

Author Accountability in Biomedical Research

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INTEGRITY AND CREDIBILITY are the core values that permit academic and clinical science to develop and evolve within the scientific community, and for securing the trust of the public. The Vancouver Declaration International Committee of Medical Journal Editors (ICMJE) guidelines, first published in 1979 and revised substantially over the past 35 years, with the latest version in 2017, outlines recommendations for acceptable conduct and publication within scientific and medical journals [1].

These guidelines have formed the backbone for ethically sound high-quality research within biomedicine and have provided an essential ethos for international collaboration. As the scientific boundaries within which scientists work expand, and societal norms, expectations, and limitations evolve, there is a need to constantly re-evaluate the content and implementation of these guidelines. This is essential to ensure that scientific conduct and advancement are compliant with the ethical and fiduciary responsibilities of each individual scientist and medical practitioner.

The need for greater clarity within the Vancouver guidelines has become apparent in the aftermath of recent investigations that have found Paolo Macchiarini guilty of research misconduct. These investigations and their conclusions include the recent Karolinska report in which a large number of individuals who collaborated with Macchiarini were determined to be guilty of research misconduct and/or blameworthy for not having objected to the publication of five of six articles containing what is now identified as fabricated or flawed data or procedures [2]. Although the Macchiarini case has had high media visibility, this is not the only case of improper conduct that warrants a re-evaluation of the policies guiding acceptable conduct and publication. Other investigations, including the ongoing inquiry into the Anversa group [3], and the more recent dismissal of Japanese scientist, Yoshinori Watanabe from the University of Tokyo for

research misconduct, raise serious ethical concerns about integrity in biomedical research [4,5].

High-impact science, particularly in the biomedical field, increasingly requires interdisciplinary expertise with basic and applied scientists from multiple disciplines working hand-in-hand with clinicians to advance knowledge. The very nature of this interdisciplinary relationship requires an environment of collaboration and especially trust as specialists contribute to key areas of investigation.

The basis of this trust has now been called into question. A standard of author culpability in group-based publications is being applied to those who published with Macchiarini, including some of us, that will seriously jeopardize future collaborative work. Retraction of a journal article per se does not hold any given author liable for misconduct. Rather it is the misconduct investigation that assigns accountability to each coauthor. However, withdrawal of a published article could be perceived in the scientific community as indicating that the work is null and void, potentially leaving a negative impression of the conduct of all the authors by the research community.

The Vancouver Declaration states, “In addition to being accountable for the parts of the work he or she has done, an author should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-authors” [1].

The declaration further states that coauthors are primarily responsible for the data that they contribute and *should be able to trust the data contributed by other coauthors*. Thus, a reasonable interpretation of the Vancouver Declaration is that if one or more authors commit misconduct, the other authors are not responsible for that misconduct but rather that a breach of trust has occurred.

This statement is open to interpretation. For example, the expert group for scientific misconduct of the Central Ethics Committee of Sweden (CEPN) has recently stated

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an opinion about coauthorship involving misconduct by Macchiarini. With reference to the Vancouver declaration, the expert group concludes, “The fourth criterion which was added in 2013, is an expression of accepted practice” ... “If a scientific article is deemed to be marred by such serious shortcomings that a conclusion of scientific misconduct can be drawn, in such cases responsibility consequently rests with all of its co-authors” ... “The fact that the six reported articles have been published in journals that have all endorsed the Vancouver rules additionally emphasizes that these rules ought to be the basis for assessing the responsibility of each co-author.” This expert committee thereby concluded that all coauthors were liable for scientific misconduct [6]. The Karolinska investigative report similarly held to an overly strict interpretation of liability [2].

These findings are untenable overinterpretations of the Vancouver guidelines’ intent. This overinterpretation is also the view of the issuer of the Vancouver Declaration, ICMJE. ICMJE’s secretary, Darren Taichman, publicly commented on how to interpret the fourth criterion of the Vancouver declaration that CEPN used to claim automatic culpability for all coauthors, “This means just what it says. If there are questions raised about the integrity of the work, each person listed as an author is responsible to assure that the issue is appropriately evaluated and resolved. This requirement cannot be used to conclude that each person was necessarily involved in or aware of scientific misconduct if indeed that occurred” [7]. This statement highlights a breach of trust rather than imputing misconduct to all who have been victimized.

Although in essence these caveats are valid, situations where coauthors are unable to either access or assess primary data are not uncommon in collaborative investigations. This accessibility to data is most clearly exemplified with the issue of data involving the privacy rights of patients and restriction of access to medical records. It is both ethically and legally untenable for coauthors, beyond the treating physicians, to access primary clinical data. Herein, the responsibility must clearly and solely reside with the author(s) who collect the clinical data and contribute this information to collaborators to prepare an article.

Similarly, in clinical and basic science, multifaceted original research studies require niche and advanced competencies. In such situations, scientists must be able to rely on their fellow collaborators’ contributions. In cases of misconduct and fraud, only those contributing and/or reporting false data should be held liable for their actions. These situations raise questions regarding the extent of responsibility, presenting a legitimate challenge to a paradigm that maintains that everyone is responsible for everything in an article.

A large number of leading scientific journals have actively rejected the crude notion of collective coauthor responsibility. These include Nature Research journals, which state that every publication requires “a statement that details each author’s role in the published work” [8]. *Proceedings of the National Academy of Sciences (PNAS)* have also written on this subject, stating, “We suggest that science has become too specialized, too collaborative, and too multidisciplinary for that rule to be applied uniformly. For example, one cannot realistically expect the project statistician to know whether polymerase chain reactions were done with

the proper controls. We believe that the principles stated above combine the best of the traditional view with the realities of modern science. We also recognize that papers may result from specialized contributions from individual authors. Accordingly, we now strongly encourage authors to indicate their specific contributions to published work” [9]. Both *PNAS* and *Science* have recently written further on the need for transparency in author contributions, with *PNAS* releasing new recommendations as to how this should be implemented [10,11].

Perhaps now is the time to look forward and learn from our experiences within the scientific community and revisit the guidelines that form the cornerstone of publication ethics. The mentioned response from ICMJE indicates the importance of collaborative ethos and the need to feel secure in trusting collaborators without fear of subsequent reproach. The request by many journals to delineate individual contributions to an article has certainly helped in this regard, but disclosure should go further. There is a need for this acknowledgment of defined contributions to be extended to include personal responsibility. For example, should authors define, in a more nuanced and detailed manner, specifics such as which figure they have contributed to, so that in the case of suspected misconduct or fraud, culpability lies, properly, at the door of the responsible individual(s)?

It is essential that scientists and clinicians, often drawn from an international community, continue to work together, sharing and trusting one another’s data, and depending upon each other’s integrity. Crude policies do not do justice to all situations and threaten the very possibility of shared inquiry. Guidelines need to better define the moral obligations and responsibilities required of individuals involved in collaborative work. That said, the issue of trust must be recognized as the scaffold on which multi-authored collaborations are built.

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