**Title:** Fraud and deceit in medical research: 'Sirens on the way to Ithaca' and current perspectives

**Short Title:** Fraud and deceit in medical research.

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**Abstract**

The role of medical research is fundamental in growing and spreading medical knowledge. However, the way it is conducted and subsequently published has been questioned on many occasions. Fraud and deceit have always represented a major issue in medical research and have been characterized as an "endemic". Fabrication, falsification, plagiarism, wasteful publication and irresponsible authorship are different types of this unethical phenomenon. Research misconduct could cause an erosion of trust in the validity of research and secondly, fraud may lead to dangerous medical practice and cause harm to patients. Although some action has been taken over the last years, it is of primary importance that the responsible organizations and regulatory bodies should continue reviewing the guidelines and putting limits to over publication and attempts for fraud. However, this problem is extremely hard to be eradicated.

**Keywords**: fraud, deceit, plagiarism, medical research

**Introduction**

Fraud and deceit have always been a significant issue in medical research. In 1991, the Royal College of Physicians in the United Kingdom stated that "Fraud in science has a long history".1 In our days, even though the volume of published work is markedly increased and it is practically impossible to tell how much fraud occurs, several cases of misconduct have been revealed. This fact has been specifically noted since the late 1980s, continued during 1990s and it has been suggested that fraud now is "endemic in many scientific disciplines and in most countries".2

The estimated incidence of misconduct varies between 0.1% and 0.4%. According to Claxton, this number is smaller and after reviewing 11 journals between 1994 and 2003 he supported that the percentage of fraudulent papers was 0.018%.3 More recently, an article in Nature in 2005 revealed that there was a 0.3% of scientists who admitted having fabricated data and a 1.4% who admitted having committed plagiarism.4 More recently, higher percentages of clinical trials researchers who admitted fabrication or falsification have been reported (pooled weighted estimate 14.1%).5

There are many examples described in the literature regarding research misconduct. Still, one of the most famous ones is that of Malcolm Pearce and Geoffrey Chamberlain. They published a paper claiming successful re-implantation in an ectopic pregnancy and full-term delivery, which had never happened. The fraud was revealed by a junior researcher, which led to Pearce being struck off the medical register and Chamberlain resigning.6

**Analyzing the terms**

Aiming to analyse fraud and deceit in medical research, it is of vital importance to define those two terms. Fraud is defined as "the crime of deceiving somebody in order to get money or goods illegally or a person who pretends to have qualities, abilities etc. that they do not really have in order to deceive other people". Deceit, on the other hand, is a "dishonest behavior that is intended to make somebody believe something that is not true" .7Another more specific definition for scientific fraud is any "behavior by a researcher, intentional or not, that falls short of good ethical and scientific standards" .8

**In search of reasons for this phenomenon**

In order to have a closer look at the problem, it is worth trying to find the causes that may lead to fraudulent publishing. In general, the primary purpose of writing is "to inform and instruct others". Specifically, in medical research, this process aims at improving healthcare and helpinng mankind.9 A possible derogation from this target can probably be due to the pressure to publish while pursuing academic advancement and career promotion. The phrase "publish or perish" that is commonly seen in the literature reflects this ongoing pressure. Also, fame and money associated with research and its outcomes can play an essential role in the increase of scientific misconduct.10 Towards this direction, Angell supports that the highly pressurized environment in which medical research is carried out has given rise to fraud and deceit.11 In his paper, Angell underlines the need for even more publishing aiming for promotion and funding. This leads to rapid and maybe invalid results produces many trivial studies and also increases the problem of authorship, where people who are only marginally involved are listed as authors. Biased trials and fraudulent research results may also be a result of the financial influence of pharmaceutical companies in order to favor the company's products. Richard Smith stated that "medical journals are an extension of the marketing arm of the pharmaceutical industry" 12 and that is in accordance with Angell's studies, which depicted the biased nature of some trials, not only by selectively promoting positive results in order to praise and promote a drug which normally shouldn't cause any enthusiasm, but also by suppressing any negative results that may show up.13 Besides all these potential causes, we should not omit but take into consideration unintentional fraud and deceit. Lohsiriwat supported in his article that there may be a misinterpretation of information mainly in the beginning of complex clinical trials which may affect the measurement of outcomes, probably not intentionally but has equally significant effects on public health.14

**Aspects of fraud and deceit in medical research**

At this point, it would be useful to have a closer look at the various aspects of fraud and deceit in medical research. There are several types of fraud but the main two are publication fraud and clinical trial fraud.15 Fraud in its most serious form may involve forging an experiment, manufacturing of data, promoting data or a certain drug discarding others that would not favor the result demanded, even presenting data from experiments that were never done, as it was mentioned in the Pearce case.9 Forging is completely unethical and apparently it is not compatible with research ethics.

