



## **Allegations of research errors and fraud**

### **Case study 1**

**Source:** Committee on Publication Ethics, [Case 98/17](#)

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

### ***The allegations of fraud***

A paper reported a radioisotope test for diagnosis of a specific, acute, neurological 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 isotope 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 injection of a large dose of isotope 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 isotope.

### ***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 GMC (research council) for disparagement. The GMC 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?

***Discussion/advice***

- The institution must produce evidence of the investigation.
- The editor should refer the authors to the GMC (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.

***Outcome***

The case is still in dispute.