Scientific Fraud: How Do We Ensure Sound Medical Literature?

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There have been some recent disturbing reports of scientific fraud over the past few decades, and the news is reaching the lay press.[1] The impact of fraudulent science goes far beyond the actual crime itself, although that is worrisome enough. Scientific fraud erodes the trust the public has in science and its practitioners. Even more concerning for clinical practitioners and researchers is the perpetuation of disinformation and contrived data poisoning of large language models (LLMs) and artificial intelligence (AI) outputs. Recently, to test AI, scientists intentionally invented a fake disease with a fake researcher and fake data in publications that included obvious clues the paper was suspect, such as a non-existent researcher (including a photo of the researcher generated from AI) and a non-existent university.[2] The impact of certain scientific challenges and communication issues during the COVID-19 pandemic has shaken the public's faith in the scientific community, the pharmaceutical industry, and global public health systems. Continued instances of scientific fraud and lack of action by the scientific community to combat it will have damaging effects on public health.

Sadly, scientific fraud has been with us for a long time. Gregor Mendel's celebrated work in pea plant genetics was, while not completely fraudulent, almost certainly "touched up" by the monk.[3] The "discovery" of the Piltdown man fossil in 1912 (which was exposed as a forged, manufactured "fossil" in 1953) was accepted for decades and had a significantly negative impact on anthropology.[4] These incidents in the natural sciences are treated as anomalies for the most part, and although damaging to the reputation of scientists and a substantial waste of resources to discover and correct the error, they have probably done little lasting harm over the span of time and persistence of validation in scientific discovery.

Scientific fraud in medicine has a much more insidious impact on society. The fraudulent work of Andrew Wakefield, who claimed to have found a link between the MMR vaccine and autism, continues to fuel mistrust in vaccines to this day, even though he was stripped of his medical license and both of his papers were retracted.[5] The continued mistrust of vaccines resulting from this fraudulent work by laypeople and even some in government may have contributed to an increase in the cases of childhood diseases, which were thought to be almost eradicated.[4] Papers on Alzheimer's disease produced by a prominent Stanford researcher were later found to contain manipulated images. Although the papers were later withdrawn, it took nearly a decade for this to happen[6] and resulted in a huge amount of wasted effort and time on the part of other researchers.

More recently, the Dana-Farber Cancer Institute agreed to a $15,000,000 fine to settle allegations that NIH funds were used to produce 14 publications that contained manipulated images.[7] This fine is likely a small fraction of the total amount of wasted resources devoted to replicating their fraudulent research, and again, it contributes to the public's mistrust in science.

Clinical pharmacology, as a discipline, has probably been less affected by fraud than the basic sciences. There are a few reasons for this. The first is that studies performed in either healthy participants or patients require a significant number of skilled personnel to do the work collaboratively with layers of oversight. In early clinical trials, the participants are typically confined to a study center, and plasma or other samples are collected frequently, which is unlike the bench researcher running Western blots alone in the laboratory. This means that outright fraud during the "experimental" portion of the clinical study (where samples are being collected) would require the collusion of several people. In addition, clinical study monitors regularly validate the data against source documents as the study is conducted. This means that any careless or fraudulent work may be caught early, before it can do any damage. An experience from one of the authors' pasts illustrates this. During a Phase 2 clinical trial, a participating site discontinued drug-of-abuse screening, despite this being a required element of the study's inclusion and exclusion criteria. The deviation was identified by a clinical monitor and promptly reported to the sponsor, who in turn notified the FDA without delay and excluded all data from the site.

While this incident incurred substantial cost, time, and operational burden, it did not compromise the study's scientific integrity. The affected data were removed from the analysis due to the site's failure

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Artificial Intelligence was not used to generate any of the text in this article

to adhere to protocol requirements, preserving the validity of the overall findings.

As a discipline, we should not be complacent about the existing checks and balances. AI has shown itself to be a very useful tool for those wanting to mislead the public, and the production of fraudulent scientific "research" will have far-reaching societal damage. AI has already been shown to be more than capable of generating convincing (but fraudulent) medical articles. Majovsky and colleagues, using ChatGPT and a series of simple prompts, created an article describing a nonexistent randomized clinical trial studying the effects of deep brain stimulation for depression.[8] The final article consisted of an abstract, an introduction, material and methods, results, and discussion, tables, and one figure, which was created by the authors from the data produced by ChatGPT. The paper was reviewed by an expert, who did note several problems with the paper (limited citations, shorter than a standard paper of this type), but overall judged it to have a high level of authenticity.[8] As discussed, there are other examples reported.[2,5] It does not take much to imagine that early clinical trial data could be generated in a similar manner, even submitting the "fake trial" to ClinicalTrials.gov (which does not review or approve the safety or science of the studies listed, nor require the inclusion of early stage trials), followed by the simulation of study data and results.

This capability to generate fraudulent data and report the results in scientific journal articles, coupled with the rise in "predatory" journals that do not provide editorial services and appropriate peer review, sets the stage for incalculable damage to medical science and practice. Steps need to be taken now to guard against the generation and publication of fraudulent clinical trials. Below are a few suggestions:

(1) This effort must begin with: (a) continued education of scientific researchers on ethics, the examples of the consequences of fraudulent research, and processes of quality assurance in research and (b) awareness of the far-reaching consequences of fraudulent data via disclosure, retraction, and impact on individuals.
(2) Journals should require written documentation of medical and study monitoring, as well as IRB/ethics board approval of each study intended for publication. This documentation should be signed by the clinical study monitor(s) responsible for the validation of source data, ensuring the integrity of study data. This alone would be a key step in stopping the inadvertent publication of fraudulent data in reputable journals.
(3) Consider requiring, as part of good clinical practice (GCP), that clinical study monitors be independent from the sponsors of the clinical trial itself. This may make producing fraudulent documentation more difficult. In addition, journals would have to independently verify the clinical study monitor's independence from the sponsor via documentation. Although this will add complexity to the publication of scientific data, the effort would safeguard the reliability of the scientific literature.
(4) University research should be subjected to quality assurance (QA) audits, similar to the processes in the pharmaceutical industry. Universities should fund QA groups capable of evaluating the scientific disciplines producing experimental or trial results and provide documentation of the QA review prior to publication in scientific journals.
(5) For submitted manuscripts, reviewers need to scrutinize references more thoroughly to ascertain that they are from real peer-reviewed journals and that the stated information is consistent with the cited publication. Ironically, this could be accomplished efficiently using AI.
(6) Importantly, laws pertaining to scientific fraud and the penalties for committing such fraud should be strengthened.

Scientific fraud in medicine is more than simply fabricating data—it can profoundly shape how laypeople engage with the health care system. Consider how many children went unvaccinated following Andrew Wakefield's claims linking the MMR vaccine. Wakefield continues to spread his anti-vaccine ideas.[9] Institutional review boards, governmental authorities, and institutions must adapt to the current risks and strengthen laws, policies, and penalties to better curtail fraud and misinformation in this new era.

There are common-sense steps that can be taken to protect the integrity of the medical literature and stop, or at least slow, the erosion of trust. The scientific community must act now to implement additional measures to curb scientific fraud in the medical literature.

Conflicts of Interest

The authors consult for the pharmaceutical industry.

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