Health Law and Ethics

Preventing Scientific Misconduct

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When a case of serious scientific misconduct comes to light, reactions from scientists, legislators, journal editors, and the press are often swift and impassioned, reflecting the importance of a problem that strikes at the heart of the scientific enterprise. Science, after all, is a search for the truth. Misconduct, especially in the form of falsification or fabrication, is its antithesis. Biomedical science seems especially vulnerable to the serious consequences forecast by those involved in the extended discussion: Congressional oversight could become a reality, public trust could fray, and perhaps most ominous of all, patients could be harmed. Few authors agree on the frequency of scientific misconduct, owing to differing definitions and difficulties in measurement. Estimates vary widely. Nevertheless, nearly everyone agrees that preventing scientific misconduct is a worthy goal. How best to achieve that goal is not so clear. The purpose of this paper is to develop a framework for the prevention of scientific misconduct based on models familiar to public health professionals, to discuss some problems that emerge from such an analysis, and to propose tentative solutions to those problems. I begin with two questions: What is scientific misconduct, and how much of it exists?

The Nature and Extent of Scientific Misconduct

Two definitions of scientific misconduct, one from the National Science Foundation and the other from the Department of Health and Human Services, emerged in the early 1990s.[1] In both, scientific misconduct was defined as fabrication, falsification, plagiarism, or any other serious deviation from accepted scientific practices in proposing, conducting, or reporting research. A debate ensued over the inclusion of the words "other serious deviation." Proponents argued that this broad term permitted scientific communities to define what constituted ethical conduct and appropriate practices specific to their branches of science.[2,3] Opponents argued that the term was too broad.[4] Although its inclusion appeared to allow sanctions against scientists who undertook innovative, groundbreaking science—which could be construed as a "serious deviation from accepted practice"—no such cases were known.[5] Recently, a federally appointed commission recast the definition in terms of a principle with examples.[6] The commission's report stated that "research misconduct is [a] serious violation of the fundamental principle that scientists be truthful and fair in the conduct of research and the dissemination of research results." It said that unethical conduct includes misappropriation (plagiarism or breaches of confidentiality), interference, misrepresentation (falsification or fabrication), obstruction of investigations of misconduct, and noncompliance with research regulations.

Not everyone agrees with the commission's expansion of the definition of misconduct.[7] Some believe such a broad definition could increase the number of investigations because it includes any type of behavior judged to be untruthful or unfair.[8] On the other hand, some authors have for years insisted that misconduct should be very broadly defined to include behaviors not only beyond falsification,

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fabrication, and plagiarism, but also beyond the categories included in the expanded definition introduced by the commission.[9–11] Deceptive scientific practices, such as the misrepresentation of research results, are the most commonly cited behaviors. Failure to explain weaknesses in data, selective reporting of results, failure to publish a study with negative results, and reporting as "negative" a study with low power are a few examples of this less serious form of misconduct.[9,10] Practices of irresponsible authorship and wasteful (i.e., repetitive) publication have also been designated misconduct.[11]

It is important to distinguish between error and misconduct. Science makes progress because error exists, in measurement and in interpretation of evidence. But these are unintentional errors. Misconduct involves intentional misrepresentation or misappropriation. To put the relationship of error to misconduct in perspective, it may be helpful to consider scientists' conduct to range across a continuum. At one end are serious forms of misconduct, followed by deceptive reporting practices and then, toward the middle, what might best be called sloppiness. At the other end of the continuum lies appropriate scientific and professional conduct, including unintentional error.

Estimating the occurrence of scientific misconduct is not made easier by conceptualizing such a continuum. The many published opinions on the topic are polarized between the belief that scientific misconduct is a rare event[12] and the belief that it is rampant.[13] A recent *Lancet* editorial claims that the prevalence of fraud alone in research studies is between 0.1% and 0.4%, although no source for this estimate is provided.[14]

Three types of empirical estimation studies of scientific misconduct have been undertaken. In the first, written records (e.g., published papers and employment applications) were examined for accuracy (see references 15 through 17). Sekas and Hutson for example, recently found that 30% of applicants for a gastroenterology fellowship who claimed prior publications fabricated either the article or the journal cited.[16] A slightly higher percentage misrepresented their research experience. Lower but significant rates of misrepresentation were found in applications to emergency medicine residency programs, with the number of misrepresentations increasing with the number of citations.[17]

In the second type of study, questionnaires were used to assess respondents' knowledge of misconduct among academic colleagues.[18,19] Swazey et al., for example, estimated that 9% of 2600 students and faculty from several university departments had "direct knowledge" of faculty members who had plagiarized.[20] When the definition of misconduct was expanded from fabrication, falsification, and plagiarism to include a long list of questionable practices such as honorary authorship, sexual harassment, misuse of research funds, and safety violations, the percentage of those who had observed or had direct evidence of these practices increased to 44% of students and 50% of faculty.

