Topic Piece

Research Ethics
2023, Vol. 19(2) 107–120

DOI: 10.1177/17470161221147440
journals.sagepub.com/home/rea

Journal editors and publishers' legal obligations with respect to medical research misconduct

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Abstract

As the burden of misconduct in medical research is increasingly recognised, questions have been raised about how best to address this problem. Whilst there are existing mechanisms for the investigation and management of misconduct in medical literature, they are inadequate to deal with the magnitude of the problem. Journal editors and publishers play an essential role in protecting the veracity of the medical literature. Whilst ethical guidance for journal editors and publishers is important, it is not as readily enforceable as legal obligations might be. This article questions the legal obligations that might exist for journal editors and publishing companies with respect to ensuring the veracity of the published literature. Ultimately, there is no enforceable legal obligation in Australia, the United Kingdom, or the United States. In light of this, more robust mechanisms are needed to deliver greater confidence and transparency in the investigative process, the management of concerns or findings of misconduct and the

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need to cleanse the literature. We show that the law disincentivises journals and publishers from ensuring truth in their publications. There are harmful consequences for medical care and public confidence in the medical profession and health care system when the foundations of medical science are questionable.

Keywords
Research misconduct, law, medical research, journal editors, publishers

Introduction

Misconduct in research is common with real consequences for the research community and the broader public. Despite increasing recognition of the problem, current mechanisms to address it can reasonably be regarded as inadequate in the sense that they are perceived to be slow and lack transparency. Although primary responsibility rests with the perpetrators of misconduct, it is important to question the role that others play in perpetuating the impact that misconduct has on medical practice. The Committee on Publication Ethics ('COPE') states that 'journals are responsible for the conduct of their editors, for safeguarding the research record, and for ensuring the reliability of everything they publish' (Wager and Kleinert, 2012). However, the ethical responsibility of journals and publishers enshrined in this guidance by COPE does not translate to a legally enforceable obligation. As a result, few mechanisms are currently available to require publication integrity in spite of the significant potential for harm. This article explores the current systems in place for dealing with concerns raised about problematic papers and the lack of legal recourse to compel action from journals and publishers.

Since there is no legal obligation for journal editors and publishing companies to check the veracity of the work that they publish, other ethical and regulatory frameworks need to be explored. This article will show that the lack of available legal mechanisms in this area disincentivises journals and publishers from ensuring truth in their publications. However, there are harmful consequences for public confidence in science and there can be real economic, social and medical harms when the foundations of science are questionable. The experience during the COVID-19 pandemic where public confidence in expert health advice was undermined by poor quality science and dangerous public messaging with devastating consequences (Belinda et al., 2022; Bennett et al., 2020; Freckelton, 2020a, 2020b). Whilst legal remedies are unlikely to offer a solution to this problem, there are regulatory measures that can and should be reviewed to provide incentives to the medical research and publication industries to ensure that disseminated research is ethically obtained, transparent and accurate.

What is research misconduct?

There is no universally accepted definition of research misconduct but there are common themes across those that have been proposed and used (Bornmann, 2013: 88; Freckelton, 2016). The US Department of Health and Human Services Office of Research Integrity interprets the term 'research misconduct' to mean fabrication, falsification or plagiarism in the conduct of research and to the explicit exclusion of honest errors or differences of opinion (Definition of Research Misconduct | The Office of Research Integrity (ORI), n.d) – this is from the US Code of Federal Regulations 42 CFR §93.103. This definition was formalised in the Final Rule on Public Health Service Policies on Research Misconduct published in the Federal Register in 2005 (US Department of Health and Human Services, 2005: 28377). To date the definition of research misconduct in the US centres heavily on 'fabrication, falsification and plagiarism' (National Academies of Sciences, Engineering, and Medicine, 2017: 64).

