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COUNTERCURRENT

Violation of research integrity principles occurs more often than we think

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ABSTRACT

The science community generally believes that the violation of research integrity is rare. Built upon this belief, the scientific system makes little effort to examine the trustworthiness of research. Research misconduct refers to an intentional violation of research integrity principles, which has an extensive and far-reaching impact on the trustworthiness and reputation of science. Emerging evidence has suggested that research misconduct is far more common than we normally perceive. Far more problematic papers should be retracted than are being retracted because of poor actions when confronting research misconduct. Research misconduct is usually driven by incentives in the form of pursuing publications for researchers' career needs and is further facilitated by poor research governance. The current strategy that tackles potential research misconduct focuses on protecting the reputation of authors and their institutions but neglects the interests of patients, clinicians and honest researchers. Removing improper incentives, training researchers and imposing better governance are vital to reducing research misconduct. Awareness of the possibility of misconduct and formalized procedures that scrutinize study trustworthiness are important during peer review and in systematic reviews.

INTRODUCTION

Research integrity is a complex concept that involves multiple dimensions. According to the definition of The Office of Research Integrity, responsible research is built on a commitment to four important principles: honesty, accuracy, efficiency and objectivity (*ORI, 2006*). Honesty asks researchers to convey information truthfully and to honour commitments; accuracy refers to reporting findings precisely and taking care to avoid errors; efficiency aims to use resources wisely and avoid research waste; objectivity demands researchers to respect facts, be transparent and avoid improper bias, including those arising from conflict of interest.

The health and medical research community generally believes that the effect is minimal because science is supposedly self-correcting. This assumption makes research easier as we can trust implicitly the methods and findings of each other's work without spending much time and effort scrutinizing it. In recent years, greater oversight of some components of research has been established; however, most of the scientific system, from the funding of research to the translation and implementation of findings, is built upon this assumption. Is there any chance this assumption could be wrong?

PREVALENCE OF RESEARCH MISCONDUCT IS UNDERESTIMATED

Research misconduct refers to an intentional violation of research integrity principles. Unintentional violations, such as ignoring errors and biases, will always occur and be more prevalent in circumstances in which expertise or presence of conflict of interest are lacking. Research misconduct has a more extensive and far-reaching effect on the trustworthiness and reputation of science, with deliberate fraud, including plagiarism, falsification and fabrication (*Titus et al., 2008*). Plagiarism is the appropriation of another person's ideas, processes, results or words without

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giving appropriate credit; falsification means manipulating research materials, equipment or processes, or changing or omitting data or results such that the research is not accurately represented when reported and published; fabrication refers to making up data, results or recordings, and reporting them (*ORI, 2000*). This opinion contribution focuses on research misconduct.

Chambers et al. (2019) systematically reviewed retracted notices of papers in obstetrics and gynaecology. From indexation until June 2018, a total of 176 articles were retracted, of which 40 (22.7%) and 37 (21.0%) were retracted because of plagiarism and data manipulation, respectively. These numbers, however, are likely to be underestimated because retraction notices and information on the publisher's website frequently used euphemistic language and concealed the real reasons, usually data fabrication, for retractions (*Li and Mol, 2019*). Also, fraud only comes to light if it is investigated. We have paid special attention to research misconduct in women's health since 2018, and our focused investigations revealed more problematic papers, particularly among randomized controlled trials (RCTs), the types of studies that purportedly generate the highest level of evidence for clinical practice. At least 20 RCTs have been retracted or issued with expressions of concern owing to problems with data validity since 2019 (*Li et al., 2021*), whereas hundreds of RCTs in women's health with apparent signs of misconduct are currently undergoing protracted investigations. These deliberations could, unfortunately, take years to conclude.

Just looking at retractions is far from sufficient to estimate the scale of research misconduct. There is a popular but fallacious argument that research misconduct is minimal given the low proportion of publications being retracted. It is true that only four in 10,000 (0.04%) of published papers have been retracted (*Brainard and You, 2018*), and the proportion of interest will further decline when considering only those that were explicitly retracted for fraud. Far more papers, however, should be retracted than are being retracted. In a review to characterize trials that have been retracted in women's health owing to data validity concerns, we found that it took a median of 11.2 years for these papers to be retracted (*Li et al., 2021*). This level of inactivity is not limited to women's health, and it is common for whistle-blowers in many fields to find that their warnings to journals and authors' institutions are met with silence, prompt denial or even threats of legal action against the complainant.

In 2009, a systematic review and meta-analysis of survey data found that 2% (range 0.3–4.9%) of scientists admitted to having fabricated, falsified, or modified data or results at least once (*Fanelli, 2009*). Interestingly, when asked if scientists were aware of a colleague who committed these behaviours, 14.1% (5.2–33.3%) of responders replied affirmatively.

Accessing first-hand information from research studies should provide a more accurate estimation of this prevalence. In an analysis of 526 RCTs submitted to *Anaesthesia*, a prestigious journal in that field, Editor John Carlisle found that 14% contained false data, and 8% he categorized as being 'zombies' (*Carlisle, 2021*). A further look into 153 randomized trials for which he had access to individual participant data, 44% had questionable data and 26% were categorized as 'zombie'. An assessment of meta-analyses evaluating ivermectin to treat COVID-19 showed that several RCTs had integrity problems or even were completely fabricated (*Lawrence et al., 2021*).

