Authorship is Broken

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In recent years, the biomedical research enterprise in the United States has been subject to considerable scrutiny and concern, after a period of relative lack of interest in the area. Biomedical research is increasingly interdisciplinary, collaborative across research sites, and expensive, requiring large sums of public financial resources and thus inviting public attention.

A steady stream of research misconduct cases of various types, even at world-renowned universities, at times has placed the biomedical research enterprise and the individual researcher on public trial. Of course, the success of biomedical research, which is heavily dependent on volunteer human subjects, is predicated on a culture of trust and faith of the participants and their families in the parties to the research enterprise—namely, the researcher and research organization, funding source, and oversight bodies. It is evident that researchers have ethical and often legal obligations, not just to their subjects but also to their institutions or universities, research colleagues, and society at large.

Many specific issues in human-subject biomedical research have recently been revisited. These include the role, functioning, and funding of institutional review boards (IRBs)²; the assessment and categorization of risk to human subjects³; the appropriateness of subject recruitment and enrollment procedures⁴; the capacity of human subjects to consent to research⁵; the process of information disclosure to subjects and the readability of research consent forms⁶; the appropriateness of surrogate consent to

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research⁷; the confidentiality of data about the subject obtained by the researcher8; conflict of interest between the researcher and the research sponsor⁹; the need for placebo controls in psychopharmacologic research¹⁰; the deficiency of studies using women, children, and minorities as subjects; the role conflict of the clinical investigator as clinician and researcher to a subject/patient; and the adequacy of the peer review process in publication of scientific research. 11 In the United States, The National Bioethics Advisory Commission has undertaken a review of several of these subjects and has issued a controversial report. 12 Resolution of these complex issues requires delicately balancing the competing societal interests of respecting and protecting individual subjects, while advancing public health through promoting biomedical research. 13

Publication Ethics

Publication of the results of a research study makes the study's methods, data, analysis, and conclusions available to other researchers, policy makers, and the general public. The Internet makes the published manuscript, which is the research product, widely available throughout the world. Publication also potentially serves to advance the career, status, authority, and income of the researcher, whether the researcher's work is evaluated by an academic promotions committee or a for-profit research institution. Thus, any compromise in the integrity of the research publication vitiates not only the research study itself, but potentially damages those who participated in and funded the study.

Publication misconduct occurs in many forms and is of uncertain prevalence, but it is by no means rare. 14 Fabrication or falsification of research studies

or data, whether by an investigator or research associate, represented 61 of the 103 allegations of research misconduct received in 2000 by the federal Office of Research Integrity (ORI). Plagiarism occurs on a variable scale, both inside and outside medical publishing, and represented 19 of the 103 new allegations received in 2000 by ORI. 15 Duplicate or repetitive publication occurs when the same or substantially similar material is republished. 16 Repetitive publication can occur deceptively, without the knowledge and consent of the editor and author, although some forms of repetitive publication are legitimate. Divided publication is a related form of repetitive publication when a single research study is divided into several publications without cross-referencing, perhaps misleading the reader into believing that more subjects were studied than was actually the case.

Definition of Authorship

Perhaps the most prevalent form of publication misconduct relates to the designation of authorship. Defining authorship is more elusive than is apparent. 14 Much contemporary biomedical research is multisite and collaborative, involving large numbers of researchers and research assistants, in contrast to earlier research, which involved smaller investigator groups. It is not surprising, therefore, that the average number of authors per scientific paper has greatly increased in the past century. Multiple authorship of empirical studies is now typical, rather than unusual. However, including large numbers of individuals as authors is impractical for the journal, for the computerized database or index in which the article is cited, and, ultimately, for the reader. Many biomedical journals have adopted policies limiting the number of individual authors and delineating the use of group or corporate authors. Such policies are often controversial, because they restrict potential authorship.

Two forms of misappropriation of authorship include gift authorship and denial of authorship. ¹⁴ Gift or guest authorship involves the citation of an individual as an author when that person did not contribute substantially to the research project or the publication. More subtly, gift authorship can occur when a coauthor is inappropriately listed before others in the sequence of coauthors. A gift coauthor may or may not even be aware that his or her name has been placed on the byline. Ghost authorship occurs

when an individual is denied listing in the byline as a coauthor. Gift and ghost authorships are common and are problematic in several respects. 17-19 Authors readily seek credit for their work but must also retain accountability and responsibility for the work they claim as their own. Gift coauthors could be held responsible for the misconduct of their coauthors or coinvestigators. With a greater number of coauthors, dilution of responsibility for the work is more likely; how, for instance, can responsibility be assessed when there are 100 coauthors to a manuscript? Gift coauthorship is inherently deceptive, and represents "false advertising." It dilutes the credit for the work of other coauthors. In fact, each author must know that it is at least in part his or her work and must be able to publicly defend it to the degree that credit is taken for it. Ghost authors should be allowed to take credit and should be expected to take responsibility for their work.

