EDITORIAL

Research : history repeats itself

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The news that patients at the Regional Cancer Centre (RCC) in Trivandrum were administered an experimental drug without their knowledge should not surprise us. However, the very fact that this trial took place is a reflection on the inadequacy of existing mechanisms to protect participants from unethical research.

Between November 1999 and April 2000, 25 oral cancer patients at the RCC had their tumours injected with tetra-O-methyl nor-dihydro-guaiaretic acid (M4N) or tetraglycinyl nor-dihydro-guaiaretic acid (G4N), an experimental chemical in an attempt to evaluate the anti-tumour properties of the chemical.The study was initiated by Professor Ru Chih C Huang of the Johns Hopkins University (JHU), USA, with funding from JHU.

Patients had not been informed of the chemical's risks and were exposed to the toxic effects of an untested drug. (In US studies the chemical was found to stimulate human cancers.) The trial was also conducted without the prior approval of the Drug Controller General of India (DCGI).

A breach of trust

The trial represented a serious breach of trust - the very basis of the doctor-patient relationship. People with cancer went to the RCC for treatment - and were used as experimental subjects. The chemicals had earlier been tested on mice at JHU, but no human trials had been done Thus, patients were exposed to a potentially dangerous chemical without their knowledge. In the belief that they were undergoing standard, life-saving procedures, they signed what they thought were routine consent forms in English, a language they did not understand well. They certainly had no idea that they were helping the RCC develop a drug from which it planned to earn royalties. Finally, Indians were used as guinea pigs to test a drug that could not be tested in the US. Thus, all principles of medical ethics - patient autonomy, beneficence, non-maleficence and justice - were flouted. How did this trial take place at all? Sanction from the Drug Controller-General of India (DCGI) was given only in February 2001, almost a year after the trial's completion. (It is not clear how approval for this phase II trial was obtained, since reportedly phase I trials were not done.) The RCC ethics committee okayed the study - despite its evident flaws, and without confirming that it had obtained DGCI approval. JHU released funds even though its ethics committee had not cleared the project.

A failure of institutional monitoring mechanisms

If two respected institutions could ignore the ICMR's ethical guidelines, international guidelines such as the Helsinki Declaration, as well as the DGCI's legal requirements, one can only speculate on what is happening in the thousands of medical research projects in public and private institutions all over India. How many unethical studies go unreported because no one steps forward to complain?

Health authorities recently enquired into how patients in a private New Delhi hospital received an experimental treatment for coronary artery disease - developed in the US but not tested there. But such action is the exception not the rule. Women's and health groups had to go to court before the DCGI agreed to ban the unapproved testing of quinacrine as a 'chemical sterilising agent'. By that time, thousands of poor rural Indian women had been sterilised, with unknown consequences, and the court did not sanction a follow-up of the women who have been experimented on.

Further, the ICMR does not have the machinery to effectively monitor the research it does fund; it has no authority over studies funded by other organisations. In fact the RCC plans to continue its work and the trial is scheduled to continue in three other hospitals. In effect, there is nothing to protect Indians from unethical research.

The situation is all the more frightening as India becomes the site for increasing amounts of collaborative drug research, especially for multinational drug companies. We have competent medical professionals, the technical facilities - and thousands of poor patients. A trial in India costs a fraction of what it would in the US.

Such horror stories only contribute to the bad press that the medical profession has been getting in recent years. Dr V N Bhattathiri's petition to the Kerala state human rights commission -- which exposed the trial in the first place -- has sought a review of all trials in the RCC. While this is a start, we have much more to do. An open enquiry followed by punishment of all those found guilty, and an evaluation of the problems and their solutions, are required immediately. The ICMR's finalised guidelines for medical research must be translated into more than just guidelines. Unless justice is done and seen to be done, history will repeat itself, again.

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