Research misconduct is often believed to be a 'shameful action of a few' and there is not much reflection on the system that had nurtured its rise. The system of biomedical research, which centres around peer-reviewed publication, inevitably stimulates research misconduct as a by-product. Investigators need to publish research, preferably frequently and of high impact, to advance their careers. Funders, universities and institutions have strong incentives to fund and hire prolific researchers. Publication is a successful business model for the publishers of journals. As institutions and journals are mostly self-regulatory, they do not have enough or any incentive to reveal known instances of research misconduct to the public. Both institutions and publishers that admit the discovery of fraud may experience reputational damage, possible legal risk, loss of trust and even revenue.

Even if journals and institutions have a strong will to safeguard research integrity, it could be challenging to gather adequate resources to fulfil the governance requirements, recognizing that proving research misconduct is technically challenging. As an issue that has long been neglected, few people are equipped with competent knowledge and experience to investigate research misconduct. The lack of will and relevant expertise explain why the evident research misconduct we have observed is just the tip of the iceberg. On top of that, there are no incentives for whistle-blowers other than searching for the truth, whereas raising concerns itself is time-consuming and brings considerable professional and personal risks.

PITFALLS IN INVESTIGATING RESEARCH MISCONDUCT

Publishers and journals should abide to retraction guidelines of the Committee on Publication Ethics (COPE) to investigate research misconduct. Unfortunately, the COPE guidelines are far from what would be required to resolve any concerns in an efficient and timely way. The process could be seriously delayed or even halted by inaction of authors and their institutions because it relies heavily on the response of the subject of investigation and does not give a deadline. In most investigations of research misconduct, authors or their institutions do not cooperate in the process, making it difficult to reach conclusions. The current strategy exercises caution to protect the reputation of authors and their institutions by keeping investigations confidential and allowing them to take years. Importantly, this approach completely neglects the interests of patients, clinicians and honest researchers who trust and use these studies that are undergoing investigations behind the scenes, usually without disclosing any of the concerns.

These issues in the current system have downplayed the extent and effect of research misconduct in biomedical research. The problem is larger than many realize and might affect more than 20% of published research. Patients who are being given futile or even harmful treatments by ignorant clinicians and scientists who build their research based on problematic data pay the highest price.

IMPROVING RESEARCH GOVERNANCE

Reduction of research misconduct or its impact can happen at the level where it is committed, when its results are presented during peer review and in meta-analysis, or after publication, when fraud is suspected in the academic community.

Research misconduct can be prevented by training researchers and imposing better governance. In some regions researchers suffer under an overwhelming burden of paperwork, whereas, in other areas of the world, any form of governance is virtually absent. Research misconduct is usually driven by impossible incentives in the form of publishing as many papers as possible in a limited period for the researchers to get promoted. As a fundamental way to remove improper incentives, the mechanism that evaluates the performance of researchers needs to move away from the current publication-centric model while placing more weight on the effect of research in the real world and the long-term reputation of the researcher.

During the submission of papers, editors and peer reviewers should be aware of the possibility of research misconduct. Although peer-review of research papers focuses on the impact and the quality of a study, the question of whether the data underlying the research are genuine is not normally asked. Awareness of the possibility of misconduct as well as formalized procedures, such as checklists, would be an enormous step forward (*Li et al., 2021*). Also, a requirement to make underlying data available upon request or even as a routine, i.e. post them in anonymized spreadsheets, would facilitate the required transparency (*Carlisle, 2021*). Meta-analysis should, apart from the effort to include all data and assess them on quality, incorporate the question if the data are true in the first place. The Cochrane collaboration has adopted a policy this year for managing potentially problematic studies in systematic reviews (*Boughton et al., 2021*).

It is also important to introduce third-party supervision of research integrity rather than solely relying on self-regulation by institutions and journals. Independent committees that oversee research should be established at institutional, regional and national levels. They must have the authority to regulate researchers, be empowered to operate without conflict of interest and interference, and include experts on detecting research misconduct.

The COPE retraction guidelines, rather than allowing for indefinite waiting of authors and their institutions for a reply, should ask journals to issue an expression of concern at the start of an investigation and regularly offer updates on the status, until a conclusion has been made. Details in the COPE guidelines could be further elaborated, such as the threshold to initiate the investigation, maximum waiting time for response, e.g. 6 months, and the format of retraction notice. Although local institutions should be involved in an investigation, they should not be expected to take the initiative. If research misconduct occurs in institutions with insufficient governance, then it is not realistic to expect a fair and transparent investigation that is led by the same institution. For any investigation, it is crucial to assess the original data. If such data cannot be provided, and there is reasonable suspicion on the integrity of the paper, this should be explained in an expression of concern.

Investigations of research misconduct should be communicated between journals and publishers in the same field. Presently, no channel exists in which journals share such information with their counterparts, making it easy for authors who commit research misconduct to continue publications in other journals without tightened scrutiny. A blacklist system can be established, and mechanisms should be instituted that trigger an investigation of all the work of an author who has one or more articles retracted because of research misconduct.

Finally, independent research and open discussion without euphemistic language about research misconduct should be encouraged. Trustworthiness of research is at stake here, and the interest of patients should prevail over that of publishers, journals and authors.

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