The third type of study reported the results of routine data auditing of investigational drug programs.[21,22] Shapiro and Charrow found that the percentage of serious deficiencies had diminished between 1985 and 1988 from 12% to 7% in the work of nearly 2000 investigators.[22] The occurrence of scientific misconduct can also be tracked through the records of cases investigated by the Office of Research Integrity of the US Public Health Service and other investigational bodies.

Although quantitative assessments will help answer the question of how much misconduct exists, it is an unfortunate fact that big effects may arise from small numbers. A single well-publicized case of serious misconduct, such as the recent case of fabrication in a large government-sponsored cancer treatment trial,[23,24] can do considerable damage to institutions, to scientists' reputations, and to the public's already precipitously balanced perception of science. Therefore, scientific misconduct must not be ignored or trivialized, regardless of its prevalence.[25]

A Framework for Prevention

Preventing scientific misconduct is a widely recognized goal.[1,26–30] Attainment of this goal may require that we consider misconduct a professional affliction amenable to both primary and secondary prevention efforts. The implications of such an analysis have not been carefully examined.

Primary Prevention of Scientific Misconduct

Primary prevention is typically conceived as identifying and removing causes of events and as identifying factors whose presence (rather than absence) actively reduces the occurrence of those events. Frequently proposed causes of scientific misconduct fall into two categories overlapping those mentioned above, and in some cases overlapping each other. There are causes *external* to the individual scientist, such as publication pressure,[18,31–34] competition,[35,36] the large scale of science (reducing opportunities for effective mentoring),[34,35] and mentors setting bad examples.[36] There are also *internal* causes, such as personal financial gain,[28,29] ego or vanity,[28–30] and psychiatric illness.[13,28]

Psychiatric illness readily fits the traditional conception of primary prevention. "Remove" it by effective psychiatric treatment and some cases of scientific misconduct, specifically those involving mentally impaired yet employable scientists, could be prevented. How much misconduct is attributable to mental disease is an open and important question. Any answer must consider the possibility that those accused of misconduct may run (perhaps instinctively) to a psychiatrist, claiming illness and thereby avoiding responsibility for what may best be described as a character flaw rather than an uncontrollable personality disorder.

The most frequently posited causes of misconduct are publication pressure and competition. However, it is not clear how reducing—much less eliminating—these factors would reduce scientific misconduct without also reducing some of that which makes science the rigorous and productive enterprise it has become. Perhaps it is a matter of degree. Indeed, to reduce publication pressure, suggested interventions typically involve emphasizing quality over quantity in academic appointments and promotions as well as eliminating honorary authorship.[34] Although these are reasonable proposals, they may have little impact on the publication pressure inherent in science.

Another proposed external cause of scientific misconduct—ineffective mentoring owing to the large scale of science—reflects the idea that having too few senior scientist mentors relative to the number of junior scientists reduces the ability to monitor the (mis)behavior of those mentored. Nor can good examples be set if there are too few mentors. In either case, recommendations to increase opportunities for mentoring by increasing the ratio of senior to junior scientists seem reasonable, assuming resources are available. Nevertheless, providing more mentors and providing good mentors may not be equivalent. Indeed, bad mentoring (a proposed external cause of scientific misconduct) and the proposed internal causes of personal financial gain and vanity—which Kassirer combined into one "fame and fortune viper"[29]—together reveal an implicit claim regarding the etiology of scientific misconduct: that many scientists, because of ignorance or by design, are seriously unskilled in ethics, if not morally bankrupt. Indeed, descriptions of some cases make it reasonable to wonder if scientific misconduct is a product of basic flaws in the characters of scientists. To what extent, then, can ethics training shore up what has eroded or was never planted: a coherent and useful professional scientific ethic?

An often-cited approach to teaching ethics within the context of scientific misconduct involves codes of responsible conduct, that is, rules or guidelines for good (appropriate) scientific and professional practice.[1,28] Yet there are some fundamental problems with teaching ethics as a set of rules, just as it would be seriously deficient to teach science as a set of rules for the laboratory or for the computer. In any professional scientific practice there are thousands of decisions not covered in the rules. In addition, there is the issue (at least in ethics) of what kind of individual follows rules in the first place. Ethics, like science, has its theories and methodologies beyond the rules that help to interpret the rules and to guide practice where the rules are missing.[37,38] Which of these theories and methods will prove most helpful as a foundation for preventing scientific misconduct is an important question, given the prominent theoretical plurality in contemporary bioethics.

