**Case 02/12**

# Babies needlessly subjected to a painful procedure for research

A paper was received, which detailed a research project conducted on newborn babies, which involved taking an invasive (and painful) sample from them.

The paper was worthy of publication from the point of view of scientific value, but two issues worried the editors. First, it was unclear whether the sick babies' samples were going to be used as part of their clinical management or whether these samples were taken simply for the trial. The referee thought that certain reported parameters indicated the latter.

Second, and more worryingly, the control group of healthy babies had a similar sample taken. The control group comprised all the babies meeting the inclusion criteria. The editors were concerned that this would not have been possible without some coercion of the parents.

The editors wrote to the authors, asking for elucidation and learned that the samples were, indeed, taken by staff when they were collecting another routine sample. The authors added: "We took the chance and asked parents for consent in taking a little more blood . . . our ethics committee would never sanction [the invasive procedure] in normal infants just for research."

The editors then asked for clarification of the precise nature of the ethics committee approval and parent consent forms, pointing out that the routine sample collection would not involve the invasive procedure performed except in limited circumstances. The authors responded by withdrawing the paper and declining to send the relevant documents. They complained that the editors had mistrusted them.

Should this be taken further? The editors think it should, on the grounds that the babies were unnecessarily subjected to a painful procedure.

## Discussion/Advice

- The editors should pursue the issue further and approach the head of the authors' institution, and if necessary, involve higher authorities.
- A deadline should be imposed for a response.
- As there appeared to be a discrepancy between the authors' assertion that the sampling was undertaken as part of a routine procedure and the fact that the trial sample would have to be an additional invasive procedure, it was important to follow this up.

## Outcome

The authors' institution has not replied to either of the two letters sent. The editor plans to approach a higher authority.

**Case 02/15**

# Possibly unethical report on the safety and efficacy of a minor operation

Two companion papers from a single author, a paediatric surgeon working in a secondary/tertiary unit, were received. He had performed the same minor operation on 420 babies and 60 children over two years. His paper purported to report safety and efficacy.

From the hanging committee's own knowledge, and after checking with a surgical board member, a paediatric surgeon might be expected to do four or five such procedures in a year in an average practice, but there were over 200 in the report.

Paediatricians regard the procedure as unnecessary. All paediatric textbooks agree. Apparently, some paediatric surgeons overseas, parent support groups, and speech therapists are quite keen on it.

There is no good evidence base on which to decide who is right.

The concerns were:

1. As there was no known indication for the treatment, should it have been part of a randomised controlled trial?
2. Ethics committee approval was not sought.
3. The stated indications for surgery were highly subjective and, in any case, mostly regarded by paediatricians as representing normal and transient physiological or behavioural events.
4. There were no statements made about mode of referral, and these surely could not have been made by local paediatricians.
5. Many infants were not anaesthetised, although the author claimed it caused no distress.

The papers were rejected, and the author was informed of the anxieties. What should be done now?

## Discussion/Advice

- In the absence of an evidence base relating to the procedure's indications any trial should have a control arm and be approved by the institution's research ethics committee.
- The papers were submitted as cases series, where there had been a range of preoperative symptoms and no standardised pre or postoperative assessment reported. It was unclear whether the procedures were carried out in private or public practice. Did the papers represent a research study?
- In similar previous cases, investigators had to go back to the theatre records, patient notes, and original statistical analysis. It is sometimes difficult to draw a line between where clinical innovation ends and experimentation begins.
- The editor should seek clarification from the author, advising him that he would raise his concerns with the institution where the surgeon was based/operations being carried out, over the failure to obtain ethical committee approval for an unusual procedure.
- If patient safety is an issue there is a statutory duty on the chief executive of the hospital to ensure this.

## Outcome

The editor wrote to the author's institution, informing the author about this course of action. The author had requested a copy of the letter and also the COPE minute on the case. The chief executive of the institution agreed to fully investigate the case.

The medical director convened a Trust committee/panel, which concluded that the doctor's activities did not count as research and gave the procedure a clean bill of health. The panel felt that the work submitted to the journal was a case series. The editor was not informed of the membership of the inquiry. He felt that the committee of inquiry appeared to have not taken external advice on the procedure under scrutiny.