**Plagiarism: a common form of fraud**

Apart from the previously mentioned problems, plagiarism is also a commonly observed unethical practice. As it was defined by John Armstrong, plagiarism is the "failure to assign credit for ideas, data or language of one's own or another's writing" .16 Plagiarism in more simple words can be described as copying or even paraphrasing someone's ideas, work or research results without mentioning his name can either be accidental (unintentional) or deliberate (intentional). In extreme circumstances, it can present as using published or even unpublished ideas under new authorship.17 Also, one can include in this category the failure of the author to attribute referencing for the original parts he is using. Although plagiarism is considered as an unethical technique and a serious aspect of deceit, a lighter version of plagiarism can be described and that is self-plagiarism. This can be termed as an author's reproduction of his own previous publications or ideas, in the same or altered words.9,18 Plagiarism is an equally serious aspect of misconduct in medical research which may bring about various consequences for the person who is committing plagiarism.

**Concealing truth results**

Another example of intellectual dishonesty is concealing negative results or constructing positive results, frequently associated with financial funding from pharmaceutical industry or with grants given to an institution. Recording facts that do not reflect the truth is a significantly serious problem as it might hinder the advancement of science. One can deduce that it is very uncommon to have negative results published in the competitive setting of research. Equally infrequent is the possibility of concluding that the hypothesis of the research is false and having it changed by the author. Obviously, not necessarily every research has to prove that the hypothesis is right. In that case, the author should accept that the hypothesis is wrong and correct it. Failure to do that on purpose forms a behavior which is unethical as it supports a mistake, with all the consequences it can bring about for healthcare.9

**The role of statistics**

Statistical analysis is a useful tool in medical research but also may become a mean of deliberate deceit in order to promote a false hypothesis for the reasons that have already been mentioned. Forging of results, selective reporting of findings, trimming, inappropriate use of statistical tests or inadequate sampling to prove the hypothesis may alter the whole concept of research and lead to adverse outcomes. 19Ignorance is another issue with less significance maybe but leading to the same results. This may exist due to a lack of training or the absence of statisticians in the research team.

**Conflict of interest**

Deceit also appears as inappropriate citing. From the reviewer's aspect, misconduct in research may occur when there is conflict of interest which exists "when a participant in the peer review and publication process – author, reviewer and editor – has ties to activities that could inappropriately influence their judgment, whether or not judgment is in fact affected" .20,21

**Wasteful publication: undermining the ethic of honesty**

A minor phenomenon that cannot be considered dishonest but can be characterized as unethical is wasteful publication. In this broader category of wasteful publication, "salami slicing" technique, duplicate publication, inappropriate publication and padding of articles can be included. "Salami slicing" is a technique where the data of a research are divided in a way to produce more than one articles using the same set of data instead of reporting all the data in the same paper.22 It is a kind of waste of resources, as every different article needs a separate process of publication, without eventually contributing to the literature and generally speaking to science as much as an original article could do.9 Duplicate publication occurs when the same article is published in more than one journals or when an extension to a previously published article is reported. This is probably done only for personal reasons and career improvement and it deviates from the initial aim "to inform and instruct others" while it destructs the attention of the readers and it is definitely not a good practice. A characteristic proof for the extend of misconduct is a review of 660 journals which demonstrated that 3% were dual publications and furthermore they led to 77 "salami slicing" publications.23 Inappropriate publishing can be described as a publication in a way that is not meaningful for the reader or it is not published to the appropriate journal. Finally, padding articlesleads to the article taking up more journal space, with the author trying to emphasize as much as possible on the points he wants to prove instead of actually informing the reader.9

**Irresponsible Authorship**

Another issue is authorship and the question raised is who should be included as an author in a published article and whose name must be cited first. Unfortunately, more and more people are included as authors in the context of competition and pressure for academic advancement. Consequently, an article may end up having dozens of authors, some of whom have little or even no active contribution or they may be included just because they are in the close circle of the author. According to the guidelines introduced by the International Committee of Medical Journal Editors, an author should be involved in 1) the conception and design of the study and /or analysis and interpretation of the data, 2) drafting the article or significant involvement in revision and 3) final approval of the version to be published.20,24 Thus an author must be fully aware of the content of the published article and he is responsible for checking the honesty of the data included. Most journals have specific regulations of authorship considering the degree of participation of each doctor.9,25

**The role of the whistleblowers**

We should not forget to mention whistleblowers, those people who know about fraud in medical research and do report it, while others chose the route of apathy and try to conceal it. According to a study conducted by Ranstam et al. in 1999, 51% of the biostatisticians they interviewed knew about fraudulent projects. This percentage confirms that turning a blind eye is not such an uncommon phenomenon. The same article underlines that most of the scientists interviewed believe that the strongest motive for fraud is career advancement and power and also that the fraud committed is a significant problem for medical practice. In addition, it is interesting that a rather substantial number of scientists (63%) do not know if the organisation they work for has a system for handling suspected fraud or not, or do know that such a system does not exist.2 In that case, one should refer to the editor or even better, discuss it beforehand with the person involved or a more experienced colleague in order to get guidance about how he should act. Apparently, the next step is to inform the responsible institution formally or ask Committee of publication Ethics (COPE) for advice.26 Whistleblowing may also have a negative effect not only on a personal basis for the scientist who is reporting the fraud but also on the institution's reputation, which may lose grants and industry support. A characteristic example of apathy from the institute's side is the Olivieri example. In 1989 Dr Nancy Olivieri was studying the effectiveness of deferiprone as a treatment for thalassaemia. In 1996, Dr Olivieri found out that the drug was not effective or causing liver toxicity in some patients and reported those findings. Then, the drug manufacturer disputed her results and also tried to suppress her evidence. Her institution, the University of Toronto, instead of supporting her honest behavior, closed down her laboratory and dismissed her. Only after several years she was restored to her position, after the intervention of the Canadian Association of University Teachers.27

