1] and the subsequent Declaration of Helsinki 1964 (and later revised in 2002),^[2,3] which explain the responsibilities of scientists and physicians when conducting medical research on humans. However, despite the morality underpinning medical research, scientific research has a long history of fraud and deception,^[4-6] with this behavior adversely affecting the very lives researchers are seeking to help.

Additionally, the seriousness of fraud in the biological sciences – science directly influencing the physical and

psychological well-being of the individual – should also be acknowledged. As a result of the implementation of detection policies and the management of misconduct cases by regulatory bodies, who have seen an unprecedented increase in misconduct cases, the prevalence of fraud and deceit has become increasingly documented within research circles.^[7] In recognition of the seriousness of the situation, multiple organizations have been created to deal with the problem.

However, despite the publication of cases in the media and in working sessions of regulatory governing bodies throughout the world,^[8-12] fraud and deception in medical research has often been underreported. One reason for this could be the fact that there is no standard definition of what constitutes scientific deception,^[5] making it more difficult to identify cases and prevent it from continuing. In order to fully understand this, we must discuss the definitions available to us.

RESEARCH MISCONDUCT

The Oxford English Dictionary describes fraud as "wrongful or criminal deception intended to result in financial or personal gain" and deceit as "the action or practice of deceiving someone by concealing or misrepresenting the truth."^[13] Research organizations and the literature have defined these behavioral patterns within the umbrella title of "Research Misconduct."^[14]

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An array of definitions is used to define research misconduct within the literature depending on the country in which they originate. Given the international nature of publications and research, and the cross-fertilization of research across continents, through departmental and institutional collaboration in the 21st century, it is surprising that a single global definition is yet to be utilized.^[14]

From the United Kingdom (UK) perspective, following much impetus for change by Stephen Lock,^[15] in 1999, The Royal College of Physicians of Edinburgh hosted the Consensus Conference on Misconduct in Biomedical Research, which aimed to address the issues in research misconduct.^[16] Their definition was the broadest yet from the UK and was stated as: “Behaviour by a researcher, intentional or not, that falls short of good ethical and scientific standard.” The UK Committee on Public Ethics (COPE) describes misconduct as the “intention to cause others to regard as true that which is not true.”^[17] Additionally, the United States of America’s key regulatory body, the Office of Research Integrity (ORI), defines research misconduct using the FFP model, i.e. the serious aspects of misconduct. These include:^[18,19]

- Fabrication – Making up data or results and recording or reporting them.
- Falsification – Manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- Person’s ideas, processes, results, or words without giving appropriate credit.
- Research misconduct does not include honest error or differences of opinion

Consequently, given the breadth of definitions, it is clear that the question “what is misconduct?” arises. Evidently, varying degrees of medical research misconduct do exist, ranging from the serious (i.e. the FFP model) to cases of “ghost” authors and duplication of presentations, often regarded as trivial deviations from standards. Richard Smith has described a “taxonomy of research misconduct” illustrating the spectrum of definitions and their relative seriousness [Table 1].^[16]

Fabrication and falsification

As Smith states, fabrication and falsification of data, and neglecting to seek ethical approval for research that involves human participants, are both unethical and go against the spirit of scientific research. However, it is questionable whether a clinical researcher who fabricates data to enrol a terminally ill patient into a trial that ultimately may lead to that individual receiving treatment that may prolong their life should receive the same penalty as someone fabricating data for their own professional gain.

Plagiarism

Whilst being recognized as morally wrong, it is debateable as to whether the third branch of the FFP model, plagiarism—the use of published or unpublished material without due acknowledgment of the primary author—constitutes misconduct research in the same way as does the fabrication and/or the falsification of data. Arguably, the repercussion of plagiarism is merely damage to the ego of the individual whose ideas/words are taken. Moreover, since the work is already published and in the public domain, there is, arguably, no harm in utilizing the same information, saving on further expense and time. Daniel David, editor of *The Journal of Cognitive and Behavioural Psychotherapies*, believes, “if duplication of content... helps the author to reach a new or larger readership...” and “if text recycling within these constraints helps to present the same idea more accurately across several publications, they become legitimate conduct.”^[20]

Referring to the United States’ ORI definition of plagiarism, which is “unattributed textual copying,” many have questioned its applicability in real life situations. One definition of plagiarism suggests it is the repetition of 11 words or the overlap of 30 letter strings,^[21] although this is by no means a standard definition.

