Ethics in human medical research

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Ethics in human medical research

Views of a non-medical person.

R. P. Ravindra[1]

(As promised in the last issue, we feature an essay on ethics in medical research. We hope this will form the basis for meaningful discussion on steps to improve the current situation. *Editor)*

Ethics - neglected in India

Ethics is an important yet neglected issue in the field of medicine. When discussed. it provokes controversy.In the West we find conscious and continuous debate on this subject. Ethics is not a forbidden word there nor are ethical issues brushed under the carpet. The scientific communities in western countries have nourished a tradition, a culture, an ethos where ethical issues are articulated and debated within and outside professional groups. Declarations made following detailed discussions form the basis of action but remain subject to review. Self-regulatory codes of conduct have evolved and are scrupulously implemented.

The common man in bio-medical research

I speak on behalf of those for whose benefit biomedical research is supposed to be conducted. those who participate in clinical trials, consume the medicines prescribed by doctors and who often are too apprehensive to be able to ask questions.

What is the role of the common man is biomedical research'? Is he a mere passive recipient or should he be an active participant in the process of understanding more about how the human body functions in health and disease and how disease can be treated? What are the rights of the common man and how can they be safeguarded? (The rights of consumers/subjects of research and those of researchers are not contradictory.)

These questions gain significance as the use of human models has grown over the decades and as advances in research have resulted in new dilemmas and contradictions.

International conventions

The World Medical Association. in its Helsinki Declaration of 1975 states unequivocally: 'Concern for the interest of the subject must always prevail over the interests of science and society.' Guiding principles have been formulated on a number of issues. Let us consider just two of them - informed consent and the creation of ethics committees.

Informed consent:

The Charter of Nuremberg (1967) and conclusions of other expert groups state that informed consent must be:

i) a free, enlightened decision by the individual concerned

ii) given by that person only after adequate information on the objects and nature of the study and the possible positive and negative side-effects have been explained to him/her

iii) obtained by a person not in a position to influence the patient (it should not be obtained by the treating physician but by a medical social worker)

iv) obtained only after giving the subject the freedom not to participate in the study without in any way diminishing the quality of medical care provided

v) obtained without offering any economic inducements to influence the decision of the subject

vi) obtained after ensuring that the subject has the right to withdraw from the trial at any stage of the project.

Ethics committees:

The work party of Council for Science and Society, England states in its report: 'What we advocate is the setting up of a standing committee on a national basis, one which will have a balance of strong professional and lay representation and whose objective would be to keep a watching brief over all new developments as they arise. The establishment of such a body is particularly desirable in view of the possibility that one or more techniques may emerge eventually which society would wish decisively to reject.'

The 1974 CIOMS conference on 'Protection of human rights in the light of recent developments in biology and medicine' strongly plead for setting up an international body and for coordination between national bodies set up for this purpose.

The ICMR Guidetines for Clinical Trials advocate the setting up of ethics committees at institutional levels. No research project was to be taken up until this committee had scrutinised it and approved its ethics.

It is recognised by physicians and researchers the world over that the issue of medical ethics cannot be left to the discretion of doctors alone.

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From rhetoric to reality

To what extent are these principles followed?

Most research institutions in India either do not have an ethics committee or, when formed, lack adequate representation on it by lay persons. An ethics committee must be dynamic and vibrant. It must. of course. scrutinise research projects and confirm their ethical validity but it must do much more. It must take a stand on various ethical issues. It's work must be open to scrutiny. It must be responsive and responsible to the people. The public has sanctioned the right of the scientific committee to conduct research. Shouldn't the scientific committee serve the public's right to information and self-determination?

Public information on details of how clinical trials are conducted is meagre. When the trial involves the illiterate and the poor, hardly anything is explained to them. In many trials there is a dropout rate of upto 80%. In such instances, when the trial involves drugs that are injected or implanted into the body, there is little or no attempt at tracing the subjects and confirming that they have suffered no harm. Such experiences, not at all uncommon in India, make a mockery of the lofty concepts of informed consent and ethics committees.

Some researchers and clinicians argue that the concept of informed consent cannot be enforced when the subjects are intellectually or psychologically incapable of comprehension or of making a meaningful choice. Illiteracy and poverty and automatically and illogically equated with an inability to understand and make a rational decision. Very few make the attempt needed to cross an educational or cultural barrier and communicate sincerely with the patient or subject.

Even if it was true that the subjects were unable to understand and make a decision, is it right to proceed with the trial on them?

Judicial experts here and elsewhere have proclaimed again and again the absolute rights of patients and subjects. Every human adult with a sound mind has a right to determine what shall be done with her or his body. No clinician or researcher has the right to use them as subjects against their will merely to serve the ends of the research project or therapeutic protocol even when the ultimate goal is to benefit them. It is a transgression of ethical principles to victimise the poor under these circumstances.

If a research project demands a sufficient number of subjects and the illiterate and poor are deemed unable to offer informed concept, the only solution must be to recruit subjects from the supposedly knowledgable, elite sections of society. A bonus from such recruitment would be the better quality of feedback on all aspects of the trial, especially the complications, from these enlightened subjects.

What about the rights of patients?

Research on drugs does not end with the conclusion of clinical trials. In fact, it begins at this stage for each patient is, to some extent, an experimental subject of the physician. Therapy is always an extended research. The ethical principles applicable to research trials are equally valid in therapy.

What rights do consumers of medicine have in India? Take the common example of a parent taking a child with coryza and cough to the doctor. The prescription includes a broad-spectrum antibiotic, a tonic, a drug intended to reduce irritation in the throat, a cough-suppressant and vitamins. Few doctors explain that the antibiotic will have no effect on the virus causing the child's symptoms or the ill-effects that may ensue from it. The role of a tonic and vitamins in a well-fed and nourished child is also not discussed. Most doctors dispense several tablets in a packet without revealing the precise nature of any of them. What manner of information are our doctors providing their patients? Is it not especially important for us to tell our patients what we are giving them when there is a such a bewildering number and range of formulations - many of them irrational and even hazardous - in the market and when some of our patients arc itinerants, here today and there tomorrow?

> From inability to let well alone; from putting too much zeal for the new and contempt for the old; from putting knowledge before wisdom, science before art and cleverness before common sense; from treating patients as cases and making the cure of the disease more grievous than its endurance; may the Good Lord deliver us.
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> Sir Robert Hutchinson