

Fraud and Deceit in Published Medical Research

Varut Lohsiriwat MD*,
Supatra Lohsiriwat MD**

* Department of Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok
** Department of Physiology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok

Medical research casts a great impact on health of the entire human population so it must be conducted and publicized without dishonesty or bias. Any misrepresentation can have extremely serious consequences for patients and clinical practice. Unfortunately, fraud and deceit have increasingly been detected and have become a problem in today's research. They are falsification, fabrication, plagiarism, and deliberate use of inappropriate statistical analysis. It is sometimes difficult to differentiate fraud from incompetence, errors, bias, and misunderstanding. Many fraudulent articles are still undercover. The question is how to detect and prevent the fraud and deceit in medical research. In addition, the system of handling research misconduct is still lacking. Critical audit and inspection are required to diagnose it. There is no standard guideline to treat fraud. Prevention is the best way of treatment. This relies on research institutions, editors of journals, citing authors, and, most of all the researchers who must adhere strictly to medical professionalism, which is solely based on honesty and ethics to self-regulate and conduct only ethical and genuine research.

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Medical research is unique in the general field of scientific exploration in that it has a dramatic and life-changing impact on the health of the entire human population. It follows that this type of research must be characterized by impeccable ethical standards. Both the search for truth and its reporting must be conducted without dishonesty or bias.

Unfortunately, some research falls short of the probity required. In their enthusiasm to win professional recognition, some researchers are guilty of fraud and deceit, such as faking data or using unethical methods. Such misrepresentation can have extremely serious consequences for patients and clinical practice.

Research fraud did occur before the mid-twentieth century⁽¹⁾. The number of fraudulent articles has increasingly been reported in a wide range of medical literatures especially in the last two decades. The objective of the present study was to delineate the

crucial aspects of this particular problem in today's medicine.

Definitions

According to Oxford advanced learner's dictionary of current English⁽²⁾, 'fraud' means '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' and 'deceit' means 'dishonest behavior that is intended to make somebody believe something that is not true'. Misconduct is another word that can be used instead of fraud and deceit, which was referred to an unacceptable or dishonest behavior of someone in a position of authority or trust. Fraud has recently expanded beyond money because some people make fraudulent documents to achieve certifications or degrees.

The Deutsche Forschungsgemeinschaft, the German main research funding body, gave the definitions of misconduct as follows: falsification and fabrication of data, selective use of data without making it

Correspondence to : Lohsiriwat S, Department of Physiology, Faculty of Medicine, Siriraj Hospital, Mahidol University, Prannok Rd, Bangkok 10700, Thailand. Phone: 0-2419-8077, Fax: 0-2411-5009. E-mail: sislr@mahidol.ac.th

explicit, manipulation of graphs and figures, use of false information in grant and job applications, destruction of primary data, sabotage of others' work and plagiarism⁽³⁾.

Nevertheless, it is sometimes difficult to differentiate fraud from incompetence, errors, bias, and misunderstanding⁽⁴⁾. Incompetence is defined as unqualified, not capable, or unfit to perform a specific task. Errors can be defined in terms of mistakes in the process of eligibility criteria, measurement, and investigation without intention to fabricate the data. Errors may be random or systematic. Bias is usually defined as a prejudice or partiality, whether conscious or not. The authors can, unintentionally introduce bias into the study design, the study conduct, and the analysis of the results. In addition, the authors' prejudices can enter into the interpretation of the analysis.

Are fraud and deceit in published medical research a common problem?

The US Office of Research Integrity has investigated almost 3,000 allegations of possible misconduct since 1992 of which, nearly 200 research projects were cases of misconduct⁽⁵⁾. For the years 2000-2002, the PubMed database recorded 78 retracted articles and 60 letters of retraction. This is approximately 0.02% of scientific manuscripts that were published each year in journals covered by PubMed⁽¹⁾. In accordance with published data in Nature in 2005, 0.3% of scientists admitted to fabricating data, 1.4% to plagiarism⁽⁵⁾. However, the real problem may be far more frequent than detected and published.

In the past, discussions of fraud have mostly focused on clinical trials because the results of clinical trials have more direct medical consequences than epidemiological studies and that regulatory authorities control the conduct trials. However, the international survey of biostatisticians by Ramstan et al⁽⁶⁾ in 1998 revealed that fraud might be more prevalent in epidemiological studies than in clinical trials.

