NIMH Assigns Blame for Tainted Studies

An investigation faults two former Stanford psychiatrists for misclassifying patients; 11 studies deemed compromised

Berkeley, California

NINE MONTHS after "The Case of the Tainted Data" made headlines, word is spreading through the mental health research community that sleuths from the National Institute of Mental Health (NIMH) have solved it.

The case went public last fall, when Stanford University announced that 11 papers published over an 8-year period by researchers associated with the university's Mental Health Clinical Research Center had been so compromised by the use of questionable data that they should be withdrawn, corrected, or clarified. The episode, the university said, resulted from "a serious departure from acceptable scientific procedure." But its own internal investigations failed to determine who was to blame for the contaminated studies (*Science*, 4 November 1988, p. 659).

Now NIMH, which had funded the center's work, has pinned the blame on two researchers, both of whom left Stanford before allegations over the papers were raised. In a report completed in May, but unpublicized until now, NIMH fingers psychiatrists Philip Berger, who is currently in private practice, and Stephen Stahl, today at the University of California at San Diego. Berger was faulted for using inappropriate controls, and Stahl was criticized for inaccurately describing patients in two studies.

As a result, NIMH has recommended that Berger be excluded from receiving funding from the Department of Health and Human Services for 3 years. Both Berger and Stahl have been barred from serving on Public Health Service committees for 5 years. And grant applications in which the two researchers participate in the next 5 years must include certification of their reliability from the institution applying for the funds.

Stanford, too, comes under fire in the NIMH report for failing to conduct a thorough enough investigation to establish who was at fault. Indeed, the report raises broad questions about how universities should run this kind of investigation. Should they reach beyond their own campus to ferret out details of misconduct involving a former faculty member? Must they challenge all the collaborators, even if it appears they were not directly involved in some aspects of the research? Or is this dragnet approach incompatible with the standards of academic life?

The tainted papers, which were published between 1979 and 1986, reported studies of neurotransmitter metabolites in patients with psychiatric illness. The work was performed collaboratively by clinicians at the clinical center, then led by Berger, and biochemists working with Jack Barchas in Stanford's psychiatry department.

Berger resigned from Stanford in May 1987 during an investigation of his handling of grant funds. It was only during a follow-up review of the center's progress reports, which was requested by NIMH, that irregularities were discovered in a database containing information on research subjects.

That discovery prompted an investigation by Stanford's Committee on Ethical Scientific Performance. Eleven papers were found to be flawed, primarily because patients identified in one study as suffering from mild senile dementia had been used in these studies as normal controls. Stanford blamed the flaws on poor judgment and lack of communication among collaborators, but stopped short of assigning blame. "We couldn't decide who held a smoking gun," says medical school dean David Korn, who ordered the study.

Stanford is criticized for conducting an incomplete investigation of the case.

Instead, Stanford spread the blame among all the coauthors, suggesting that every author on a paper is responsible for all the data in it.

The NIMH panel did find the smoking gun, however. After interviews with participants and a review of the records, it concluded that Berger was responsible for reclassifying the patients as normal rather than mentally impaired, which led to their use as controls. Berger, in fact, admitted as much in an interview with *Science* last fall. His explanation was that he believed the original diagnosis of senile dementia was incorrect. NIMH says Berger did not tell his collaborators of this decision, however.

The committee also placed blame on Stahl for misrepresenting patients in two movement disorder studies as being drug free, when in fact they had been taking antipsychotic medications. NIMH also held Stahl responsible for the preparation of a book chapter that contained verbatim passages from previously published papers, without permission or attribution.

Unlike Stanford, NIMH vindicated the other authors. "I don't think it is realistic to expect that any of the other authors would necessarily be able to identify those problems," says Suzanne Hadley, cochair of the NIMH panel, and now acting deputy director of the new NIH Office of Scientific Integrity. "I do not think that coauthors are blithely free to reap all the credits of putting their names on coauthored papers, and then disclaim any responsibility for problems," shoots back Korn.

As for NIMH's criticism of Stanford for not establishing guilt, university officials argue that their priority was to correct the scientific record, not to pinpoint blame—especially as it became apparent that those responsible were no longer at Stanford.

Hadley concedes that Stanford is not alone in rejecting responsibility to investigate researchers no longer on its faculty. But she says she hopes to change that view and thus reduce the need for federal investigation. If institutions leave stones unturned in their inquiries, she says, her office may be left with more work than it can handle.

Despite the differences between the Stanford and NIMH panels, both committees agree that a cavalier attitude toward authorship and carelessness in handling data contributed to the errors. A perceived pressure to publish may have been the root cause. "When you read this opus of papers [containing the errors], there's not a lot to them," says Robert Cutler, who chaired the Stanford investigation. As a result, Cutler says Stanford issued an official statement on its promotion standards, to remind faculty that the total number of publications is not as important as quality, and "least publishable unit" or repetitive publications are a detriment to one's record.

In addition, Stanford's Committee on Research has drawn up a set of guidelines on interdisciplinary research, due to be released this fall. Committee chairman Arthur Bienenstock says the guidelines will stress the ultimate responsibility of the principal investigator for the cohesiveness of the work, the responsibility of all authors for its content, and their right to review all data and procedures, as well as the manuscript, prior to submission. ■ MARCIA BARINAGA