There are other ways to conceptualise research misconduct and other countries and institutions have also grappled with a definition and come to differing conclusions. These alternative definitions still utilise the core concepts of 'fabrication, falsification and plagiarism' but differ in how they include other behaviours in the definition. (National Academies of Sciences, Engineering, and Medicine, 2017: 65). In the UK, for instance, the Office of Research Integrity defines research misconduct as including fabrication, falsification, plagiarism, like the US definition, but adds the misrepresentation of data, interests, or involvement and failure to follow accepted procedures or to exercise due care in the handling of privileged or private information and the avoidance of unreasonable risk or harm (UK Research Integrity Office, n.d). Tugwell and Knottnerus (2017) proposed a definition of research misconduct that included fabrication, falsification, unethical author conduct and error.

Not all unethical and damaging practices in research are rightly considered misconduct; the related concepts of detrimental research practices (DRPs) and questionable research practices (QRPs) attempt to capture lesser but still serious departures from ethical research practice. QRPs are practices that are not misconduct but that undermine the 'traditional values of the research enterprise' and 'may be detrimental to the research process' as defined in the *Responsible Science* report (National Academies of Sciences, Engineering, and Medicine, 2017: 16). DRPs are practices that are damaging to institutions and to research practice that fall short of misconduct; these may include neglectful or exploitative supervision, demanding or denying authorship and misleading statistical analysis (National Academies of Sciences, Engineering, and Medicine, 2017: 74). It was the opinion of the Committee on Responsible Science that authored the *Fostering Integrity in Research* report that many of the practices that had previously been considered

questionable should be reclassified as detrimental (National Academies of Sciences, Engineering, and Medicine, 2017: 74).

Clear definitions of research misconduct are appealing but too much focus on identifying these behaviours can have unwanted side-effects. This point was made in the recently published CLUE recommendations which focussed on strengthening collaboration between universities and editors on issues relating to research integrity (Wager and Kleinert, 2021). In those recommendations the differing roles and priorities of editors compared to research institutions and universities were explored. Relevant to this point, they observed that institutions tend to focus on identifying and managing more narrowly defined research misconduct, by contrast with editors who must concern themselves with research integrity which may encompass a broader range of questionable practices (Wager and Kleinert, 2021: 6). As a result, thresholds for investigation of allegations may differ between the parties and impede communication between editors and institutions.

In spite of these issues and the differing definitions of research misconduct, there are consistent themes across the definitions that make it possible to identify what is generally accepted to be research misconduct and to estimate the extent of the problem faced.

What is the extent of the problem with research misconduct?

The true extent of research misconduct is difficult to estimate but is likely to be greater than currently appreciated in spite of increasing recognition of the problem (Bornmann, 2013: 92; Thiese et al., 2017: 4117; Zuckerman, 2020: 949). The problem pervades all disciplines of scientific research and specialities of medical research crossing international borders and journal impact factors (Bennett et al., 2020; Chambers et al., 2019; Chauvin et al., 2019; Dal-Ré, 2019; Freckelton, 2016; Grieneisen and Zhang, 2012: 12–13; Mena et al., 2019; Wang et al., 2019). A number of recent studies investigating retracted articles in scientific and medical journals have commented on the rising number of incidence of misconduct even when accounting for the rise in published articles (Zuckerman, 2020: 949). Others have disagreed that the problem is as extensive as claimed, especially for health sciences (Bhutta and Crane, 2014: 2). The actual incidence of misconduct in research is impossible to know for certain owing to the challenges of obtaining misconduct data (Zuckerman, 2020: 947, 957), whilst there are over 38,000 retracted articles collated on the Retraction Watch database as of August 2022. A survey of retracted articles in 2013 estimated that only 20% of retracted articles were due to alleged research misconduct (Grieneisen and Zhang, 2012: 13). Rising rates of retracted articles can be explained by a multitude of factors, including a steady lowering of barriers over time to publishing flawed work, and that

retraction rates may be skewed by serial misconduct (Freckelton, 2016; National Academies of Sciences, Engineering, and Medicine, 2017: 80). Even more concerning is evidence that problematic papers are never retracted (National Academies of Sciences, Engineering, and Medicine, 2017: 81).

