Random Audit of Papers Proposed

Audit, conducted as scientific experiment, could provide factual evidence on integrity of published papers

This is the fifth in a series of occasional articles on conduct in science.

THE POSSIBILITY THAT FRAUD is widespread in science is for researchers and their congressional patrons one of the most troublesome prospects of our time. Some people argue that the scientific literature is laced with more flawed papers than anyone is willing to admit. But they do not know this for a fact.

Many others take the position that fraud—particularly defined as outright fabrication—is extremely rare. However, because hard evidence has not been collected yet, it is not now possible to prove this contention any more than it is possible to prove its opposite. One can say, however, that the incidence of reported cases of fraud appears not to be going up.

But few argue that subtler problems are of concern. Colin Norman's article (p. 659) on a dispute over data in a collaborative research project is illustrative of the complex issues that the scientific community is grappling with.

Drummond Rennie, the West Coast editor of the *Journal of the American Medical Association*, proposes that journal editors join forces to find out just what the extent of the problem is. At a recent meeting on the "responsible conduct of science," sponsored by the Institute of Medicine, and again at a conference on "ethics and policy in scientific publication" organized by the Council of Biology Editors, Rennie suggested an audit of the literature. Noting that Congress has already proposed creating a new cop-shop within the Department of Health and Human Services that would have authority to audit papers at random (*Science*, 30 September, p. 1748), Rennie proposed an audit as a preemptive strike against bureaucracy.

"Surely for political as well as for scientific reasons we should know the extent of the problem," Rennie stated at the editors, meeting which was held at the National Academy of Sciences. The audit he proposes "would be scholarly and would not demand the setting up of a large federal bureaucracy which could not easily be dismantled," he said. And, if properly conducted, an audit might go a long way toward settling the debate about the extent of fraud and misrepresentation which is grounded now only in anecdotal evidence.

"We would begin to get some crude idea about whether the problem is one that is so rife that it is destroying science. If it is, then we can, with the research institutions, set up really serious procedures for policing it. If it is negligible, we can feel relieved. We can then reassure our congressional masters, and this time we might appear credible instead of merely looking ludicrous to them, and we will be able to stop having round-the-clock meetings about a subject on which there are absolutely no data."

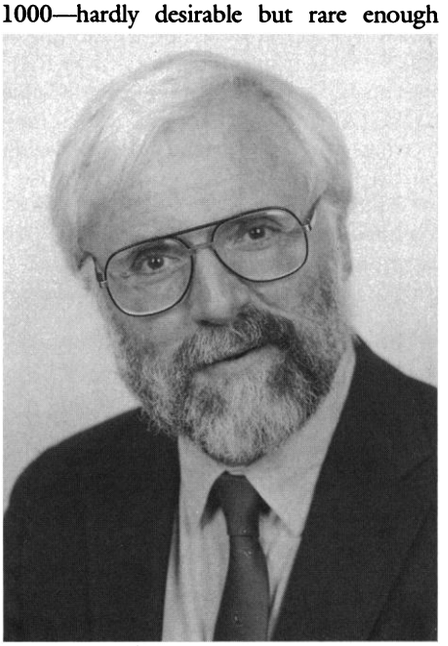
Random audits by government authorities is an idea that smacks of Big Brother and has virtually no support among researchers. But an audit to collect data that could be scientifically valid drew considerable backing. *Science* editor Daniel Koshland said that as an "experiment, a scientific experiment," it could be quite useful. Maxine Singer, president of the Carnegie Institution of Washington and former chairman of the *Proceedings of the National Academy of Sciences*, declared herself "initially favorable" to the idea of a basic audit that, with a simple checklist, could provide information on "all sorts of authorship issues, including multiple publication of data, and the reasonableness of references" to previously published work.

Others, including Arnold Relman, editor-in-chief of *The New England Journal of Medicine*, take a less sanguine view of an experimental audit. "I do not share enthusiasm for an audit," he said, arguing that the better solution lies in a stringent demand that everyone whose name is on a paper take full responsibility for it.

But Rennie's view of the inevitability of an audit in some guise is probably sound. "Audit is going to be part of our scientific as well as our medical and tax-paying lives and I am proposing that we should seize the initiative and direct, rather than merely record events."

What would an audit look like? As conceived by Rennie and others, it would be a tool for examining broad questions about scientific papers. "Was the work done?" "Did the patients exist?" "Are the records preserved?" "Do the data in the charts correspond to those in the report and is the report fairly representative of these data?" It is the sort of audit that could be done by having a group of biomedical graduate students or postdoctoral fellows check hospital records and peruse data books. The purpose would not, nearly everyone who is sympathetic to the idea emphasizes, be to adjudicate gray areas of scientific disagreement.

Statistician John C. Bailar III, a coorganizer of the biology editors' conference, said in an interview with *Science* that the size of the audit would depend, in part, on the nature of the questions asked and the percentage of fraud one might consider tolerable. For instance, if it were decided to search the literature to see if one could detect one fraudulent paper in 1000, 3000 papers would have to be audited to get an answer at 95% statistical accuracy. If no fraudulent paper turned up, one could conclude that the incidence of fraud is less than 1 in 1000—hardly desirable but rare enough



Drummond Rennie *suggests an audit as a preemptive strike against the bureaucracy.*

perhaps to support the contention that fraud really is uncommon. "An incidence of 1 in 1000 would not be a serious problem in terms of science overall, in terms of knowledge" statistician Bailar argues, "but it would be a serious blow in terms of public perception."

