

A History of Fraud and Deceit in Medical Research

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Abstract: There have been many cases of fraudulent research work in recent years. Science has progressed through years of research and trial of pioneering ideas. However, the intentions for promoting such research have not always been pure. In some cases, fraudulent research has been used as means to promote personal and financial gains. In this study, cases of previous fraudulent research are reviewed. Grey areas of misconduct and fraud are clarified. The aims of the study are to define misconduct and grey areas of research fraud. The study will also review famous cases of research fraud and the reasons of why such cases may have been committed are outlined. A review of Medline between the years 1960-2009 has yielded studies reviewed by this study. Cases involving research misconduct and fraud are identified. All cases are discussed and inferences to why such acts committed are outlined. There are insufficient protocols in place to limit fraudulent research. However, an international coordination of effort in defining research misconduct and invoking legal and procedural accountability may be a solution to this problem.

Key words: Fraud, deceit, medical research, plagiarism, misconduct, grey areas

INTRODUCTION

Science has progressed through years of research. It is almost impossible to carry out research without bias or errors in judgement. The motives to do research in science and the intention to conduct research projects have not always been sincere or pure. Research can be a tempting path to achieve fame, improve income and miss few steps climbing up the career ladder. On the other hand research may be humanity's only way to improving life, preventing disease and securing a better future for the next generations.

In the study, the researcher will attempt to define fraud and misconduct in medical research. The researcher will attempt to clarify the grey areas that many researchers feel are dubious but not fraudulent. In many circumstances, these acts do constitute behavioural misconduct and may be in essence fraudulent acts.

The researcher will highlight examples of researchers who have misused the trust given to them by the public and funding institutions or charities to make up fraudulent claims and scientific achievements for purposes that are not yet fully clear. The researcher will also review the steps that have been put in place to prevent fraud and deceit during the research process. The researcher will discuss the necessary steps required to prevent individuals and beneficiaries such as the industry from making fraudulent acts to promote individual fame or financial gain.

Many cases of fraud in medical research have surfaced into the public eye since the mid 1970's. During

the period of 1974-1981 >12 cases of research misconduct were made public in the United States (Ryan, 1999). From the famous painted mice case by William Summerlin, dermatologist to the case of study fabrications by Alsabti (1979), researchers have had to face the spotlight. The 1980's were not only famous for when Michael Jackson hit the headlines by being pictured inside an oxygen chamber but also Stephen Breuning made headlines. Stephen Breuning's considerable body of work on the treatment of the mentally retarded using tranquilizers lead to national changes of social policies for treating mentally ill patients in the United States during the 1980's (Garfield and Dorof, 1990). His research was deemed to be fabricated and he was convicted for academic fraud in the district court of Maryland in 1988.

The early 1990's were turbulent times for researchers, with the economic downturns in many developed countries such as Britain and Japan reshaping public grant funding for the purposes of medical research. However, the mid 90's witnessed a downturn of another nature. A sensational case of fraud emerged when Malcolm Pearce published a case report in 1994 in the British Journal of Obstetrics and Gynaecology in which he claims that he has successfully re-implanted an ectopic pregnancy (Lock, 1995). This study was co-authored by Professor Geoffrey Chamberlain, Head of Department of Obstetrics and Gynaecology at St. George's and president of the royal college who later claimed that this was a gift authorship by Pearce and that he did not know the work, was fraudulent. Pearce was struck off by the General Medical Council (GMC) and fired from his post. Chamberlain resigned from all positions and his career was practically over.

Stem cell research quickly gathered pace during the late 1990's. The announcement by Professor Campbell to have successfully cloned the first animal dolly the sheep using the technique of nuclear transfer prompted intense research into this area (Wilmot *et al.*, 1997). This was a historical moment and the press coverage worldwide of such a medical achievement was unprecedented. This may have prompted another pioneering claim but of another nature. Hwang *et al.* (2004, 2005) was a South Korean researcher and Professor at Seoul National University who made headlines when he claimed to have succeeded in creating human embryonic stem cells by cloning. He published 2 papers in the science journal during 2004 and 2005 which were later retracted. The official probe by Seoul National University found in 2006 that Professor Hwang fabricated the data in both the 2004 and the 2005 papers and the investigating panel considered this was an act of deception (Cyranoski, 2006).

