An Instance of Data Manipulation

Labs A & B had been collaborating for some time, leading to a publication that appeared in a very prestigious journal. Some months later, Mary, who is a researcher from Lab A, visited Lab B to learn a technique used in the paper. While there, she became highly suspicious of the technique that the lab technicians and researchers were using. When she questioned them, they were very vague in their explanations and never really showed her how to do the experiment that she visited to learn. When she returned and reported all this to her PI, he decided to do an experiment on his own. Instead of sending the next batch of dissolved protein to Lab B as it was expecting, Mary's PI sent pure water. Lab B generated data from the water. Mary's PI then called the PI of Lab B, who denied wrongdoing and broke off the collaboration. Mary's PI did not publicly report the false data, however, for fear that the earlier paper the labs had co-authored might be suspected of data manipulation.

The PI from Lab B was clearly in an ethical bind. On the one hand, it certainly appeared he had an obligation to report falsified data. On the other, he has an obligation to protect his lab's future. The retraction of a previously published paper in a very high impact journal would put his career and the future of his and his collaborator's labs in jeopardy. Indeed, the consequences of a blemish to one PI's ethical conduct would affect everyone else in the labs as they attempt to procure future funding and jobs.

My PI appeared to feel more obligated to protect his lab's interests since he was not involved in any fabrication, and had no proof of wrongdoing related to the published paper. Still, these kinds of instances are probably not all that uncommon, leading one to wonder how much data fabrication and fraud exist in scientific literature.

Expert Opinion

This case offers the opportunity to examine how data manipulation or fabrication relates to the moral significance of scientific research as well as to the obligation to report suspicions of research misconduct.

According to the U.S. Department of Health and Human Services Office of Research Integrity (ORI), research misconduct is defined as the "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results."[1] The fabrication of research data not only violates ORI mandates but is unequivocally repudiated by most professional organizations as a violation of the most basic ethical standards of research conduct. Caplan has remarked that individuals who lie about research data suffer from a failure of morals,[2] while Hofmann offers the important insight that certain moral norms—particularly openness, honesty, and truthfulness—are so important to the practice of scientific research, that *their presence or absence serves to distinguish between what can be considered science or non-science.* Because anyone can submit false or fabricated "data," Hoffman argues that "(T)he assessment of whether a work holds scientific quality appears to be less dependent on

the results or consequences of a certain type of work, than on moral norms."[3] Telling the truth, honestly reporting data, and not "creating" data are so morally fundamental to the scientific enterprise that their absence contradicts the activity calling itself "science." The primacy of knowledge production is a fundamental element of science that requires absolute faithfulness to honesty and truth telling.

In this case, the data submitted on the specimen of water may well have been fabricated. Both PIs should at least be suspicious about the incident and, clearly, both bear responsibility for managing it. But while it was certainly appropriate for the PI of Lab A to report the findings to the PI of Lab B, now what? What about further reporting this incident?

The *Guidelines for Responsible Conduct of Research* issued by ORI in January 2007 state the following:

> Reporting suspected research misconduct is a shared and serious responsibility of all members of the academic community. Any person who suspects research misconduct has an obligation to report the allegation to the dean of the unit in which the suspected misconduct occurred or to the Research Integrity Officer. Allegations are handled under procedures described in the University's Research Integrity Policy. All reports are treated confidentially to the extent possible, and no adverse action will be taken, either directly or indirectly, against a person who makes such an allegation in good faith. Protection of whistleblowers against retaliation is guaranteed under policies of both the University and the federal and state governments.
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> The Research Integrity Officer must report findings of research misconduct to the funding agency, and in some cases even an allegation must be reported at some stage of the investigation. [4]

But even with this mandate on handling research misconduct, institutional policies can vary widely, leaving the reporting of a particular incident of possible data fabrication like the one described above subject to the interpretation of the particular institution's policies.

There seems to be clear evidence that researchers and institutions interpret this mandate in a very narrow way, suggesting a severe under-reporting of misconduct. ORI reports an average of 24 institutional investigational reports on research misconduct per year. However, in 2006 ORI surveyed researchers about their own observations of misconduct over a 3 year period. They concluded that a very conservative estimate of observed possible research misconduct could be as high as 2,325 incidents per year, almost 100 times the actual rate of reported investigations.

In analyzing why there is so much under-reporting, ORI identified a multitude of institution-wide circumstances and recommended a number of strategies including a zero tolerance for misconduct, protecting whistleblowers, defining clear mechanisms for reporting misconduct, better training of mentors, identifying alternative mechanisms to review and evaluate research misconduct, and modeling of ethical behavior.[5]

In the above case, the ethical response would be to report it. A reasonable approach would be for the PI in Lab A (which received the faulty data) to report this

directly to his compliance officer. Most likely, the compliance officer would then contact the appropriate official responsible for Lab B, assuming Lab B is at another institution. That officer would investigate the current complaint and could decide to more broadly investigate other data generated by Lab B. While this may culminate in a formal investigation and perhaps call into question the data reported in the previously published paper, the PI from Lab A has positioned himself on the moral high ground rather than in an overt or covert cover-up. Indeed, looking to more practical considerations, many scientific fields are so competitive that incorrect or falsified data are readily identified by competitors. To the extent that it is discovered that the PIs remained mum about the possibility of fabricated data, both their reputations may be sullied.

As a final note, one wonders if there shouldn't be an "intermediary" stage of investigation somewhere between the two PIs and a Research Integrity Office (RIO). Notice that the clinical environment has such an intermediate stage in the form of the "incident" report that goes to risk management. Risk management, which strongly encourages a nonpunitive/blameless posture, then investigates the claim with a view to targeting those system weaknesses that contribute to or facilitate the incident and that need repair. But such a more benign sounding intermediary doesn't seem to exist in a research environment. One simply takes one's suspicions to the RIO, whose title conjures up a ruthless instrument of justice. Of course, the two entities would be rather different in that clinical/risk management scenarios typically witness no intentional misconduct, insurance coverage exists for negligences, and so forth, while in the research analogue we are envisioning, one might see intentional falsification, no insurance coverage, reputation at serious risk, and so on. So, perhaps the research intermediary we are proposing could be tried on a pilot basis and "choreographed" with a view to providing as much support to those involved as possible. As it currently exists in suspicions about research misconduct, if one wonders why such suspicions remain under an institution's official moral radar screen, the fear inducing nature of the RIO may be an answer.

Summary: Any fabrication of data is research misconduct and seriously undermines the basic integrity of science and scientific research. As such it is never acceptable. Responsible conduct of research requires that incidents of suspected fabrication of data be reported so that an appropriate investigation can be conducted and actions to correct the data and prevent further misconduct needed to assure integrity is maintained. This will take institutional support for a culture of integrity as well as appropriate actions on the part of the individual researcher.

1 United States Department of Health and Human Services. 2005. Public Health Service policies on research misconduct: Final rule. 42 CFR parts 50 and 93. *Federal Register* 2005; 70: 28370-28400.

2 Caplan, A. 1998. *Due Consideration: Controversy in the Age of Medical Miracles*. John Wiley & sons, Inc., New York, NY.

3 Hofmann, B. 2007. That's not science! The role of moral philosophy in the science/non-science divide. *Theoretical Medicine and Bioethics* 28: 243-256.
4 Office of Research Integrity. January 2007. *Guidelines for Responsible Conduct of Research*. Downloaded from http://www.pitt.edu/~provost/ethresearch.html#_Toc153961828 on 10/13/08.

5 Titus, SL, Wells, JA, Rhoades, LJ. June 2008, Repairing research integrity, *NATURE*, 453 (19) 80-982.