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Research Errors and Fraud Case study 1

[The COPE Report 1999, case 98/17](#)

Allegations of scientific fraud and unethical conduct of experiments with attempts to silence the whistleblower

The allegations of fraud

A paper reported a test for diagnosis of a specific, acute, disease with 100% accuracy. Replication studies failed to confirm the findings and suggested that the test is positive in about half those affected and in a similar proportion of normal controls. Other publications by the same authors produced results at variance with their claims and misreported their findings. One author admitted that the data had been altered to show a better result. An earlier publication from the same department described another test for detecting an unrelated disease with 100% accuracy. It was later proved to be without value for the diagnosis of that disease.

The allegations of unethical experimentation

The study involved injections into patients with acute injury, in whom certain functions were likely to be impaired. There was no mention of ethics approval or informed consent. The authors later stated that approval was not required because the test was used for clinical management. There was no previous or subsequent publication demonstrating clinical utility. The employing authority was therefore asked to explain how the test could have been used for clinical management. They replied that it was only a preliminary study. When it was pointed out that such a study would require ethics approval, they stated that this had been obtained, although they had not mentioned this in the paper or subsequent correspondence. When asked to provide a copy of the approval form, they threatened legal action. It is believed that the institution did not have appropriate approval to administer the injection.

Attempts to silence the whistle blower

The whistleblower failed to replicate the observations and noted discrepancies in other papers by the same group. He contacted the patients involved in the study. They described events at variance with those of the published paper and produced documents to prove it. He challenged one of the authors who admitted that data had been altered to give a perfect result. The whistleblower approached the institution and asked for an investigation. Shortly afterwards he was told that an internal enquiry had found no cause for concern. The whistleblower asked why he had not been asked for the names of the patients who disputed the events described in the paper or asked to produce documents. He was threatened with legal action and expelled from a research committee on which he sat. The committee chairman was one of the authors of the disputed study. The institution blocked a request from the whistleblower to use information on a national database which is managed, but not owned, by the institution: the database is theoretically open to all investigators in the field.

Having received no satisfactory response to his request from the head of the institution, the whistleblower approached the journal which published the paper, requesting that the journal publish a paper from him explaining that there had been scientific fraud and unethical experimentation, followed by a response from the authors. The editor felt that there was a case to answer and asked the authors of the original paper to respond. The editor copied the request to the head of the institution. The head of the institution,

instead, referred the whistleblower to the research council for disparagement. The research council investigated the whistleblower for eight months before he was exonerated and the focus of the investigation turned to the authors. What should the editor do now?

The Editor will be expected to make a determination, in his or her reasonable judgment, as to the underlying facts and to make a recommendation to Elsevier (and possibly the society for society journals), which we will implement normally through the retraction and removal process

It may be advisable for the Editor in this fact-finding process to request the views and comments of third parties (in this case research council) who may be expected to have knowledge of the facts alleged by the complainant

Discussion/Advice

- The institution must produce evidence of the investigation.
- The editor should refer the authors to the research council if they are registered because there are legitimate doubts about the ethical procedures for this study.
- A copy of the referring letter should be sent to the head of the institution.