**The detrimental effect on medical research**

In order to evaluate the extent of the problem, one should consider the consequences of fraud. We could summarize them in two points: firstly, there will be an erosion of trust in the validity of research and secondly, fraud may lead to dangerous medical practice and cause harm to patients.26 It is evident that when a patient agrees to treatment declares that he trusts the doctor and his methods. The same happens when a patient accepts to take part in a clinical trial. In that case, the doctor has to provide adequate explanation about the methods and the procedures. Apparently it is necessary to obtain the patient's consent if he is sure that everything is understood.28 Any erosion of the relationship between doctor and patient caused by the attempt to deceive is not only unethical but also dangerous, as it may have serious implications in healthcare, putting the patients to even more risks due to the wrong results.10 It is also worth describing the possible consequences on personal level, regarding the doctor or researcher who commits fraud. While in the beginning the doctor gets all the benefits and reputation, this behavior may sooner or later lead to a disaster. It is not only the personal embarrassment but the legal costs as well. When there is suspicious behavior or evidence, the researcher can be referred to the professional conduct committee of the General Medical Council (GMC). This person could also be prosecuted for the criminal offence of deception with intends to defraud by the police, in or outside the United Kingdom. Generally, the first way seems to be preferred, as it is a much shorter process to be carried out. It is the Professional Conduct Committee which will decide whether the accused researcher will be admonished, suspended or struck off the medical register.15 There are several examples for both ways of punishment: between 1989 and 1997, 16 cases were referred to GMC. All were found guilty of serious professional misconduct, three were suspended for periods of three to six months, four were cautioned and the remainder had their names erased from the Medical Register.29 There is also an example of a researcher in the United States who was jailed for fraud in research. It was Eric Poehlman in 2006.30 In addition, it should be mentioned that there is definitely damage to the reputation of any other doctors contributing to such research and of course to the reputation of the hospital or university where the fraudulent scientist works.

**Taking actions**

Finally, of vital importance is to act and create measures and guidelines towards reducing fraud and deceit in medical research. COPE was founded in 1997 and aims to give advice, discuss, provide training and guidance on good practice and give a proper response to inappropriate behavior.26,31 A similar organization is created in the United States, it is the Office of Research Integrity (ORI), and has adopted a similar role to COPE.3 In addition to that, there are already accepted guidelines of Good Clinical (Research) Practice that are applied not only in Europe but in the whole developed world. Several improvements have been made at a European and international level. In 1996 the international GCP guidelines were adopted in the International Conference of Harmonisation (ICH). The scientist should be aware of these guidelines, they should be included in training and this will prevent any kind of misconduct and will give the opportunity to trace fraud easier.15 In January 2017, the Parliamentary Office of Science and Technology (POST) initiated a formal inquiry into trends and developments on fraud, misconduct and mistakes in research and the publication of research results.32 Although there are various regulatory organizations, none of them has any legal power and consequently they cannot police or punish scientific journals.33

**Preventing scientific misconduct**

In 2000, NHS published a research governance framework in order to stop fraudulent behavior. It sets the standards, monitoring mechanisms and the rules which are useful in two axons: firstly the integrity and the quality of research and secondly the well being of the participants.34 Other essential action can be to teach ethics on medical research to medical students, involve in a more active way research supervisors and make the journals to update their instructions to authors, create a "roof" for the number of articles they accept and address issues as conflicts of interest not only for the authors but for the reviewers and editors as well.31 Furthermore, as fraud can be potentially caused by the amazingly large amount of research conducted, Petersdorf suggested that universities and research institutes should select carefully the personnel they employ and reduce any excessively large groups. These measures, in combination with close supervision of the researchers' work may help to weaken the phenomenon of misconduct in research.33

**Conclusion**

Medical research should follow the fundamental principle of medical ethics according to the Hippocratic oath, which is "beneficence and non-maleficence". That means that any medical trial, research or publication has to be conducted for the development of science and improvement of medicine and contribute to public healthcare. As long as academic competition exists, pharmaceutical companies press for positive results and there is a thirst for reputation, fraud and deceit will not vanish. It is up to every doctor and researcher to respect and follow the ethical rules and the existing guidelines, as deceit in a significant degree is a matter of attitude. At the same time, the responsible organizations and regulatory bodies should continue reviewing the guidelines and putting limits to over publication and attempts for fraud, although this problem is extremely hard to be eradicated.

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