

EDITORIAL

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“Whatever the future direction we set for addressing the issue of research misconduct, we will always need a strong reliance on the moral character and professional codes of ethics of those engaged in the enterprise.”

Investigating the investigators: research malfeasance

Blair Henry

“I never had a policy, I just tried to do my best each and every day.”

Abraham Lincoln

Medical research has had its own incredulous history of misconduct and malfeasance. The horrific and notable findings of the American military tribunal that opened proceeding in Nuremberg in 1946 would only be the beginning. Regrettably, this dark stain in history would not be an isolated event, with varying reports of research misconduct and malfeasance continuing to this day [1,2]. To counter these worrisome trends regulatory bodies, laws and ethical oversight mechanisms have flourished since 1946 to address the need to keep research and its researchers on track [3]. Any trace of a system that may have once relied on ‘individual moral character’, of the integrity hinted at by Abraham Lincoln, appears now to be passé. A relatively new oversight body (*circa* 1992) has appeared on the scene – ironically called the Office of Research Integrity – and is helping to redefine the evolving landscape of research misconduct, investigation and integrity at an institutional, national and international level.

Terminology & taxonomy (what is the problem?)

Discussions of research malfeasance typically involve the words ‘fraud and misconduct’. Fraud is a well-established legal term used in criminal law cases to characterize the acts of a person who intentionally deceives another for personal gain or to willfully damage another [4]. In the arena of science and research, deception for the purposes of personal prestige would meet the legal definition of fraud. Misconduct, in reference to research, refers to a broader understanding of malfeasance, of which fraud would be a subset, and institutional policies should steer clear of appropriating legal terms explicitly in its initial review of misconduct cases.

Misconduct can occur at any point across the continuum of a project. Some occurrences are noted during the actual conduct or running of the research, others can happen at the publication stages with inappropriate practices such as ‘ghost’, ‘covert’ and ‘gift’ authorships, or in the chopping up of one’s research findings into multiple articles for greater impact [5].

Shared terminology and a common understanding of what constitutes misconduct is crucial. Of note, in 2010 the Canadian Expert Panel on Research Integrity reported that no national definition of misconduct or of research integrity existed and that considerable variation in terminology existed [101]. A consensus of understanding is particularly important if a fair system for both misconduct investigation and the allocation of disciplinary punishment is to be created, which can serve to act as an appropriate vanguard to promote **researcher integrity** [6].

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Evidence & trends (do we have a problem?)

Reports and studies suggest that we do indeed have a problem with research misconduct. However, with the exception of sensational news articles drawing attention to the issue, the only way to understand the real scope of the problem is by surveying researchers and asking them to report on this matter. In a 2012 report in the BMJ, a poll of >2700 researchers reported that 13% of respondents knew of colleagues intentionally altering/fabricating data during their research [7]. Studies into the scope of the problem are typically complicated by terminology (see above) – one person’s interpretation of ‘falsification and fabrication’ can be another’s definition of ‘modification and alteration’. This confusion around interpretation can also be compounded by what is referred to as the ‘Muhammad Ali effect’, wherein people, when asked, will usually perceive themselves as more honest than their peers [8].

“Research misconduct continues to occur and unfortunately we do not have a ‘best-practice’ standard to direct us in its detection or scrutiny.”

A systematic review and meta-analysis of survey data published on research misconduct in 2009 found that 2% of scientists polled self-reported to having falsified and fabricated data at least once, whilst 34% admitted to having taken part in other questionable research practices (namely, dropping data, changing research designs and so forth) [9]. When the same group was asked to report on their observations of others: 14% reported knowing scientists who falsified or fabricated data and 72% knew others who engaged in questionable research practices. A 2003 report from the Council of Science Editors reported the following sources of misconduct in substantiated cases: 70% involved plagiarism, 11% fabrication, 11% falsification and 8% were miscellaneous [102].

Unfortunately, any fulsome assessment of research misconduct will mean a reliance on incomplete data, since much of it goes unreported. A typical research study can represent a process that can easily span a period of several years. The timing of when a research misconduct allegation is made and the stage at which it occurred in the timeline will play a major role in whether the event ever reaches public disclosure. The sources for allegations can include: initial scientific reviewers, research ethics committees, research participants, peers within the institution, coinvestigators, site monitors and inspectors (institutional and sponsor), journal peer reviewers and members of the larger scientific community who read the published studies.

Just the allegation of research misconduct itself has the potential to cause harm (to the researcher accused, to the accuser or to the institution) and may often solicit a parochial response – no one wants to air their affairs in public and in some cases the issue is resolved by a negotiated voluntary agreement between parties, which is protected by strict confidentiality rules. Similarly, the issue of jurisdiction to conduct a research misconduct investigation can be called into question. If the misconduct is detected after the results are published, journals have recourse to publish an errata, expression of concern, partial retraction or, in confirmed cases, a formal withdrawal of the publication can be issued drawing attention to the fact that concerns in the conduct of the research exists; however, in many cases, full public disclosure of the true nature of the concern remains unstated [10].

“...institutional policies should steer clear of appropriating legal terms explicitly in its initial review of misconduct cases.”

Despite the growing number of oversight mechanisms, many parts of the research will still remain a self-regulating enterprise. Traditionally, much of the medical research was conducted in larger university-based health sciences centers; however, a movement towards smaller clinical settings, such as community hospitals and primary care centers, means some locations will have very little experience with conducting investigative procedures of the type needed to address these cases of research misconduct, which will also result in a lower incidence of reporting [11].

Context & culture (why do we have this ‘problem?’)

It would appear that for some, at a personal and professional level, the drawing of a boundary to actually define misconduct may be arbitrary. The practice of removing bad data to provide a clearer signal towards a desired outcome (biasing) may be viewed less egregious than the actual fabrication or falsification of results for personal gain only. Similarly, some scientist view a charge of plagiarism in a research proposal or grant application to be less serious or problematic than if detected in a published work [9].

We need to appreciate that we do not have good evidence on what motivates individuals to engage in research misconduct: dismissing these behaviors to environmental pressures such as the ‘publish-or-perish’ world of academia, or attribution directed singularly to the poor moral character of select individuals may be limiting our ability to address

this issue proactively [12].

Ultimately, the incidence of research misconduct needs to be considered a problem that is broader than just a failure of moral character – it needs to be treated as a system failure – facilitating a more multidimensional perspective on how it should be addressed.

Procedural justice (how do we ‘investigate the investigators?’)

Oversight responsibility typically lies with the institution where the accused is employed. However, when the same body leads the investigational, prosecutorial and judgment phases of a research misconduct allegation – how are the interest of all parties protected [13]? Fundamental process questions – such as, should the activity of fact finding be separate from adjudicatory proceedings – needs to be considered by the investigating oversight group. Many organizations have moved beyond a purely responsive, *ad hoc* system to deal with these events, and many research institutes have adopted formal procedures based on administrative law in the process towards examining research misconduct [13].

A fair investigational process should uphold the procedural values of confidentiality, impartiality, honesty, being evidence-informed, sensitive, timely and transparent. Better protection is needed for the

and jurisdictional issues continue to complicate the picture. Some advocate for jurisdictional issues to be directed towards medical licensing bodies; however, research involves more than just physicians [13] – and so the problem continues.

Whatever the future direction we set for addressing the issue of research misconduct, we will always need a strong reliance on the moral character and professional codes of ethics of those engaged in the enterprise. Virtues, such as those epitomized by Abraham Lincoln, of honesty and integrity, can never be replaced.

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