There are many different forms of fraud and deceit in medical research including fabrication and falsification of data, deceptive reporting of results, deceptive design or analysis, throwing away negative results and reporting only positive results (data suppression or holding), misleading presentation, careless reviewing of post doctoral fellows and graduate student's outcomes, and allegedly stealing someone's data. Inappropriately admitting their names as authors on papers and changing a study's design to satisfy sponsors should also be considered as fraud.

In medicine, fraud erodes many parts of the medical development where trust and integrity are essential for progress from research to research. This particular problem is indeed much larger than people realize. Most of the fraudulent research is still under-cover and neglected. The considerable question is how the authors can detect and prevent the fraud and deceit in medical research.

Patterns of fraud and deceit in published medical research

There are four common methods in conducting fraudulent research⁽¹⁾. The first one is "fabrication" that is the process that researchers produce their data to deceive people without either any material or patients. A hallmark of the fabrication is a lack of variability in the reported data. The second one is "falsification" which is the process whereby researchers change some of their data to more desirable results corresponding to the objective of studies or repeat an experiment until the right results are arrived at. The third one is "plagiarism" which is to duplicate data or statements from previously published literatures. Plagiarism also includes using the ideas or data of another as one's own and using those ideas or data without appropriate credit or compensation. In addition, the last one is "deliberate use of inappropriate statistical analysis" that may falsify the results of studies.

Example of dishonestly fraudulent research

One of the most terrifying frauds in medical research is the fraudulent human embryonic stem cell research using somatic cell nuclear transfer in South Korea, which has now been retracted from Science. This notorious research became front-page news at the end of 2005 when Dr. Woo Suk Hwang, the South Korean stem cell researcher, admitted to fabricating data about cloned human embryonic stem cell lines that he claimed were created from patients⁽⁷⁾. Although TIME magazine included Hwang in a list of "People Who Mattered 2004", much of the press coverage recently focused on the fallout of Hwang's actions not only on the poor image of stem cell research but also on the public's trust in science.

Why do the fraud and deceit in published medical research occur?

There are multiple agents and agencies which may contribute to fraud, including researchers (research students, junior researchers, senior researchers or even professors), research institutes or hospitals,

journals and research sponsoring bodies (drug or health-product companies).

There are many pressures on researchers that may lead them to commit misconduct in their research such as pressure to secure grants, pressure to publish articles for advancement in professional career and financial incentives from pharmaceutical companies.

Researchers are usually motivated by the desire to become well-known. In order to increase a researcher's number of publications, an author or group of authors unsuitably duplicate production of the same study into more than one journal. Sometimes, the author inappropriately divided a single study into multiple papers by using a different number of samples or substantial overlapping with one paper already published, known as "salami" work.

Sometimes, the fraud and deceit in medical research unintentionally happened. For instance, the clinical trials are often complex, and therefore a misunderstanding or incompetence of some aspect can be encountered, especially in the early stages of the trial⁽⁴⁾. If the researcher has misunderstandings in measurement of primary outcome, it will seriously jeopardize the trial. Thus, the faulty results of that clinical trial can have a direct and immediate impact on health care and health-care policy.

The failure of senior staff to detect the fraud earlier and the failure of fellows and assistants to alert higher-ups were also reported. In the case of Hwang et al's research, basic principles of individual integrity (intellectual honesty and accuracy in representing contributions to research) were violated⁽⁸⁾. Not only were data fabricated, but also there were fundamental misunderstandings among the researchers about their responsibilities as authors.

Research sponsors need some beneficial effects or the research that have positive impacts on their product. They may provide some financial support or commission to researchers. Sometimes, pharmaceutical companies hire physicians, mainly well-known pioneers in that particular field, to review the paper on some clinical trial especially for a new drug where they did not get involved in the preparation of manuscript⁽⁹⁾. This may cause bias in its favor. The journals also contribute to research misconduct because they are often unwilling to consider negative studies.

In addition, the system of handling research misconduct is still lacking. It is evident that it is relatively simple to fabricate data and get it published in a reputable medical journal. In the majority of cases, it

will be literally impossible for reviewers and editors to detect fraudulent data⁽¹⁰⁾.

Diagnosis of fraud and deceit in medical research

Fraud is often hard to detect and prove, and thus it is not easy to determine the limits of fraudulent activity in the research⁽¹¹⁾. Although there are many specific organizations to detect and investigate fraud and deceit, the methods of detection are based on general principles of commonsense rather than formal approach. In addition, it is impossible to examine every submitted paper for fabrication and falsification. It is also extremely difficult to detect these abuses before publication.