In spite of the acknowledged challenges of estimating the true prevalence of research misconduct, numerous attempts have been published in the scholarly literature. Some published estimates of the number of fabricated randomised clinical trials are as high as 20%–40% (Carlisle, 2021; EPPPIC Group, 2021; Ioannidis, 2021). In 2009, for instance, Fanelli (2009) published a systematic analysis of the literature of quantitative survey data that had accumulated at the time the search was run. That analysis consisted of 21 surveys and found that a pooled weighted average of 1.97% of scientists admitted to falsification, fabrication, or modification of data and 33.7% admitted to QRPs (Fanelli, 2009: 1). In 2015 Pupovac and Fanelli (2015), performed a systematic review of anonymous surveys of scientists about plagiarism from May to December 2011, and found that 1.7% admitted to committing plagiarism and 30% had witnessed plagiarism. More recently, in 2021, another systematic review was performed by Xie et al. (2021) who reviewed all articles published with prevalence data until July 17, 2022. That review identified 42 articles and found the prevalence of admitted research misconduct was 2.9% among scientists, and the prevalence of QRPs was 12.5% (Xie et al., 2021: 6). The prevalence of witnessed research misconduct was 15.5%, and witnessed QRPs was 39.7% (Xie et al., 2021: 14).

Whatever the actual prevalence of research misconduct is, the monetary and human cost of research misconduct is considerable. Clinical trials can be justified when there is potential for a significant contribution to knowledge in the field to be researched, but this is wasted and the risks to patients can be for no benefit when there is misconduct (Zhang and Grieneisen, 2013). There is harm to the reputations of institutions and colleagues as well as the wasted time and effort of colleagues who work on futile investigations (National Academies of Sciences, Engineering, and Medicine, 2017: 81) Further to this, the insinuation of unreliable data into clinical practice and policies by way of transferred credibility through publication and integration into systematic reviews and citations undermines confidence in research and may harm patients (Freckelton, 2016).

Publication legitimises the misconduct and bestows plausibility, which has a damaging flow-on effect to clinical practice and thereby to patient care and safety. For example, in the case of Joachim Boldt the result of the fabricated studies altered medical practice (Freckelton, 2016; Wise, 2013). Boldt's studies masked the harm of colloid solutions to increase the risk of death and kidney injury; once the discredited studies were removed and a meta-analysis conducted the harm became clear. The lead author on the Cochrane review, Ian Roberts, estimated that

their use contributed to the death of between 200 and 300 patients per year in the UK (Freckelton, 2016; Wise, 2013: 18). Further, indirect harms to clinical practice occur if the dilution of the body of medical scientific knowledge with unreliable data undermines the trust in evidence (Carney Almroth et al., 2020). It is not only the public's trust in the data that is important; clinicians should be able to trust the data since it is they who must apply the data in the clinical context. If clinicians are unable to rely on the data in clinical practice and are ill-equipped in terms of skills and time to distinguish between good and bad information, they may avoid data to guide management.

How is research misconduct currently addressed?

There are frameworks that guide journal editors and publishers in their response to concerns raised about misconduct. Although there have been improvements in the handling and reporting of retractions because of these guidelines, concerns have been raised that the responses from journals remain inadequate, slow and lack consistency and transparency. The Committee on Publication Ethics ('COPE') provides the most comprehensive resource and is referred to widely including by journal editor associations such as the Council of Science Editors, the World Association of Medical Editors and European Association of Science Editors. The other resource for editorial guidance on misconduct to which reference is commonly made is that provided by the International Committee of Medical Journal Editors ('ICMJE'), but even this resource directs its readers to the COPE guidance.