It is difficult to believe that the future of medical research will not hold more sensational stories of fraud like the ones above when recently, a prominent Norwegian cancer scientist, Sudbo *et al.* (2005) fraudulently claimed that anti inflammatory drugs can prevent oral cancer. More than 900 patients and data were all fabricated. An independent commission was set up by Rikshospitalet and the Oslo University to investigate the case. The report criticized the university, hospital and the Rikshospitalet for lack of vigilance and policy control. The commission also found that such fraudulent claims would have had detrimental effects on the treatment of oral cancer worldwide. This danger prompted the Norwegian government to consider and adopt laws that would impose prison sentences on researchers, who commit fraud and deceit in their research process.

MATERIALS AND METHODS

A structured search of the Medline using MeSH terms has been conducted between the years 1960-2009. The search engine was accessed using the national library for health website. The following key and MeSH terms have been used to conduct the search; fraud, deceit, medical research, plagiarism and misconduct.

Definitions and accountability: You can fool too many of the people too much of the time (Thurber, 1940). The story of the Owl who was God bears so much resemblance in essence to many cases where researchers committed fraud intentionally and even managed to manipulate other co-authors into committing such acts. The Owl preyed on the weak and ignorant of all animals making claims supported by wit. This lead to all animals following its

lead until divine status was bestowed on the owl, just like a researcher reaches divine status with wealth of publications and huge sums of funding to his name. Eventually, when the owl wanted to cross the highway all animals followed except the hawk considered to be an outsider. The hawk managed to observe a truck coming towards them at 50 miles h⁻¹. The owl died with most animals dead or injured but the hawk cleverly saved its skin.

It is difficult to define fraud in scientific terms. The difficulty in defining fraud and research misconduct has made it impossible so far to reach an international consensus to deal with the phenomenon of research fraud.

The United States was the first country to define research misconduct and introduce legislation and federal laws to deal with this problem. The American Congress took action as early as 1985 by introducing the Health Research Extension Act (Ryan, 1999). This allowed for implementation of administrative processes on reporting of fraud to be organised nationally. By 1989, the Office of Scientific Integrity (OSI) and the Office of Scientific Integrity Review (OSIR) were established. These offices began a process of taking over the responsibility of dealing with research misconduct from funding bodies and amalgamated into the current Office of Research Integrity (ORI). This process was completed by 1993, when President Clinton signed the Revitalization Act of 1993 commissioning the establishment of ORI as an independent body (Ryan, 1999). The ORI has since introduced several policies and commissions in addition to amendments and clarifications to deal with the growing problem of research misconduct.

The Federal Policy on Research Misconduct defines research misconduct as fabrication, falsification or plagiarism in proposing, performing or reviewing research or in reporting research results (Spece and Bernstein, 2007; Keranen, 2006).

Across the Atlantic, Scandinavian countries and France and Germany developed national mechanisms that can deal with the problem of research misconduct. How effective these mechanisms are is still not clear. However, a recent survey and report of 32 countries by the European Science Foundation (ESF) claims that most countries in Europe have established mechanisms to safeguard research integrity and promote good research codes and practices (Summerskill *et al.*, 2009).

The situation in the United Kingdom, however is very different. Despite a wealth of researchers and medical research projects, the United Kingdom has been slow to react. This is reflected by adopting a relatively late approach in dealing with the problem of research

misconduct and the progress is far from being complete. The report by the Royal College of Physicians in 1991 on research misconduct went under the radar and did not receive the attention it deserved despite compelling findings that action to tackle this problem is needed (Wilmshurst, 2002; Farthing *et al.*, 2000).

However, following the Pearce scandal of the mid 1990's, a group of prominent journal editors realized the scale of the problem and quickly founded the Committee on Publication Ethics (COPE) in July 1997 (Jones, 1999). The committee assumed an advisory role to editors on how to deal with research misconduct. By 2008, COPE was a founded charity with a code of conduct and constitution. However in the UK, only the GMC can take effective action if a case of research fraud has been committed and even then the GMC has been very slow to react. COPE underlies the general principle confirming misconduct is the intention to cause others to regard as true that which is not true (Committee on Publication Ethics, 2000).