What if the audit turned up two or three or even ten or more papers that were not fraudulent but that were nonetheless imperfect—papers in which the authors had used inappropriate statistical techniques for analyzing their data, for instance, or in which data interpretations were ambiguous. This, Bailar speculates, is the more likely outcome of an audit, and highlights the need to make sharp distinctions between outright fraud, poor science, and honest error.

Designing a first-class protocol for an audit, if one is to be done, will be crucial. "An inappropriate study of fraud that confuses fraud with mistaken or challengeable judgment could be destructive in the long run," Bailar believes.

How much would an audit cost? Estimates vary, but it surely would cost $100 a paper, and maybe as much as $1000. Financially, it could be done with support from one or more federal agencies.

Bailar and others who tend to favor the idea of an audit think the next step is to actually design a real protocol for an audit so that the proposition can be debated and evaluated in specific scientific terms. Just who will do that remains to be seen.

■ BARBARA J. CULLITON

Authorship, Data Ownership Examined

As the research community examines the problem of scientific fraud, misconduct, and honest error, a number of issues assume importance. Two of them—ownership of data and authorship policies—are among several that have been raised at recent conferences on responsibility in science.

■ **Authorship and other credit.** Who should be listed as an author of a paper? It sounds like a simple question, but many scientists suggest that it is both subjective and complex—sufficiently complex that at several meetings on the subject during the past few months it has not been possible to get a definition everyone can agree on.

New England Journal of Medicine editor Arnold Relman, at an authorship meeting at the National Institutes of Health in May, and again at the Institute of Medicine (IOM) and Council of Biology Editors meetings this fall, sketched the following definition. To qualify as an author, a person must fulfill two of four requirements:

1) Conception of idea and design of experiment.

2) Actual execution of experiment; hands-on lab work.

3) Analysis and interpretation of data.

4) Actual writing of manuscript.

Response has varied. Edward Huth, editor of the *Annals of Internal Medicine*, said at the IOM conference that to qualify as an author, one should fulfill three (not just two) of Relman's postulated requirements. Others take the position that appropriate decisions about who is an author cannot be based on a checklist.

And, although virtually everyone states that "honorary authorship"—for instance, the practice of putting the lab chief's name on the paper even though he made no substantial contribution to the work—is deplorable, it has been difficult for scientists to reach an agreed upon definition of honorary.

Although certain bounds are clear, conferees debated whether strict authorship guidelines would unfairly exclude postdocs from papers. And one said that credit for an idea is sometimes hard to pin down in retrospect.

Various observers have suggested that the authorship problem could be resolved by establishing categories of authorship and other credits which would separate full authorship from other contributions. Relman suggests categories such as "with the assistance of" or "with the collaboration of."

Constance C. Conrad of Emory University says science might look to television and the movies for inspiration. The cameraman is listed as cameraman; the makeup artist is recognized for his specific talent; the set designer gets his due. So, Conrad suggests, why not give lab chiefs credit for assistance in grant-getting and in providing a good research environment, without calling them authors if they are not? To meet the need all researchers have for credit when it comes to promotion and tenure, she suggests that "credit" be accepted as a legitimate category of professional contribution that can be listed on one's résumé. Were this accepted, she believes, "authorship would be restored to meaning."

Existing attempts by various professional groups, including the biology editors, are ripe for study. Says Huth, the first step to a solution would be wider dissemination of editors' definitions of authorship and a requirement that authors indicate at the point of submission of their paper how their contributions fit the definition.

■ **Who owns the data?** Ownership of research data has, until recently, never been much of an issue. It is a question nearly all academic scientists could answer with confidence and consensus. The researcher owns the data. That may not be so, or not exclusively so. It is a point that requires resolution; recent comments illustrate the complexity of the question.

At an IOM meeting in September, Linda Lorimer, a lawyer who is president of Randolph-Macon Woman's College was rapporteur for a panel on institutional oversight, comprised of attorneys, deans, and administrators. "The institution, not the investigator, is probably the ultimate owner," she reported, adding that there should be written policies about who keeps data and for how long.

Carl Djerassi of Stanford, taking the more traditional position, replied: "I object to the view that institutions own the data. That's not correct. Universities might not even want them."

Harvard Medical School recently had this to say on the subject in its new policy on guidelines for research (*Science*, 29 July, p. 525): "Custody of all original laboratory data must be retained by the unit in which they were generated"—a virtual assertion of institutional ownership or, at least, coownership. The new policy also states that "An investigator may make copies of the primary data for his/her own use."

At a Council of Biology Editors conference 2 weeks ago, a legal perspective on data ownership was offered by Richard Riseberg, chief counsel of the Public Health Service and former chief counsel to NIH. In the academic sector, he noted, the researcher usually is free to keep the data because the "university rarely asserts ownership rights." In industry, ownership is defined by contract; data usually belong to the company. And in government, well, said Riseberg, "What a government scientist produces on government time belongs to the government. But that is hard to tell young NIH researchers who do not view themselves as government employees."

Within NIH, Riseberg made it plain, the rights of access to data are broad. "Clearly a supervisor has a right of access. The Secretary of HHS probably does too." In any lab with NIH funding, the inspector general has a right of access. Congressional oversight committees have subpoena power, and in cases of dispute, so do the courts. "The courts have a right to every person's evidence," Riseberg reminded the editors.

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