The Committee on Publication Ethics ('COPE') provides guidance to journal editors for the handling of concerns about an article. Suspicion of research misconduct may arise during any part of the publication process and may be alleged by the journal, the peer-reviewers, the author's colleagues or institution, or the readership. Concerns raised about a manuscript or publication should be acknowledged by the journal editor and promptly and transparently addressed. COPE advises editors to communicate openly with institutions about allegations so that investigations may be conducted by the institution and not by the journal (Wager and Kleinert, 2012). Findings of misconduct should be acted upon and COPE offers guidance to journals on handling retractions (Barbour et al., 2009). The guidance advises journal editors to consider retracting an article if there is clear evidence that the findings are unreliable because of falsification, fabrication, plagiarism or major error, or are unethical. The form of the retraction should be clearly and readily identifiable, freely available to all readers, published promptly, state who is retracting the article and the reasons for the retraction in objective and factual language. COPE states that the purpose of the retraction is to correct the literature and not to be punitive.

The stakes are high in research misconduct because the consequences for all parties should not be underestimated (Freckelton, 2020a: 160). The academic and research community is competitive and both findings and allegations of research misconduct may have considerable financial and professional repercussions. Neither the finding of misconduct nor the allegation should be treated lightly, and it is appropriate to maintain high standards during the investigative process with due regard to the impact that it will have on authors and associated parties. It is not clear what is meant by COPE when it refers to 'clear evidence'; however, it is clear that this is a high threshold in terms of proof. There is a risk that institutions and journals might confuse 'clear evidence' with the 'magnitude' of the misconduct, compounding the problem of the threshold for journal action being problematically high.

The COPE guidance also recommends journals maintain distance from the misconduct and focus instead on the responsibility for truth of the research record. It advises that the investigation be handled by the author's institution. It also emphasises that the purpose of a retraction is to maintain the veracity of the literature rather than to hold the authors accountable for their actions. However, if the journal is made aware of concerns, then it has its own responsibility to make enquiries but will have limitations in terms of its capacity to do so in most cases to the extent required for 'clear evidence'.

Criticisms directed at this process highlight lack of transparency, delay and inconsistency as major obstacles to research publication integrity. The guidance offered by COPE may be aspirational in many cases, especially with regard to small to medium-sized journals. The average time for investigations and outcomes from the time that concerns are raised is difficult to estimate, but the median time from publication to retraction is between 1 and 2 year (Chambers et al., 2019; Serghiou et al., 2021). The form of retractions is inconsistent across journals and the reasons provided have been accused both of lacking transparency and being misleadingly soft on authors (Frampton et al., 2021). Discovering retractions and reasons for them, though, is far from straightforward. Resources such as Retraction Watch are invaluable but the veracity of the literature should not be dependent on ad hoc processes initiated by concerned citizen scientists.

The sheer magnitude of the problem may also deter journals and publishers from tackling it. If misconduct is endemic and a troubling percentage of professional literature is irrevocably tainted, the battle with authors and institutions might seem wholly unappealing to journal editors who largely hold their positions on an honorary basis (Carlisle, 2021; Ioannidis, 2021). It is difficult to justify holding a volunteer workforce legally liable when they have neither the resources nor the employment incentive to address the problem. The consequences flowing from failing to attract journal editors into such positions would be far worse.

Ethical guidelines and frameworks such as that provided by COPE rely on moral incentives to act, rather than legal ones.

Legal obligations of editors and publishers with respect to research misconduct

Whilst a cursory search to set out the responsibilities of journals will yield results that describe duties 'to avoid misleading their readers' and 'correct or retract published work' (Wager and Kleinert, 2021: 9), this describes ethical duties only. No legal obligation exists to require journal editors or publishers to address the publication of false, fabricated or plagiarised research. This article identifies four areas of law where an argument to claim redress for failing to respond adequately to concerns or evidence of research misconduct might exist. Ultimately, the likelihood that any of these actions would be successful is low.

Negligent publication

The tort of negligent publication has evolved in the United States and envisages that a publisher may owe a duty of care to the reader with respect to information, advice or instructions that ultimately led to the injury suffered by the reader (Hoffman, 1985). In order to succeed in this action the plaintiff must prove that there was a duty of care, that the harm was a result of the breach of the duty of care and that the harm was reasonably foreseeable by the publisher. However, in *Sony Computer Entertainment America, Inc v American Home Insurance Co* (No. C04-0492 PJH (ND Cal. Dec. 1, 2005), n.d) the United States District Court for the Northern District of California held that the term 'negligent publication' should be construed to refer only to that category of tort claims typified by defamation and misappropriation claims, thereby reading down the ambit of the tort.