Critical audit and inspection are required to diagnose fraudulent research⁽¹²⁾. The detection of fraud needs good cooperation from many staffs and institutes to achieve this work. For example, biostatisticians working together with physicians and scientists in many branches of medical research have unique insight into data. In addition, they have methodological competence to detect fraud and could be expected to have a professional interest in valid results. Biostatisticians can also provide reliable information on the characteristics of fraud in medical research⁽⁶⁾.

Whistle blowers, external editors and researchers from other centers who performed similar studies, are needed to draw attention to the possibility of fraud because they are usually fair and unprejudiced. Most whistle blowers are senior academics. They can inform the fraud detectors regarding the research in some special fields⁽¹³⁾.

Treatment of fraud and deceit in published medical research

There is no standard guideline developed to treat fraud. There are only a few countries with a governmental system for evaluating allegations of scientific fraud. The journals themselves have little power. What they can do is only to refuse publishing work or to publish a retraction. Sometimes, there is insufficient evidence to conclude whether or not the research is fraudulent. The journal editors probably issued expression of concern about that article⁽¹⁴⁾. However, the major responsibility for investigation is based on institutions and funding agencies.

The most common actions of the scientific committee or research institution are composed of retracting the published article and punishing the guilty researcher^(5,15). The scientific community is responsible for notifying physicians and other people to ignore an

article containing faked data. In addition, the scientific community must try to prevent inadvertent citation of fraudulent article by “retraction of publication” and linking to electronic indexes of the medical literature, such as Ovid Medline and PubMed⁽¹⁰⁾. The other responsibilities of the scientific community are to verify the integrity of other articles published by the author of a fraudulent article.

Similar to criminals, the fraudsters should be punished under the criminal law because the fraud can adversely affect people and the health-care system. However, there is no precise law for scientific fraud. Hence, the dishonest professionals must be punished under the regulation of medical council. The punishment may include temporary suspension of medical license, cancellation of professional or academic position, loss of research contracts and barring from obtaining research grants. Nevertheless, the penalty of the co-authors and collaborators is still debated.

Proposals to improve regulation include incorporation of individuals in the process of deciding on sanctions and creation of more explicit guidelines for reporting and punishment.

Prevention of fraud and deceit in medical research

It is a fact that prevention is the best way of treatment. Because of the complexity of fraud and deceit in medical research, prevention of it should get involved in multiple modalities and multidisciplinary panels including a research committee, editors, citing authors and, the most important people, researchers.

Research institutions

Research institutions should educate researchers on their responsibilities as scientists and as role models. The teachers or researchers must make it clear to their students early in their training that research integrity is crucial and as closely linked to the right to practice as clinical integrity. The morality lessons including examples of fraudulent research should be mandatory in every course. Moreover, brochures or books on good research practice should be published and distributed to everyone. This method will improve education in medical research and increase opportunities for readers to get an insight into the proper details of conducting non-fraudulent research.

Research institutions may require international agreement on collecting data on scientific fraud to enable those policing medical researchers to make valid international comparisons. Research institutions should arrange a specific research committee to disci-

pline researchers, and propose measurement such as the random selection of grant reviewers to prevent accusation. The committee also set up a robust system to adequately manage and audit grants.

The international and national scientific committee, such as the Medical Council of Thailand and UK-based Committee on Publication Ethics, should develop publication procedures and guidelines for documentation of research results, which help prevent not only fraudulent behavior, but also other types of unethical or undesirable behaviors.

In the long term, the medical professional must develop other measures of success rather than rely exclusively on a number of publications in journals with high impact factors. For example, in Germany, promotion decisions are no longer dependent on quantitative measures but on quality and originality⁽³⁾.

Editors of the journals

Editors in chief of the relevant journals should initiate more extensive reviewing of submitted manuscripts by a larger panel of experts. Peer review is geared toward evaluating the study design, to gauge whether it supports the interpretation being made, and to determine whether the primary and raw data are true. Editors can ask for the raw data if necessary, but it must be informed in the instructions to authors. At the same time, confidentiality is an essential part of peer review to protect an author’s creative work from misappropriation.

Editors also set up many considerable options for providing additional procedural safeguards. There are many implications for journal policy. For example, the journal may require all authors to detail their specific contributions to the research submitted and to sign statements of concurrence with the conclusions of the work prior to publication. The journal should necessitate one author to claim major responsibility for the integrity of each submission. The members of the surgical journal editor group set up a consensus statement on surgery journal authorship in 2006 and conflict of interest must be disclosed⁽¹⁶⁾.