Several bodies followed suit with the establishment of The UK Panel for Research Integrity in Health and Biomedical Sciences and the UK Research Integrity Office (UKRIO) in 2006. Unlike the ORI, this is merely an advisory body to universities and trusts with no legal or legislative arm in implementing or overseeing the application of its own advice. Similar to COPE, it has established its own code of good research conduct and steps to deal with misconduct. The most serious attempt to establish an effective action against research misconduct is currently underway by the Research Councils UK (RCUK). RCUK has recently published the consultation document on the governance of good research conduct in October 2008 (Schneider, 2000). This will hopefully lead to the establishment of robust mechanisms which will enforce the good research governance procedures. However, a legislative support on the behalf of parliament may also be needed.

The Deutsche Forschungsgemeinschaft is considered Germany's leading body for funding health research and the largest in Europe. Following several cases of high profiled research fraud in the late 80's and 90's, the Forschungsgemeinschaft was quick to react in establishing new binding guidelines to prevent fraud in research. The Forschungsgemeinschaft defines fraud as deliberate or grossly negligent falsification or fabrication of data (Schneider, 2000).

The Scandinavian countries have also responded to the global crackdown on fraud in medical research by forming committees to deal with such misconduct. The Danish committee established by the national research council defined fraud as an Intentional or gross

negligence leading to fabrication of the scientific message or a false credit or emphasis given to a scientist. This is similar to the Swedish definition of fraud.

RESULTS

The classical classification of fraud includes: Falsification, Fabrication and Plagiarism (Ryan, 1999). In general term falsification is defined as manipulation of results or hiding critical data. Fabrication is the reporting of data that is made up with the intent of publishing it. Plagiarism is the ultimate act of taking other people's work or ideas and attributing it to one's self. Using different terminology, Guenin (1999) reclassified research misconduct as: misrepresentation, misuse of another's work and plagiarism which is the intentional presentation of the words of another as the presenter's own.

Regardless of classifications or definitions of research misconduct, the malicious intent to commit fraud remains the underlying principle for any definition and subsequent conviction. The term research misconduct is loose and in many cases is too broad to apply to specific cases. Therefore, a better understanding of classification would help to clarify any grey areas.

Famous cases of fabrication over the last few years include the Poehlman's case and the case of Herrmann and Brach which rocked the scientific community worldwide. Eric Poehlman was a leading researcher in obesity and nutrition until one of his researchers, Walter DeNino, discovered a case of data fabrication that eventually lead to one of the most sensational and expensive trials of research fraud in the United States. Eric Poehlman also became the first academic to be jailed for committing fraudulent research projects. Dr. Poehlman falsified and fabricated research data for >10 years mainly the period from 1992-2002 (Interlandi, 2006). This included grant applications and research papers related to several topics including this study of the impact of the menopause transition on women's metabolism.

On the other side of the Atlantic, Europe's worst case of scientific fraud dates as back as 1988, when Friedhelm Herrmann and Marion Brach, both professors at the University of Lübeck were accused of fabrication and falsification of data in >90 peer reviewed publications over many years (Tuffs, 2000). The forgery involved research in haematology including the use of cytokines and gene therapy.

Perhaps the most accurate account of plagiarism cases in medical research comes from the United States. Since 1992, the ORI has considered plagiarism as a serious case of misconduct and 19 cases between 1992 and 2005 have been made public (Pascal, 2006). It is important to

note however that the ORI considers cases of plagiarism only where the person committing plagiarism is a noncollaborator on the study. In addition, the ORI does not consider cases of self-plagiarism which is the reuse of material by researchers in redundant research (Pascal, 2006).

The incidence of research misconduct has increased over the last few years. This is because of better definitions that have been put in place. In addition, the mechanisms and reviews that have been implemented following international collaboration have made it more likely to detect fraudulent research. The prevalence of research misconduct is difficult to estimate and may be as little as 1.5% and as high as 56% in extreme cases depending on the definition used (Wadman, 2005; Ranstam *et al.*, 2000).

DISCUSSION

The grey areas are really shaded by scientists themselves. The researcher would define the grey area in scientific misconduct as an area, which most scientists agree is common but not necessary right. However, the problem with being common is that researchers start to accept these practices and later embrace them. What would make common wrong, is if the scientific community as a whole puts an end to such practices. In this study, the researcher would like to use the term dubious misconduct to point to these grey areas.