It is beyond the scope of this paper to fully discuss the role of moral theory in ethics education. Nevertheless, one such theory—the theory of virtue ethics or character ethics—may be necessary in any account of the ethics of scientific misconduct and so deserves attention.[25] The virtues are traits of character habitually exhibited and important for attaining the goods internal to a practice.[39] By many accounts, the good internal to the practice of science is the truth; science is a search for the "really real" of the world. Fabrication and falsification, or misappropriation and misrepresentation, are direct affronts to this search, as are deceptive scientific practices. While there are many virtues to consider,[40] those of honesty, self-effacement, and excellence seem best suited to helping scientists stay on their appointed path. Put another way, scientists should develop and habitually exhibit honesty rather than dishonesty, and they should put the interests of the profession and of society (especially those of research subjects) before their personal interests, whether financial gain or fame or both. Scientists should habitually exhibit excellence rather than sloppiness. These virtues provide a moral foundation for preventing not only serious forms of misconduct (e.g., fabrication and falsification) but also the lesser offenses (e.g., misrepresentation of research results) that Bailar[9] and others have argued are part of the continuum of misconduct.

An obvious concern regarding virtue ethics as one pillar of ethics education is how to go about developing character traits within individual scientists. Pellegrino argues that virtue ethics, like all moral theories, can be taught from the literature and from case studies illustrating its dimensions, although the most efficacious approach may be to learn by example—by observing, emulating, and reflecting upon the virtuous behavior of a respected mentor.[25,40] Clearly, such mentors must not only possess the requisite virtues but also habitually display them in their everyday scientific practice. Judging from recent cases of serious misconduct, remedial ethics education for some senior scientists may be necessary. There is no guarantee, of course, that learning the virtuous scientific life from a virtuous mentor will lead to right actions or the right motivations for actions. Nevertheless, if the virtues of honesty, self-effacement, and excellence could be instilled in scientists during their training, three of the seven causes of scientific misconduct—mentors' setting bad examples, personal finanical gain, and ego or vanity—could potentially be modified.

Problems Emerging within a Framework of Primary Prevention

Three problems deserve scrutiny. First, on what evidentiary and inferential bases have the proposed causes of scientific misconduct been judged? Second, how much scientific misconduct can be attributed to these causes, and how much misconduct remains unexplained? Finally, how can we determine whether suggested preventive interventions, inasmuch as they relate directly to purported causes of scientific misconduct, are effective in reducing the occurrence of misconduct, however broadly defined? These are closely related questions in the public health model. Attribution requires a decision regarding causality. Thus, to attribute cases of misconduct to a particular factor is to assume implicitly that the factor is (or can reasonably be judged to be) causal. In turn, an answer to the intervention question may help answer the question regarding cause. One of the best tests of a causal hypothesis is to remove the cause and observe the effect of the preventive intervention. But to observe preventive effects, surveillance systems must be in place to track the occurrence of misconduct before and after the intervention. In addition, primary preventive interventions in public health are rarely attempted without a reasonable body of evidence supporting the underlying causal hypothesis. The evidence supporting proposed causes of scientific misconduct is extraordinarily weak; it consists solely of expert opinion, an evidentiary category almost always fraught with opposing views. For example, Pellegrino states that "fraud is not the product of deranged or unhinged minds,"[25] while the Royal College of Physicians report states that "a . . . cause of scientific misconduct is psychiatric illness," with an accompanying note that "there [are] no data on [this issue]."[28]

Perhaps it is time to formally study the determinants of scientific misconduct.[41] This task will require behavioral and social science methodologies if scientific misconduct represents, for the most part, deliberate and conscious acts on the part of its perpetrators. Its causes, therefore, are more "historical" than "natural," according to Collingwood's classic categorization of causation.[42] A difficult aspect of such a study will be to tease out the effects of the most commonly cited causes, publication pressure and competition, because they are analogous to universal environmental factors; nearly everyone in science is exposed to them.[43] Furthermore, they are not independent of one another. Nevertheless, it makes sense to undertake surveys of professional groups regarding their knowledge, attitudes, and beliefs about misconduct in science; to obtain better empirical estimates of prevalence and incidence rates of misconduct; and to conduct case–control studies in which case subjects are those who have committed misconduct. Problems of case ascertainment, recall and other forms of information bias, and confounding should be expected.