Only a few negligent publication claims have been successful. A recurring theme leading to the failure of these claims is concern that the burden of checking information would overly burden the publishing industry (Ausness, 2000: 619–620).[1] The tort of negligent publication does not exist in Australian or UK law.

Negligent publication cases can be categorised into four subcategories: those where readers that have relied on faulty published material; those where readers followed faulty instructions or advice; those where the readers have been harmed as a result of published advertising; and those that involve the publication of faulty aeronautical charts (Ausness, 2000: 611–613). In most cases, plaintiffs have unsuccessfully argued that there was liability in negligence on the part of the publishers and this is due to the reliance on product liability principles that allow the publisher to argue that, despite the faulty information, the product produced by them was fit for purpose. This is because information is not considered a product

(Ausness, 2000: 623). This is apart from aeronautical charts where courts have largely sided with plaintiffs.

Misleading and deceptive conduct

An action for misleading and deceptive conduct against a publisher of a journal might involve claiming that the publisher has promoted itself as a source of high quality information and that this claim is not true. This could be addressed pre-emptively by the provision of a disclaimer that the publisher is not responsible for the content of the journal and that any actions taken based on the information provided are at the reader's own risk. Most journals also take care in their advertising to avoid making claims that they publish true information. A successful misleading and deceptive conduct claim is unlikely, although it would need to rely on the specific facts surrounding the behaviour of the journal or publisher.

Contract

An action in contract would be between the subscriber and the publishing company on the basis that the publisher had not met its contractual obligations to provide accurate scientific information. The subscription contract is likely to be drafted in such a way as to specify that the contract is for the provision of access to information and to the form of the information, but not its substance. An implied term as to the quality of the information is unlikely to be incorporated by a court.

Another way that contract may be relevant to the role of journal editors and publishers in the handling or perpetuation of research misconduct in the literature is through employment contracts. An employee of the publishing company that may be an internal journal editor will be required to adhere to the terms of their employment contract and to any internal policies, and codes of professional and ethical conduct relating to COPE or other relevant guidelines. If an employee or journal editor acted in a way that breached the terms of their employment contract, they may have their position terminated or another form of disciplinary action taken against them. Researchers guilty of research misconduct may face similar consequences in relation to their employment contracts with their institutions.

Fraud

Fraud is another form of tort and in this context would involve a claim that the publisher has intentionally misrepresented itself for its own gain. There would need to be particularly egregious behaviour on the part of a journal or publisher for a successful claim of fraud to be made out. Again, this is most unlikely. An action in fraud may be successful when directed at the researcher; in the US research

misconduct in the use of federal funds may result in a researcher being found guilty of fraud. For example, in the case of Dong-Pyou Han who was jailed for fraud after fabricating and falsifying data relating to vaccine experiments conducted Iowa State University that relied on federal grants (Freckelton, 2016; Reardon, 2015). Whilst fraud provides important legal redress against researchers for misconduct, it is unlikely that the role of the journal editor or publisher in the perpetuation of scientific literature borne of research misconduct would be found to amount to fraud.

Professional regulation

Disciplinary procedures are also relevant to research misconduct. For example, there are regulatory bodies that are relevant to health care practitioners. Cases of research misconduct on the part of health care practitioner may result in disciplinary action against that individual and a decision against them might result in loss of entitlement to practise their profession (Freckelton, 2016). There is no regulatory body for scientific journals and publishing companies in this area but there are regulatory bodies for the media that address press conduct and publication. If a journal is edited by a health care practitioner and their behaviour was so egregiously unethical with respect to their editorial role, they might attract the attention of the regulator or board and a complaint. The outcome of the complaint may be a warning, restrictions on their licence/registration, or loss of entitlement to practise.

