

Fraud and Deceit in Medical Research: Insights and Current Perspectives

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ABSTRACT

The number of scientific articles published per year has been steadily increasing; so have the instances of misconduct in medical research. While increasing scientific knowledge is beneficial, it is imperative that research be authentic and bias-free. This article explores why fraud and other misconduct occur, presents the consequences of the phenomenon, and proposes measures to eliminate unethical practices in medical research. The main reason scientists engage in unethical practices is the pressure to publish which is directly related to their academic advancement and career development. Additional factors include the pressure to get research funds, the pressure from funding sources on researchers to deliver results, how scientific publishing has evolved over the years, and the over-publication of research in general. Fraud in medical research damages trust and reliability in science and potentially harms individuals.

Keywords: Fraud, Misconduct, Undue influence, Research Ethics, Publish, Unified Patient Lobby

INTRODUCTION

Since the introduction of Evidence-Based Medicine (EBM) in the early 1990s, scientific articles published per year have increased steadily. No one knows the exact number of scientific articles published per year, but several estimates point to around 2,000,000.¹ EBM aims to integrate the clinical experience and the best available scientific knowledge in managing individual patients.² The EBM model is based on the accumulation of as much clinical and research data as possible, which has propelled a significant rise in research. Unfortunately, its incentive structure has also led to a rise in research misconduct.

“Fraud in science has a long history.”³ Cases of misconduct began to surface in the late 1980s and increased during the 1990s. Experts suggest that today fraud is “endemic in many scientific disciplines and in most countries.”⁴ In recent reporting, the majority of cases of scientific fraud involved falsification and fabrication of the data, while plagiarism was much less frequent. 8 percent of scientists and 10 percent of

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medical and life-sciences researchers admitted to falsifying data at least once between 2017 and 2021 in a Dutch study of 6,813 researchers, while more than half engaged in at least one questionable research practice.⁵ Questionable research practices include research design flaws or unfairness in decisions surrounding publication or grants.⁶ In an older study, closer to 2 percent of those surveyed reported having engaged in falsification or fabrication,⁷ while in a more recent survey of 3,000 scientists with NIH grants in the United States, 0.3 percent of the scientists responding admitted fabricating research data and 1.4 percent of them admitted plagiarizing.⁸ These numbers are almost certainly not reflective of the true incidence of fraud as many scientists admitted that they engaged in a range of behaviors beyond fabrication, falsification, and plagiarism that undermine the integrity of science, such as changing the results of a study under pressure from a funding source or failing to present data that contradicts one's previous research. It is also unclear whether surveys are the best method to investigate misconduct because a scientist answering the survey may be unsure of anonymity and may not be truthful.

This article explores why misconduct occurs, presents the consequences, and proposes measures to eliminate unethical practices in medical research. In the 1999 Joint Consensus Conference on Misconduct in Biomedical Research, "scientific fraud" was defined as any "behavior by a researcher, intentional or not, that falls short of good ethical and scientific standards."⁹

ANALYSIS

I. The Scientific Publishing Landscape

There are several reasons scientists may commit misconduct and engage in unethical practices. There is an increasing pressure to publish, which the motto "publish or perish" reflects.¹⁰ The number of scientific papers published by a researcher is directly related to their academic advancement and career development. Similarly, academic institutions rely on scientific publications to gain prestige and access research grants.

Pressure to get research grants may create environments that make it challenging to research integrity. Researchers are often tempted to alter their data to fulfill the desired results, separately report the results of one research in multiple end publications, commonly referred to as "salami publication," or even simultaneously submit their scientific articles to more than one journal. This creates a vicious cycle in which the need for funding leads to scientific misconduct, which in turn secures more research funding. Meanwhile, the pressure from the funding sources cannot be overlooked either. Although researchers must report the role of the funding sources, selection and publication bias often may advantage articles that support the interests of the financial sponsor. Disclosure does not alter the conflict of interest.

The growing number of scientific articles published per year has practically overwhelmed the peer-review system. Manuscript submissions are often reviewed superficially or assigned to inexperienced reviewers; therefore, misconduct cases may go unnoticed. The rise of "predatory" journals that charge authors publication fees and do not review work for authenticity and the dissemination of information through preprints has worsened the situation.