Patients had been referred from a substantial group of non-clinicians, a normal practice in this field, but there is some disquiet in local medical circles that this procedure is being carried out in such volume.

**Case 02/15** ***continued***

## Further advice

- The editor should try to get more information on the Trust's investigation.
- The editor should take his concerns to the doctor's and medical director's regulatory body, notifying the doctor and the Trust of his intentions. As a registered physician, the editor has a duty to report any serious concerns to the regulatory body.
- The editor is a member of the regulatory body. which imposes a higher duty to report his concerns and act on them.
- The editor's case for reporting was strengthened by the fact that he had taken the advice of COPE on the matter.

**Case 02/16**

# Co authors' unwillingness to support retraction of a review

A review by three authors, with Dr X as the lead author, was published in Journal A.

Five months later, the editor of Journal A was informed by Professor W that a figure in the review by Dr X had originally appeared in a research paper, co-authored by Professor W in Journal B in 1990. The professor also said that Dr X had published the same or very similar figures in journals C, D (research papers), and E (review). The Journal C paper was reference 5 in the Journal A review.

Dr X denied that he had "stolen" the figure. However, after an "expert review" Journal C concluded that the figures were the same and the journal's editors retracted Dr X's paper. Dr X has since started legal proceedings against one of the editors of Journal C.

Professor W is pushing for a complete retraction of the review in Journal A. Dr X is willing to voluntarily retract the paper, but his co authors do not support this, because the figure in question makes no difference to the uncontroversial conclusions of the review. Journal A published a statement noting the retraction by Journal C, and Journal E has published a similar statement.

Journal D recruited an expert to examine Professor W's original pathological material. Journal A has collaborated with this investigation. The expert concluded that the figures published by journals A and D are the same as Professor W's original slides. Dr X has been told by journals A and D that they will request his institution to investigate the allegations made against him.

This case refers to the same disputed figure brought to COPE by another member journal in case 02/02.

## Discussion/Advice

- If the figure was originally Professor W's and published in 1990, then the original journal would have copyright over the figure.
- If the review was adequate without the figure, then the journal could either withdraw the figure or acknowledge the original copyright holder.
- The original slide would have to be studied to make a correct assessment of the professor's claim.
- How could a figure belonging to one author come into the possession of another? The journal has been told that Professor W and Dr X were collaborators in the past and that the image had been entered into a database of clinical images and had allegedly been extracted from there.
- Had any copyright documents been associated with the deposit of the image on the database?
- If Dr X's co authors do not wish to retract the paper, then the journal could publish an addendum/erratum explaining the issues surrounding the figure ownership, acknowledging the original copyright holder.
- It is not the journal's duty to resolve the dispute between Professor W and Dr X.
- The editor could decide on a course of action after hearing the results of Dr X's institutional investigation.

**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 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 neurological injury, in whom cognitive function was 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 an MRC 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 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 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.

**Keywords:** whistleblowing; ethics committee approval; fraud; unethical experimentation

**Case 02/01**

# New surgical technique without evidence of either ethics committee approval or patient consent

A study was submitted in which the authors describe a new surgical technique, which includes radio frequency coagulation, to treat complete prolapse of the rectum. They say in their paper that: "in the treatment of complete rectal prolapse, no operation stands out in comparison to the others."

The authors do not seem to have received either ethics committee approval or consent from the patients.

How should the editors proceed?

## Discussion/Advice

- The committee assumed that the editor had already queried whether or not the authors had ethical approval and consent.
- What constitutes research in a surgical case series is a very grey area.
- How "informed" would the patient consent be?
- If the editor has any remaining doubts then he should report the authors to the head of their institution.

## Outcome

The case was sent to the journal's ethics committee as well as COPE, who disputed the authors' suggestion that their country "did not have any ethical committee whose permission is needed to carry out any new procedure."

The authors' country had recently enacted research guidelines. The key issue would be whether surgical innovations would fall within the guidelines' remit. The editor wrote to the authors including the new guidelines adopted in their country and invited a reply.

To date the editor has received no reply. It was unclear who the editor should approach as a higher authority, because the authors appeared to be working at their own organisation. The journal's ethics committee suggested that if there is no local ethics committee, then the editor should consider writing to the relevant licensing body.