Furthermore, “salami-slicing” – the selective use of research- project results to maximize the number of presentations possible – has also been classed as a type of plagiarism by some, but not by others.^[22] The contention here is whether this constitutes misconduct. Berk argues that although it is difficult to qualify the degree of deceit,

Table 1: A taxonomy of research misconduct*

Research misconduct (in descending order of seriousness)

- Fabrication: Invention of data or cases
- Falsification: Wilful distortion of data
- Plagiarism: Copying of ideas, data, or words without attribution
- Failing to get consent from an ethics committee for research
- Not admitting that some data are missing
- Ignoring outliers without declaring it
- Not including data on side effects in a clinical trial
- Conducting research in humans without informed consent or without justifying why consent was not obtained to an ethics committee
- Publication of *post-hoc* analyses without declaration that they were *post hoc*
- Gift authorship
- Not attributing other authors
- Redundant publication
- Not disclosing a conflict of interest
- Not attempting to publish completed research
- Failure to do an adequate search of existing research before beginning new research

*Taken from Ref. 16: Evans S. How Common is it? Royal College of Physicians of Edinburgh. Joint Consensus Conference on Misconduct in Biomedical Research. Suppl. 7 2000;(30)1

plagiarism is “a breach of professional ethics that must be explored and unreservedly deplored.”^[23]

Is fraud and deceit in medical research black and white?

When considering the definitions of “deceit” and “deception,” there is little agreement on less serious cases. It is debateable as to whether dual publications (submitting to several journals simultaneously) or placing an individual’s name on the list of authors of a publication when their contribution is minimal (gift/ghost authorship) amount to the same level of misconduct as fabrication of data, and whether this amounts to misconduct at all. Furthermore, it is arguable that the current lack of funding for research may potentially drive many to commit “deception” in order to reach their goals. However, some may argue that such minor indiscretions may lead to more serious breaches of research conduct. In addition, the failing of senior authors to supervise the work lends them to be just as culpable for the indiscretions.^[12]

Sismondo *et al.* and others describe the implications, on the nation’s health, of ghost-authoring by pharmaceutical companies, who exert their financial might in “controlling” and “shaping” crucial steps of research and publication, allowing the pharmaceutical industry to “shape the literature in ways that serve its interests.”^[24,25] The important question is how can we halt this stem of deception in research and who is available to assist in this cause.

NATIONAL BODIES

Following revelations of fraudulent research in the UK, medical editors set up COPE in 1997. It now has over 7000 members worldwide from a variety of academic disciplines and covers a number of significant publishers. Although COPE provides advice, support, and guidance to editors and publishers on publication ethics,^[17] it is unable to offer sanctions other than to expel members from its panel. The UK Research Integrity Office (UKRIO) is another body representing the interests of over 50 universities and organizations dedicated to scientific research.^[26] Set up in 2006, its aims are to:^[26]

- promote the good governance, management, and conduct of academic, scientific, and medical research;
- share good practice on how to address poor practice, misconduct, and unethical behavior; and
- give confidential, independent, and expert advice and guidance about the conduct of academic, scientific, and medical research.

Many medical practitioners undertake research at some point in their careers, with the vast majority of medical schools now incorporating this within the undergraduate curriculum. Although the General Medical Council (GMC)

has statutory powers, it has no authority to monitor and regulate a medical practitioner’s research conduct.

One of the oldest organizations dealing with research misconduct is the ORI in the United States.^[18] Set up in 1992, it oversees and directs Public Health Service (PHS) research integrity activities. With a huge budget of \$30 billion, it provides significant funds in the areas of health, research, and development, and oversees bodies such as The National Institute of Health and The Office of Public Health and Science.

PREVALENCE OF RESEARCH MISCONDUCT

There is no accurate data on the prevalence of research misconduct.^[12] The absence of a standardized definition in the global world of publications has proved a major impetus in support of the traditional view that deception is rare.^[27] Koshland goes further stating, “99.9999% of all reports are accurate and truthful,” and that science should not adopt a change in practice, thus allowing the propagation of knowledge.^[28] However, as conveyed by numerous cases in the international media, it is arguable that there is potential for serious harm to the nation where research misconduct takes place.

Surprisingly, some reports suggest a developed psychology for deceit at a young age when minimal exposure to research has been obtained. Taradi *et al.*, in a survey of 508 medical students, show that over 90% of the students admitted to engaging in education dishonestly and over 78% engaging in academic misconduct.^[29] Nilstun *et al.* contradict this in their study on doctoral students, suggesting that “students appear to be too inexperienced to have cheated by themselves....”^[30] Furthermore, Martinson *et al.* surveyed a total of 3247 mid-career (majority at the associate professor level or above) and early-career scientists (majority at post-doctoral level) working in the United States on their practices in research. The results showed at the serious end of the spectrum, i.e. falsification or fabricating data, the percentage engaging in such activity was low (<2%). However, over 33% of the respondents described involvement in research misconduct that would necessitate investigation by the institution or federal agencies. Interestingly, the more senior group demonstrated a greater propensity to engage in questionable activity than did their juniors.^[7]