Dubious acts of misconduct can be classified into: Bias, misinterpretation and misrepresentation.

An example of misrepresentation is the citation of journals. The process of citation requires that all journals quoted are given credit. However, the process of citation can be a process of bulking up the work and giving it a beefy impact. In some cases journals that need to be cited are not because this may affect the grant application or are too awkward to cite. This in fact is a misrepresentation of the truth. Another example of misrepresentation can be gift authorship where the co-author plays a very limited role if any in the research and then claims co-authorship merely because head of departments and professors have to continuously develop their profile for funding purposes.

The process of research needs to be as meticulous as possible. However, bias in selection and interpretation of data has become common to an extent that as long as it is recognized then it is unavoidable. The bias that plagues research can be initially prevented by seeking appropriate statistical advice and implementing robust measures, such as interim analysis of data. However, slamming of data in a statistical package without accounting for errors or

only reporting the experiment that works would be like making a milkshake with expired milk no matter how good it looks, it tastes sour. The process of getting the right results by using the laws of probability is what some researchers commonly refer to as data fudging. This process of data fudging can be difficult to detect unless a whistleblower decides to pull the plug.

Nearly all cases of scientific fraud that have led to successful prosecution needed inside knowledge inevitably provided by a whistleblower. The role of whistleblowers has been recently highlighted by recovering billion of pounds following the successful prosecution of fraudulent researchers (Kesselheim and Studdert, 2008). Whistleblowers usually represent the victory of consciousness and truth over matter and corruption. However, as the researcher has explained before, not all research is pure and bias or misrepresentation can be accepted by the scientific community and might be extremely difficult to prove as fraud. Therefore, the person who wants to blow the whistle need to be absolutely sure that the intention of fraud is clear beyond suspicion and that there is enough evidence gathered. The other issue concerns protection laws for whistleblowers. This would mean protective employment laws and the legal support for unfair dismissal.

As highlighted by the committee set up by Rikshospitalet and the University of Oslo to investigate the fraudulent claims made by Jon Studbo, the impact of such a fraud would have had ramifications on cancer patients worldwide. The results of Studbo's research would have been used by other medical researchers worldwide to treat patients at risk of oral cancer thus treating patients unnecessarily in addition several trials were underway to copy Jon Studbo's astonishing findings. This would have wasted public and charity funding that otherwise would have benefited other genuine research with cancer patients.

Fraud in research can be damaging to all those who are involved. The fraudster may face career devastation and lose all academic merit and in addition to retraction of key publications and other higher degrees, the fraudster may eventually face prosecution and jail sentence. In medicine, the researcher spends years of work establishing a career which can be ruined by the selfish needs to promote such a career in the first place. The journal where the study is published faces scrutiny and defamation. The editor will be under pressure to resign or introduce further measures to prevent this from happening thus delaying good research from finding its way to the journal. The funding body will be under pressure to pull out funding, thus good researchers jobs lost and more bureaucracy put in place to add to the

mounting hurdle of grant applications. The public will lose trust and become sceptical with any scientific discovery. This means that years of further research would be needed to reproduce results before any effective treatment is available and thus potential lives lost in the process.

CONCLUSION

The notion that science is self regulatory is practically over. The fact that research goes through a filtering system of ethical approval, peer review and reproducibility does not mean that the study we read as researchers and clinicians is necessarily evidence based medicine. In order to prevent fraud, independent supervisory bodies need to be established with powers to intervene and implement corrective measures. However, these bodies whether independent or public need to be on the side of the researchers facilitating their work and at the same time easing the pressures to commit fraud such as time restraints and funding constraints.

In the story, the Owl Who Was God, the hawk realised who the fraudster was because he was aware of the facts but lacked the power to intervene. Legislation could be the other arm that would act as a possible deterrent for the future.

The research team also takes responsibility for ensuring coordination of findings and experiments and carry the responsibility to limit gift authorship that has plagued many research studies to an extent an observer only needs to read the department where the study was conducted to guess the names of the researchers. Finally, an international effort is really mandated by the scientific community to prevent further cases of fraud. This can be done by agreeing on a definition for research misconduct and fraud. Organised measures need to be put in place to prevent such acts and when things do go wrong there need to be transparent process of accountability.

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