Legal avenues do not create a legal obligation for publishers and journal editors to act

There is no legal obligation that requires journal editors or publishers to ensure the veracity or reliability of the information that they publish, even though there is a real potential for harm. Any obligation on the part of journal editors and publishers to make enquiries or correct the record is ethical, rather than legal.

The law of tort does not provide effective redress for those who rely to their disadvantage on what is published in a journal. Demonstrating the existence of a duty of care on the part of journal editors or publishers to patients who might suffer the harm is also unlikely to be feasible. There must also be a causal link between a breach of the duty and the harm caused. Such a link between the claimed breach by the journal editors or publisher and the harm would be difficult to establish. Rarely would a single article inform clinical decision-making so directly or substantially as to be able to satisfy the requirement of causation. Rather, published research is likely to form part of the latticework that clinicians draw on to apply to the individual patient's circumstances. The fact that clinicians owe a duty to

provide care to a particular standard makes them a contributing factor along with the many others. The publication process is ultimately too remote for causation to be established.

A tension exists between the public interest to publish high quality information and correct the record on the one hand, and the public interest to avoid overburdening the publishing industry on the other. A legal obligation to check the veracity of publications in the first instance and investigate when concerns are raised would impose a heavy burden on the publishing industry and timely access to research. Moreover, generally it would readily be discharged by adherence to conventional peer-reviewing processes.

It would also be unjust to impose legal consequences on journal editors and publishers for failing to initiate and conduct investigations that are outside their means and scope (See related discussion: Wager and Kleinert, 2021: 2–3). The employing institution is better placed to perform an investigation of alleged misconduct because it is likely to have access, resources and scope to act on the findings of an investigation, all of which are unavailable to a journal. A legally enforceable obligation would be not only burdensome to the publishing process and business, but it would also be unjust.

Conclusion

Current law in Australia, which accords with the law in most other countries on the issue, has not evolved a legally enforceable obligation for journals and publishers to ensure the veracity of what they publish. This may seem surprising to some, but there are sound reasons for it that have been explored in this paper. There are ethical frameworks that deal with research misconduct in medicine, but there is a discrepancy between the guidance provided and reality. It is likely that factors such as time, cost and fear of litigation are more powerful incentives than the ethical obligations. Importantly, most journal editors are engaged on a voluntary basis or only very modestly remunerated for their time and effort, meaning that unreasonably burdensome obligations and the potential for legal liability would discourage people taking on these important roles to the overall detriment of the scientific record. More attention should be paid to developing robust systems for the ready identification of retracted and corrected articles by the readership. Additionally, research to explore the experience of journal editors and publishers dealing with concerns about published articles is needed. It is important to identify and understand better the nature of impediments to investigation, correction, retraction and transparency so that these can be addressed more effectively. Restoring confidence in the literature is the responsibility of all personnel involved in medical research, including but not limited to researchers, institutions, journals and publishers (Ioannidis et al., 2014: 172).

Despite the absence of legal redress in this area, there is reason to be optimistic about the future of research integrity. There is a growing recognition of the problem and a more open discussion about this problem is occurring across disciplines and across international borders. Much work is still to be done, but these authors are optimistic that in time confidence in the literature can be restored.

Ethical approval

Not applicable.

Funding

All articles in Research Ethics are published as open access. There are no submission charges and no Article Processing Charges as these are fully funded by institutions through Knowledge Unlatched, resulting in no direct charge to authors. For more information about Knowledge Unlatched please see here: http://www.knowledgeunlatched.org

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Note

1. The following are some interesting examples of claims of negligent publication (Hoffman 1991):
   - A student nurse self-administered an enema after reading the instructions in her textbook and suffered injury. She sued the publisher of the textbook claiming that the advice in the textbook was outdated and harmful and they should be found liable for the quality of the information.
   - A student was injured in the course of performing a science experiment that was published in a chemistry textbook
   - An encyclopaedia of mushrooms misclassified a poisonous mushroom in the printed text and the error resulted in two readers becoming severely unwell after ingesting the mushrooms.

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