In an attempt to reduce the uncertainty and disputes within the research team over authorship, the International Committee of Medical Journal Editors (ICMJE) has adopted, with revisions, a definition of authorship for over 300 medical journals throughout the world.²⁰ This definition predicates authorship on three activities, each of which must be satisfied: (1) substantial contributions to conception and design of the study, to acquisition of data, and/or to analysis and interpretation of data; (2) drafting or revising the manuscript for intellectual content; and (3) final approval of the manuscript. With application of these criteria, therefore, there would be no authorship designation for those who referred subjects to a study, provided clinical care of patients-subjects in the study, provided funding or technical assistance to the study, performed only one research function such as data collection, or was the head of the laboratory where the work was conducted but did not participate directly in the project. The Journal of the American Academy of Psychiatry and the Law has adopted the ICMJE authorship criteria, and each coauthor certifies in writing that he or she has met these criteria.

Contributor, Not Author

Despite the efforts of the ICMJE over the years, their authorship criteria are not well known, understood, or applied by medical researchers.²¹ The criteria themselves have been criticized as difficult to implement across a wide range of scientific areas.

There is no indication that authorship disputes have waned with the use of the criteria, although research teams are generally encouraged to resolve authorship issues before collecting data. Editors have difficulty verifying that a listed author has in fact satisfied the authorship criteria for the journal; but beyond the difficulties in adopting and implementing a definition of authorship is the fundamental vagueness of the scientific publication byline. ¹⁴

It is at once obvious and remarkable that the scientific publication byline provides so little information to the reader, the promotions committee, and the potential research funding source.²² The coauthors' specific contributions to, or roles in, the study are not provided.²³ The sequence of coauthors' names is not necessarily informative, given the absence of generally accepted and published rules about ordering. Gift coauthorship is not readily detectable from a byline. Coauthors may be assumed to have responsibility for work that is outside their expertise performed by other coauthors. Yet the coauthors would be likely to object to the inference that holds each coauthor responsible for all aspects of the research study. Analogous to reading the scientific byline is viewing a film that concludes with a simple list of hundreds of names of participants but does not identify their contributions.

Some authorities have therefore concluded that the authorship model for publicly attributing credit and responsibility for biomedical research is obsolete and must be replaced.²³ An alternate approach designates "contributors" rather than authors and permits or requires the contributors to specify the nature of their contributions to the research and publication effort. Such contributions include conception and design of the study, literature review, data acquisition, data analysis, statistical expertise, and preparation of the first manuscript draft or revision. Each contributor takes responsibility for the portion of the work in which she or he participated. The contributions are published at the beginning or end of the manuscript for the benefit of the reader, journal editor, academic promotions committee, and future funding agency. Beyond that, at least one coauthor is designated as a "guarantor" who takes general responsibility for the integrity of the entire work. If confronted by evidence of data fabrication by other contributors, for example, the guarantor would intervene to expose the misconduct and correct any published literature using those data.

Each journal using the contributor method would adopt specific rules for deciding how many contributors would be listed on the byline and what type or amount of contribution justifies a byline. Contributors would decide for themselves which among them merited a byline, as they do now. Journal-indexing databases and services would have to be able to include the contributor list and contributor description for the article.

Several well-known publications, including the British Medical Journal, The Lancet, and the Journal of the American Medical Association have adopted the contributor/guarantor concept in place of the authorship model, at least for empirical papers. ²⁴ The Annals of Internal Medicine requires contributors to identify their contributions from a list of defined contributions. ²⁴

Conclusions

Authorship misconduct in its various forms is surprisingly common in biomedicine. 17-19,25 Authorship disputes among coauthors are disruptive to the team, are difficult to mediate, and can result in litigation between coinvestigators. Authorship misconduct compromises the integrity of the scientific enterprise and the public's trust and participation in scientific research. Yet, authorship practice remains a complex and controversial issue, with implications for all parties to the scientific enterprise, including researchers, funding agencies, editors, editorial boards, peer reviewers, promotion committees, practicing physicians, patients, and the general public. Readers, as consumers of the professional literature, too, should care about authorship problems. There are considerable difficulties with the current authorship system, due to its imprecision and dilution of responsibility. The contributor/guarantor model ought to be widely implemented, because it offers greater fairness, accuracy, precision, and the opportunity to discourage fraudulent publication.

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