The way that profits influence scientific publishing has very likely contributed to the phenomenon of misconduct. The publishing industry is a highly profitable business.¹¹ The increased reliance on funding from sources that expect the research to appear in prestigious, open-access journals often creates conflicts of interest and funding bias. On the other hand, high-impact journals have not given space to navigate through negative results and previous failures. Nonsignificant findings commonly remain unpublished, a

phenomenon known as “the file drawer problem.” Scientists often manipulate their data to fit their initial hypothesis or change their hypothesis to fit their results, leading to outcome-reporting bias.

II. Misconduct Concerning the Reporting and Publishing Data

The types of misconduct vary and have different implications for the scientist’s career and those relying on the research. For example, plagiarism is generally not punished by law currently unless it violates the original author’s copyright. Nevertheless, publishers who detect plagiarism implement penalties such as rejection of the submitted article and expulsion of the author. While plagiarism can be either accidental or deliberate, in either case, it is a serious violation of academic integrity as it involves passing off someone else’s “work or ideas” as one’s own.¹² Plagiarism can be “verbatim” (copying sentences or paragraphs from previously published work without using quotation marks or referencing the source) or rephrasing someone’s work or ideas without citing them. In “mosaic” plagiarism, the work plagiarized comes from various sources. “Self-plagiarism” is defined as an author’s reproduction of their previous publications or ideas in the same or altered words.

According to most scientific journals, all authors of an article in part must have contributed to the conception and design of the study, drafted the article, revised it critically, or approved of its final version.¹³ The use of a ghost author (usually a professional writer who is not named an author) is generally not ethical, as it undermines the requirement that the listed authors created the article.

Moreover, wasteful publication is another practice that contributes to misconduct. Wasteful publication includes dividing the results of one single study into multiple end publications (“salami slicing”), republishing the same results in one or more articles, or extending a previously published article by adding new data without reaching new conclusions. Wasteful publication not only skews the scientific databases, but also wastes the time of the readers, the editors, and the reviewers. It is considered unethical because it unreasonably increases the authors’ citation records. Authors caught engaging in such behaviors may be banned from submitting articles for years while the submitted article is automatically rejected. Wasteful publication is an example of how the pressure to publish more articles leads to dishonest behavior, making it look like a researcher has conducted more studies and has more experience.

Conflicts of interest are not strictly prohibited in medicine but require disclosure. Although disclosure of financial interests is a critical step, it does not guarantee the absence of bias. Researchers with financial ties to a pharmaceutical company funding their research are more likely to report results that favor the sponsor, which eventually undermines the integrity of research.¹⁴ Financial sponsors should not be allowed to influence publication; rather authors need to publish their results based on their own decisions and findings.

III. Misconduct in Carrying Out Scientific Research Studies

Common forms of fabrication include concealing negative results, changing the results to fit the initial hypothesis, or selective reporting of the outcomes. Falsification is the manipulation of experimental data that leads to inaccurate presentation of the research results. Falsified data includes deliberately manipulating images, omitting, or adding data points, and removing outliers in a dataset for the sake of manipulating the outcome. In contrast to plagiarism, this type of misconduct is very difficult to detect. Scientists who fabricate or falsify their data may be banned from receiving funding grants or terminated from their institutions. Falsification and fabrication are dangerous to the public as they can result in people giving and receiving incorrect medical advice. Relying on falsified data can lead to death or injury or lead

patients to take a drug, treatment, or use a medical device that is less effective than perceived. Thus, some members of the scientific community support the criminalization of this type of misconduct.¹⁵

Research involving human participants requires respect for persons, beneficence, justice, voluntary consent, respect for autonomy, and confidentiality. Violating those principles constitutes unethical human experimentation. The Declaration of Helsinki is a statement of ethical principles for biomedical research involving human subjects, including research on identifiable human material and data. Similarly, research in which animals are subjects is also regulated. The first set of limits on the practice of animal experimentation was the Cruelty to Animals Act passed in 1876 by the Parliament of the United Kingdom. Currently, all animal experiments in the EU should be carried out in accordance with the European Directive (2010/63/EU),¹⁶ and in the US, there are many state and federal laws governing research involving animals. The incentives to compromise the ethical responsibilities surrounding human and animal practices may differ from the pressure to publish, yet some are in the same vein. They may generally include taking shortcuts, rushing to get necessary approvals, or using duress to get more research subjects, all actions that reflect a sense of urgency.