Citing authors

Citing authors should thoroughly review each referenced article before citing and consider whether it is a reliable article. Prior to submitting a manuscript, citing authors must check each referenced article if it has been retracted⁽¹⁴⁾. If it occurred, authors should retract that reference and replace it with the correct one.

Researchers

Researchers must adhere strictly to medical professionalism, which is solely based on honesty and ethics. Researchers, as professionals, have a responsibility to self-regulate and are supposed to conduct only ethical and genuine researches. Researchers should not have any result in mind that they have to demonstrate. However, they should carry out the investigation and see what happens. The research fellows should be encouraged to present their work on seminar. The young investigator's study including raw data should be reviewed by a supervisor at regular intervals⁽¹⁷⁾.

In terms of approval and validity of the genuine results, primary data should be securely stored for a certain period of time such as 5-10 years. Failure to obtain relevant research records, or their deliberate destruction, could be judged as negligence and possibly be punished.

In order to avoid plagiarism, researchers must appropriately acknowledge the source of the original idea or content. It is also better to paraphrase or rewrite the context in your own words rather than to quote the whole sentence or paragraph. It is essential that you refer to and cite your work properly.

Researchers must declare any interest they may have in a biomedical company or contract research organization⁽¹⁸⁾. This is very important to ensure that any opinions or decisions they give can be seen to be free of bias.

Conclusion

Fraud and deceit in published medical research is an international problem and requires an internationally integrated solution. All research institutions, granting committees, ethics committees and professional organizations should through mutual cooperation, set up guidelines defining good scientific practice (clinical and laboratory) and protocols for the management of suspected cases of fraud or unethical practice. Researchers must be made aware of these guidelines and the penalties they can incur if these standards are breached. These precautions and guidelines may effectively prevent and reduce the incidence of this event in the future.

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การโกงและการหลอกลวงในการตีพิมพ์งานวิจัยทางการแพทย์

วรุตม์ โล่ห์สิริวัฒน์, สุภัตรา โล่ห์สิริวัฒน์

งานวิจัยทางการแพทย์มีบทบาทและมีผลกระทบอย่างใหญ่หลวงต่อสุขภาพของมวลมนุษยชาติ ดังนั้นงานวิจัยจึงต้องดำเนินและเผยแพร่อย่างซื่อสัตย์ ไม่มีอคติ การนำเสนองานวิจัยที่ไม่ถูกต้องสามารถนำไปสู่ผลเสียอย่างร้ายแรงต่อผู้ป่วยและเวชปฏิบัติได้ แต่งานวิจัยที่โกงและหลอกลวงก็ยังคงมีอยู่ และเป็นปัญหามากขึ้น โดยแบ่งได้เป็น 4 กลุ่มใหญ่ ได้แก่ ผลงานปลอม การตกแต่งข้อมูล การขโมย และการใช้วิธีทางสถิติอย่างไม่เหมาะสมเพื่อให้ดูดีในบางครั้งอาจเป็นการยากที่จะแยกผลงานโกงเหล่านี้จากความผิดพลาดที่เกิดขึ้นจากการด้อยความสามารถ ทำผิดพลาด มีอคติ และความเข้าใจผิด งานวิจัยมากมายที่โกงไม่ได้ถูกเปิดเผย ปัญหาอยู่ที่ว่าเราจะทราบและป้องกันได้อย่างไรว่างานวิจัยนั้นโกงและหลอกลวง ระบบที่สามารถจัดการกับงานวิจัยที่มีความประพฤติผิดแบบนี้ได้ยังขาดอยู่ คงต้องอาศัยการตรวจสอบและการตรวจตราอย่างละเอียดที่เข้มงวด แม้ว่าจะยังไม่มีแนวทางที่เป็นมาตรฐานเพื่อเยียวยาการโกง แต่การป้องกันก็น่าจะเป็นวิธีเยียวยาได้ดีที่สุด การป้องกันต้องอาศัยสถาบันของผู้วิจัย บรรณาธิการวารสารที่รับตีพิมพ์ เจ้าของบทความที่ถูกอ้างอิง และกลุ่มที่สำคัญที่สุดคือนักวิจัยซึ่งต้องยึดจรรยาบรรณทางการแพทย์ ที่มีพื้นฐานอยู่บนความซื่อตรงและจริยธรรมเพื่อควบคุมตนเอง และทำแต่งงานวิจัยที่แน่นแฟ้นและถูกต้องตามจริยธรรมเท่านั้น
