Report on a workshop on ethics in biomedical research, Trivandrum

The workshop (January 19-20, 2002) was jointly organised by the Kerala Health Studies and Research Centre (KHSRC), Trivandrum, the Department of Community Medicine at the Medical College, Trivandrum, and the Forum for Medical Ethics Society, Mumbai. Participants came from all over the state, representing community medicine, pharmacology and forensic medicine and various other specialities in private and public practice.

Dr Joy Elamon, Executive Director of the KHSRC said the workshop had been organised in the light of recent research controversies, in order to discuss some central ethical questions in the conduct of research.

Dr Uma, Head of the Department of Community Medicine at the Medical College, noted that though the public displayed a keen interest in ethical issues, students had only a vague understanding of these concepts.

In his inaugural address, **Dr C R Soman**, director of Health Action for the People, noted that the setting in which medicine is practiced has become more controversial over the years, calling into question the very foundation of medical practice. The medical profession is corrupt and bereft of concern for human welfare. Ethics was an integral part of practice in the traditional systems of medicine. Doctors need to take the principles of traditional practice to western science. Finally, collaborative research had grown exponentially since the 1970s, bringing with it a host of potentially exploitative situations.

Dr B Ekbal, vice chancellor of Kerala University, said though Kerala is a progressive state and the majority of doctors practice ethically, they are often insensitive when discussing medical practice. There is little discussion on ethical questions related to various aspects of medical practice. Even as the profession is reluctant to confront long-standing ethical dilemmas, new challenges are posed every day by advances in medical science.

Presentations were made on recent unethical trials and other research controversies, principles governing medical research, the role of ethics committees, issues in collaborative research, informed consent, the ICMR's work in developing ethical guidelines, and fraud in medical research. Small group discussions were held on case studies.

Among the presentations which led to animated discussion was **Ms Neha Madhiwalla's** on informed consent, particularly in relation to contraceptive research. Ms Madhiwalla noted that written consent is often seen as a requirement to protect the researcher, instead of a way to ensure that researchers follow the protocol. It is important to see the ethos in which we see informed consent. It might be good to get researchers to sign a commitment to undertake to do their duty.

Dr G Sujatan, member of the ethics committee at the Medical College, discussed some consent forms submitted to the committee. Consent forms are often confused with patient information sheets, and both are often incomplete.

Communication and consent: Dr **Sujatan** reported that a poorly communicated consent request for emergency surgery resulted in a suspicion of negligence/malpractice allegation that the patient had been submitted to a nephrectomy under the pretext of another surgical procedure. Dr **M Nair** stated that poor communication is the reason for many allegations of malpractice or negligence. Dr Nair stated that when he knows an operation involves many risks, he explains everything to the patient, writes it out in Malayalam, and asks for written consent. However, there may be situations where there is no time to take consent.

Dr Amar Jesani stated that both consent form and patient information sheet should be in the local language. While the former is partly to protect doctors, the latter is something to which participants can always refer later. Ethics committees must demand that patient information sheets are in the vernacular language and understandable to the patients. Second, researchers could sign the information sheet to take responsibility for the information given. Third, the information sheet should contain the contact details of the ethics committee chairperson who reviewed the proposal. The ethics committee must expand its work to include grievance redressal.

What is the procedure for obtaining consent for screening procedures? A participant observed that family planning clinics do not take consent for post-partum cervical screening since it is not an invasive technique and can be included in the clinical examination. Another stated that treatment policies should be given when obtaining consent for screening. Another asked: should consent be obtained for 'opportunistic' screening?

Should research organisations reimburse patients for travel/expenses? This is going to be a concern if reimbursement — particularly when research is done in poor populations — acts as an incentive to participate in a trial.

HIV testing. Why should the doctor take consent for testing blood for HIV, which after all is a diagnostic procedure? The response was: since HIV has a social stigma, testing must be done in the context of counselling.

Retrospective (medical records) studies need consent only from the institutional head.

Other questions: What are the legal implications of informed consent? Why insist on equality in research alone?

Dr Jesani commented that most of the questions were concerned with legal problems and how to protect the doctor. We should first think of the patient. We should always take consent, even for physical examination; the issue is the form in which this consent expressed. There are certain conditions where it is important to document consent, for example, when invasive procedures are involved. The problem of communication must be addressed. We need a culture of giving patients information.