IV. Consequences of Scientific Misconduct

Fraud in medical research damages science by creating data that other researchers will be urged to follow or reproduce that wastes time, effort, and funds. Scientific misconduct undermines the trust among researchers and the public's trust in science. Meanwhile, fraud in medical trials may lead to the release of ineffective or unsafe drugs or processes that could potentially harm individuals. Most recently, a study conducted by Surgisphere Corporation supported the efficacy of hydroxychloroquine for the treatment of COVID-19 disease.¹⁷ The scientific article that presented the results of the study was retracted shortly after its release due to concerns raised over the validity of the data.

Scientific misconduct is associated with reputational and financial costs, including wasted funds for research that is practically useless, costs of an investigation into the fraudulent research, and costs to settle litigation connected with the misconduct. The retraction of scientific articles for misconduct between 1992 and 2002 accounted for \$58 million in lost funding by the NIH (which is the primary source of public funds for biomedical research in the US).¹⁸

Of retracted articles, over half are retracted due to "fabrication, falsification, and plagiarism."¹⁹ Yet it is likely that many articles that contain falsified research are never retracted. A study revealed that of 12,000 journals reviewed, most of the journals had never retracted an article. The same study suggests that some journals have improved oversight, but many do not.²⁰

V. Oversight and Public Interest Organizations

The Committee on Publication Ethics (COPE) was founded in 1997 and established practices and policies for journals and publishers to achieve the highest standards in publication ethics.²¹ The Office of Research Integrity (ORI) is an organization created in the US to do the same. In 1996, the International Conference of Harmonization (ICH) adopted the international Good Clinical Practice (GCP) guidelines.²² Finally, in 2017 the Parliamentary Office of Science and Technology (POST) initiated a formal inquiry into the trends and developments on fraud and misconduct in research and the publication of research results.²³

Despite the increasing efforts of regulatory organizations, scientific misconduct remains a major issue. To eliminate unethical practices in medical research, we must get to the root of the problem: the pressures put on scientists to increase output at the expense of quality.

In the absence of altered incentives, criminalization is a possibility. However, several less severe remedies for reducing the prevalence of scientific misconduct exist. Institutions first need to foster open and frank discussion and promote collegiality. Reducing high-stakes competition for career advancement would also help realign incentives to compromise research ethics. In career advancement, emphasis should be given to the quality rather than the quantity of scientific publications. The significance of mentorship by senior, experienced researchers over lab assistants can bolster ethical training. Adopting certain codes of conduct and close supervision of research practices in the lab and beyond should also be formalized.

The publication system plays a critical role in preserving research integrity. Computer-assisted tools that detect plagiarism and other types of misconduct need to be developed or upgraded. To improve transparency, scientific journals should establish clear authorship criteria and require that the data supporting the findings of a study be made available, a movement that is underway. Preprint repositories also might help with transparency, but they could lead to people acting on data that has not been peer-reviewed. Finally, publishing negative results is necessary so that the totality of research is not skewed or tainted by informative studies but does not produce the results researchers hoped. Consistently publishing negative results may create a new industry standard and help researchers see that all data is important.

CONCLUSION

Any medical trial, research project, or scientific publication must be conducted to develop science and improve medicine and public health. However, the pressures from the pharmaceutical industry and academic competition pose significant threats to the trustworthiness of science. Thus, it is up to every scientist to respect and follow ethical rules, while responsible organizations, regulatory bodies, and scientific journals should make every effort to prevent research misconduct.

¹ World Bank. "Scientific and technical journal articles". World Development Indicators, The World Bank Group. https://data.worldbank.org/indicator/IP.JRN.ARTC.SC?year_low_desc=true.

² Masic I, Miokovic M, Muhamedagic B. "Evidence Based Medicine - New Approaches and Challenges." *Acta Inform Med*. 2008;16(4):219-25. <https://www.bibliomed.org/mnsfulltext/6/6-1300616203.pdf?1643160950>

³ Dickenson, D. "The Medical Profession and Human Rights: Handbook for a Changing Agenda." *Zed Books*. 2002;28(5):332. doi: 10.1136/jme.28.5.332.

⁴ Ranstam J, Buyse M, George SL, Evans S, Geller NL, Scherrer B, et al. "Fraud in Medical Research: an International Survey of Biostatisticians, ISCB Subcommittee on Fraud. *Control Clin Trials*. 2000;21(5):415-27. doi: 10.1016/s0197-2456(00)00069-6.