The first meta-analysis looking into the prevalence of research misconduct was performed by Fanelli.^[9] Examining “scientific behaviors that distort scientific knowledge” only, he showed that 2% of the scientists admitted to serious misconduct (falsification or fabrication of data) at least once, and up to 34% admitted other questionable research practices. When participants were asked about their colleagues’ practices, the

results were even higher (14% for falsification of data and 72% for other questionable practices).^[9] However, Fanelli suggests these results may only represent a conservative estimate of the real prevalence of research misconduct, a similar argument put forward by Ranstam *et al.*, who, in their study of biostatisticians, showed a majority of respondents reporting knowing of at least one serious breach of fraudulent projects in the past 10 years.^[31] Geggie conveys how the majority of newly qualified medical consultants demonstrated evidence of previous misconduct.^[32] Of the respondents, 18% were either willing to commit or were unsure about future research misconduct. This may be reflective of the 17% of participants who reported having received no training in research ethics despite their seniority.^[32]

There are a number of levels at which research misconduct can occur – individual researchers, department, institution, journals, and funding bodies.^[33] When looking at the reasons for research misconduct, there is an underlying desire to be successful in science and also a fear of failure.^[25] Securing grants and financial incentives from pharmaceutical companies and professional career progression are all cited as causes for misconduct.^[34] Arguably, many researchers and departments may have equated the concept of “quantity” rather than “quality” with research success. The association between the number of publications and suitability for funding or career progression has been with us for a while.^[35] When applying for senior posts, surgical trainees are continuously questioned on the number of publications achieved, disregarding the quality of the publication or journal. Beisiegel *et al.* and Smith suggest this attitude has predisposed to a massive rise in journal titles, many of which are of low quality and are poorly maintained.^[35,36]

Broad and Wade argue that in order to improve the quality of research, “what is needed is greater competition brought about by a sharp reduction in the number of journals, especially in medicine and biology,” further claiming that “careerism” is the cause of much research fraud. They suggest a greater separation between medical education, which is perceived to create the foundations for students’ cheating behaviors, and medical research.^[37]

When one asks if organizations are successfully tackling the root causes of misconduct, there appears to be some disagreement on this topic.

On the issue of authorship, progress has been made. The International Committee of Medical Journal Editors published the “Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publications,”^[38,39] defining the rules for authorship credit as being based upon meeting all three criteria below:^[38,39]

- 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
- 2) drafting the article or revising it critically for important intellectual content; and
- 3) final approval of the version to be published.

However, these are not universally adopted by all journals. Some journals go even further and request a statement detailing individual authors’ contribution to the submitted work. Journal editors, working closely with other groups, such as biostatisticians and external editors, can play a significant role.^[33] Additionally, peer review ensures research quality and identifies issues of misconduct. Any suspicion should prompt the editor to request the raw data for verification.

Furthermore, there is a perception that results published in high impact factor journals are automatically dependable. Moreover, untimely retractions could result in the propagation of inaccurate information in other works. Wilmshurst points out that education and training of individual researchers and supervisors is crucial to combating misconduct, as well as creating an environment for whistleblowers to speak out.^[12]

CONCLUSION

In conclusion, evidently there are a number of reasons why research misconduct takes place: Academic pressure, personal desire for fame, “sloppy” science, financial gain, and an inability to determine right from wrong, to name a few. This demonstrates a need for a new system of prevention, investigation, and education to curtail research misconduct, therefore instilling, into the general public, a renewed sense of trust and respect for medical research.

In order to prevent research misconduct, further discussion of its definition and its various facets is needed, therefore resulting in an international consensus on a single, universal definition of what constitutes research misconduct. Additionally, ethical standards need to be made clear so that researchers can determine whether their work breaches certain codes. Furthermore, there needs to be an alleviation of pressure on researchers, as well as greater control of research sponsored by outside organizations.

Moreover, organizations’ investigation into research irregularities must be fair, prompt, transparent, and allow for retractions to be made promptly once evidence of misconduct has been confirmed. Also, there needs to be greater protection for whistleblowers, as well as ensuring a right of appeal. The investigation can be conducted at either institutional or national level, depending on the gravity of misconduct. However, organizations need to be equipped

with effective resources and a certain status in the wider community, thereby ensuring public confidence.

Lastly, there is a desperate need for researchers and future researchers to be educated on what constitutes research misconduct, and the seriousness of its repercussions. There is limited publicity and information of the regulatory bodies in medical institutions and places of work. It has been almost 25 years since Lock suggested a closer look at this issue,^[40] yet we are still faced with cases of fraud on an epic scale.^[41] It may be too late to change the ways of our seniors,^[32] but we have a responsibility to our nations to act. As Martinson *et al.* stated, "it is time to consider what aspects of the research environment are most salient to research integrity, which aspects are most amendable to change, and what changes are likely to be most fruitful in ensuring integrity in science."^[7] Educating potential researchers at an early stage (e.g. at medical school) on the mechanics of research ethics is essential to finding a solution to this problem and ensuring careers are constructed on honesty and integrity.

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