Tarnishing reputations: the downside of medical activism

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When I started writing essays in favour of wronged patients in the late 1960s, I was warned of this possibility. Criticisms of that section of the medical profession that hurt patients or ill-treated them or cheated them inevitably drew censure of my action. While there was never any dispute about the facts laid down by me in my papers, the admonitions I received were against tarnishing the profession. I was upset at this as I have always taken great care to point out that the miscreants were only a proportion of the professionals. Even so, I was roundly criticised at a public meeting of doctors under the aegis of the Indian Medical Association for censuring any member of the profession.

While I continue to feel that errant doctors should be disciplined, I now have before me an example of an honest doctor whose reputation is being tarnished by a colleague. I have witnessed the agony of the wronged doctor and his family and write this essay to highlight the injustice done to them.

The facts as I understand them

Dr Apoorva Pauranik is a consultant neurophysician and Professor of Neurology at the Mahatma Gandhi Memorial Medical College and at the affiliated Maharaja Yeshwant Rao Hospital (MY Hospital) in Indore, Madhya Pradesh. I have known him for some decades and have always found him a sober, sincere, hard-working and straightforward person who has the best interests of his patients at heart. He is a keen votary of inclusion of the humanities in medical education and of ethical medical practice.

Imagine my surprise when I read a headline in a newspaper: "Indore docs flout clinical trial norms, earn lakhs" (1) and in the text "…Dr Apoorva Pauranik of neurology made Rs 42 lakh…" The same report quotes Dr Chandra M Gulhati, editor of *Monthly Index of Medical Specialities* (*MIMS*), as having repeated this allegation in volume 31, number 5, of his publication dated May 2011. Some reports even stated that Dr Pauranik had conducted a trial of a drug used in bronchial asthma and another for cardiac problems! (2)

The reports were sparked off after a campaign by Dr Anand Rai of the same hospital against Dr Pauranik and other senior teachers.

My enquiries show that Dr Pauranik's trials were conducted at the MY Hospital after obtaining the approval of the Drugs Controller General of India and the ethics committee of the hospital. The ethics committee has as its chairperson Prof Dr KD Bhargava and eminent members like retired High Court Justice P D Muley. Other lay members are Mr Govindan Kutty Menon, a social worker; Mr Jayantilal Bhandari, a social worker; and Mr Yogesh Mittal, an advocate. The agreement papers for the trials, including financial details, were scrutinised and signed by the dean of the hospital. The procedure for obtaining the consent of subjects was scrupulously followed.

All subjects who served as participants in the trials were paid travel expenses and sums to compensate the loss of wages on the day they attended the clinic, in accordance with guidelines laid down by the Indian Council of Medical Research.

The agreement papers permitted the scientific investigators to be remunerated for the time and effort spent in conducting the trial. The dean and the ethics committee knew this. This is common practice and as long as the accounts are transparent and audited, there is no objection to this practice. This income featured in the audited accounts of the trials and in the income tax returns of the investigators. Funds had also been spent by the sponsors of the trials for travel by the investigators to meetings where the trials were discussed.

The single death amongst patients included in the trials conducted by Dr Pauranik occurred 10 months after the 70-year old patient with Alzheimer's disease had last attended the clinic where follow-up evaluations were carried out. I cannot see how the death can be linked to the trial which she had discontinued 10 months earlier. Five adverse events noted in Dr Pauranik's trials were evaluated by an ethics and scientific review committee. The report of these discussions, signed by the chairperson, Dr KD Bhargava, Head, Department of Medicine, and two consultant neurologists from the CHL Apollo Hospital, Indore, in no way connected with the trials, pronounced these adverse effects unrelated to the trial.

Since the audit report is not in the public domain, it is difficult to comment on it.

A criticism was made of the use of donezepil hydrochloride in the dose of 23 mg in patients with Alzheimer's disease in Dr Pauranik's trial. This is surprising for the American Food and Drugs Administration has approved such usage since 2010. In any event, institutional ethics committees at 219 centres around the world and Indian regulatory authorities had approved of this dose for the trial and of the 1,467 patients enrolled for the trial around the world, only six were from Indore. There was no evidence of any adverse event related to the use of this dose of the drug at any centre. It is worth noting that other Indian

centres participating in this trial included the Nizam's Institute of Medical Science, Hyderabad; Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram; PD Hinduja National Hospital and Research Centre, Mumbai; Kokilaben Dhirubhai Ambani Hospital, Mumbai; and St John's Medical College and Hospital, Bangalore.

Conclusion

Wherever clinical trials in India are conducted under substandard conditions, these must be uncovered and laid before public scrutiny; and if the facts speak against the investigator, suitable disciplinary action instituted. This does not mean that unfounded, misguided or vicious allegations be propagated by doctors and laypersons in the media. It is time that a mechanism was laid down for disciplining such vilifiers for slander and libel.

The lay public does not understand the intricacies of clinical trials in particular, and many medical matters in general. Editors of journals (especially those as prestigious as *MIMS*) and of the national dailies and TV networks carry a special responsibility when reporting on them. It is up to them to explain the pros and cons and double-check their statements. Few of them take the trouble to contact the individual they are about to place in the dock to obtain his version of the event(s) or scrutinise the relevant documents. In the event, they end up accusing innocent physicians and ruining their reputations.

The statement in an editorial in *The Lancet* (3) on cancer can be applied on a wider basis: "Many cancer patients are waiting for new drugs and media reports on clinical trials are increasing. The effect of mass media on the public is strong. In clinical trials, specialized knowledge and technology are required. The associated terms and skills differ from those of general medicine and are not familiar to the public and the media. If information on clinical trials is not properly shared among researchers, patients and media, it can result in chaos…"

Some suggestions on the conduct of clinical trials

Learning from the travails of Dr Pauranik, I offer the following suggestions:

a) A major problem highlighted in news reports is that Dr Pauranik profited to the tune of Rs 26,00,000. This is based on the fact that the sums sanctioned for the trials were paid directly into Dr Pauranik's personal bank account. The fact that all expenses incurred during the clinical trial were also met from this account has been ignored. Dr Pauranik maintained a separate ledger for trial-related income and expenses.

   The practice followed in the few clinical trials in which I have participated has been to open a new bank account for each clinical trial. All deposits are made into it and expenses paid from it. At the conclusion of the trial, the account is closed and audited. The chartered accountant's statement will show the exact state of financial transactions and exonerate the innocent principal investigator of the charges of malfeasance.

b) It is best to appoint an investigating body that is totally independent of those conducting trials that have been questioned. In this case, the dean could have ensured that none of the principal investigators under investigation had anything to do with the analysis of their trials.

c) Travel to meetings of principal investigators of multi-centric trials is necessary for discussions, training on protocol and conduct of the study, analysis of interim results, analysis of adverse results and eventual collation and final analysis of findings. Dr Pauranik's travel to a meeting where, apart from the several Indian investigators, those from Austria, the Czech Republic, Hungary, Italy, Korea, the Philippines, Poland, Russia, Slovakia, Spain and the UK were also invited cannot be faulted on any count. The inclusion of the reports of such meetings in the closing report on the trial will enable readers to understand the necessity for travel.

d) One of the ways forward is for institutions to set up data safety monitoring boards for oversight within the institution. Setting up of clinical research secretariats and a society within the institution to accept and disburse grants from the pharmaceutical industry would also help.

Acknowledgements *I gladly acknowledge the help kindly and promptly given by Dr Arun Bhatt, President, Clininvent Research, that resulted in a more factual and improved essay. I also wish to thank the anonymous reviewer who offered constructive suggestions for improvement*.

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