⁵ Gopalakrishna, G., Riet, G. T., Vink, G., Stoop, I., Wicherts, J. M., & Bouter, L. (2021, "Prevalence of questionable research practices, research misconduct and their potential explanatory factors: a survey among academic researchers in The Netherlands." *MetaArXiv*. July 6, 2021. doi:10.31222/osf.io/vk9yt; Chawla, Dalmeet Singh, "8% of researchers in Dutch survey have falsified or fabricated data." *Nature*. 2021. <https://www.nature.com/articles/d41586-021-02035-2> (The Dutch study's author suggests the results could be an underestimate; she also notes an older similar study that found 4.5 percent.)

⁶ Chawla.

⁷ Fanelli D. How many scientists fabricate and falsify research? A systematic review and meta-analysis of survey data. *PLoS One*. 2009;4(5):e5738. doi:10.1371/journal.pone.0005738

⁸ Martinson BC, Anderson MS, de Vries R. "Scientists behaving badly" *Nature*. 2005;435(7043):737-8. <https://www.nature.com/articles/435737a>.

- ⁹ Munby J, Weetman, DF. Joint Consensus Conference on Misconduct in Biomedical Research: The Royal College of Physicians of Edinburgh. *Indoor Built Environ*. 1999;8:336–338. doi: 10.1177/1420326X9900800511.
- ¹⁰ Stephen Beale “Large Dutch Survey Shines Light on Fraud and Questionable Research Practices in Medical Studies Published in Scientific Journals,” *The Dark Daily*, Aug 30, 2021. <https://www.darkdaily.com/2021/08/30/large-dutch-survey-shines-light-on-fraud-and-questionable-research-practices-in-medical-studies-published-in-scientific-journals/>
- ¹¹ Buranyi S. Is the staggeringly profitable business of scientific publishing bad for science? *The Guardian*. June 27, 2017. <https://www.theguardian.com/science/2017/jun/27/profitable-business-scientific-publishing-bad-for-science>
- ¹² Cambridge English Dictionary. <https://dictionary.cambridge.org/us/dictionary/english/plagiarism>
- ¹³ International Committee of Medical Journal Editors. Defining the Role of Authors and Contributors <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>
- ¹⁴ Resnik DB, Elliott KC. “Taking Financial Relationships into Account When Assessing Research.” *Accountability in Research*. 2013;20(3):184-205. doi: 10.1080/08989621.2013.788383.
- ¹⁵ Bülow W, Helgesson G. Criminalization of scientific misconduct. *Med Health Care and Philos*. 2019;22:245–252.
- ¹⁶ Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes. *Official Journal of the European Union*. <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:en:PDF>
- ¹⁷ Mehra MR, Desai SS, Ruschitzka F, Patel AN. “RETRACTED: Hydroxychloroquine or Chloroquine with or without a Macrolide for Treatment of COVID-19: a Multinational Registry Analysis.” *The Lancet*. 2020. doi: 10.1016/S0140-6736(20)31180-6.
- ¹⁸ Stern AM, Casadevall A, Steen RG, Fang FC. “Financial Costs and Personal Consequences of Research Misconduct Resulting in Retracted Publications,” *eLife*. 2014;3:e02956. doi: 10.7554/eLife.02956.
- ¹⁹ Brainard, Jeffrey and Jia You, “What a massive database of retracted papers reveals about science publishing's ‘death penalty’: Better editorial oversight, not more flawed papers, might explain flood of retractions,” *Science*, Oct 25, 2018 <https://www.science.org/content/article/what-massive-database-retracted-papers-reveals-about-science-publishing-s-death-penalty>
- ²⁰ Brainard and You.
- ²¹ Doherty M, Van De Putte Lbcope. Guidelines on Good Publication Practice; *Annals of the Rheumatic Diseases* 2000;59:403-404.
- ²² Dixon JR Jr. The International Conference on Harmonization Good Clinical Practice Guideline. *Qual Assur*. 1998 Apr-Jun;6(2):65-74. doi: 10.1080/105294199277860. PMID: 10386329.
- ²³ “Research Integrity Terms of Reference.” Science and Technology Committee, 14 Sept. 2017, committees.parliament.uk/committee/135/science-and-technology-committee/news/100920/research-integrity-terms-of-reference/.