Secondary Prevention of Scientific Misconduct

In the classic public health model, secondary prevention involves early detection of disease events coupled with effective treatment. For the secondary prevention of scientific misconduct, early detection involves increasing opportunities for discovering instances of misconduct, and "treatment" refers to procedures for investigating cases as well as the sanctions delivered to those responsible for the misconduct.

Auditing is the most obvious strategy for finding instances of scientific misconduct, although less drastic measures have been suggested: periodic review of scientific records, publications, and workloads.[18,22,28] Increasing the ratio of senior to junior scientists, discussed previously, is also a form of secondary prevention, inasmuch as one role for the mentor is to monitor the behavior of junior colleagues. These approaches to early detection require the concomitant acceptance of responsibility on the part of institutions and their leaders and especially on the part of working scientists. This is a responsibility to *do* something about scientific misconduct. Perhaps the most difficult responsibility is to report misconduct perpetrated by colleagues; small wonder so many authors recommend protection for whistle-blowers.[6,44]

Institutionalization of investigative procedures for handling cases of alleged misconduct is often recommended. On moral and legal grounds, due process is essential to an institutional review process in the same way that informed consent is an essential part of medical research. Fair and public investigative procedures provide a structure for judging the facts of the case so that appropriate penalties—the "treatment"—can be meted out.[45] Kassirer[29] mentioned "how much trouble and disgrace are entailed in misconduct investigations," effects that apply not only to those found guilty but also to those wrongly accused.[46,47] The regular reports of the Office of Research Integrity detail a common sanction against those convicted of misconduct: ineligibility for federal funding, a serious punishment for any scientist whose livelihood depends upon outside funds. At least one journal has published sanctions to be meted out to authors involved in inappropriate acts;[48] fabrication, for example, brings a penalty of "two years to life" during which time the author may not submit a manuscript to that journal for consideration. A recent legal case involving theft of intellectual property resulted in a monetary award of just over $3 million to the plaintiff.[49]

Problems Emerging within a Framework of Secondary Prevention

As in the case of primary prevention, there are some problems in approaching scientific misconduct from the perspective of secondary prevention. If any form of increased surveillance occurs (including formal auditing procedures or the less formal approach of encouraging scientists to take seriously their responsibility to report misconduct), then we can expect an increase in the number of cases of scientific misconduct detected. However, such an increase may represent not a true change in the underlying incidence of events, but rather an apparent change due solely to more intense surveillance. This is a well-known phenomenon in programs designed to detect disease early. For the early detection of scientific misconduct, the inevitable increase in numbers of misconduct cases arising from increased surveillance could be misconstrued by commentators, the press, legislators, and others as indicative of a larger problem than truly exists.

A second problem involves the effects of financial penalties and other sanctions. The extent to which sanctions prevent further incidents of scientific misconduct is an unexplored empirical question. Institutional investigational procedures, monetary and publishing disincentives, and other strategies, such as firing the guilty party, may have a preventive effect by engendering second thoughts about committing misconduct among both would-be repeat offenders and would-be first offenders.[29]

Summary

Disease prevention frameworks sometimes include a category of tertiary prevention, which typically involves rehabilitation and other aspects of long-term care. Tertiary prevention can also be applied to scientific misconduct, inasmuch as those who commit such misconduct may require rehabilitation before they return to scientific practice. A more complete analysis will likely lead, as it did in the case of primary and secondary prevention, to questions with answers based on relatively little empirical information. Indeed, in the foregoing analysis, a host of such questions have emerged. Answers will be difficult to obtain, especially if precise scientific methodologies are to be employed. But then, we are scientists, and solving difficult empirical problems is what we do best. Perhaps the essential question is less methodological than motivational: Are we as scientists willing to study our conduct as scientists? If so, then one day we may discover why we suffer from an important and sometimes disabling professional affliction and what works to prevent it.

I am not suggesting, however, that we should postpone interventions until we fully understand the etiology, including the underlying biological, behavioral, and social mechanisms involved in the range of activities we call scientific misconduct. We need fair investigative procedures. We can accept (perhaps on faith) that the discussion of the role of ethics in the conduct of science and medicine[50] should be expanded. Those of us who act as mentors can and should conduct ourselves virtuously.[25] For the sake of those we train, and especially for those whose lives are improved by our scientific results, we must exhibit excellence, self-effacement, and, perhaps above all, an unwavering commitment to the truth. □

Acknowledgments

Drs Jeff Kahn and Robert E. McKeown provided helpful suggestions on an earlier draft.

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