

Hospital Ethics Committee

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Introduction

Most Indian hospitals have instituted such a committee principally for the purpose of checking whether proposals submitted for research meet established guidelines. Once this has been established, the researcher is permitted to proceed with his work and the committee turns to subsequent proposals. This approach makes a very limited usage of the personnel recruited on such a committee. Much more can be done to improve not only the quality of research undertaken by the institution but also the care of patients in the institution.

'Mission statement of the committee'

The committee must start with an open statement on its aims and objectives. These should be circulated throughout the institution and feedback sought on how this can be improved. It is also necessary to review this mission statement periodically and revise it when necessary.

The following could form the heads under which details can be entered:

- Care of the patient in this institution.
- Research.
- Education of the staff on biomedical ethics.

How should the committee function?

At the helm

There must be at least two senior persons complementing and supplementing each other. They should, preferably, belong to different disciplines.

Who should be a member?

The obvious answer is anyone with a deep commitment to medical ethics. It is important not to skew membership by having several persons from the same discipline. It is also essential to ensure representatives from:

- administration
- clinicians - medical, surgical, other disciplines
- basic sciences
- social worker
- nurse
- rehabilitation personnel
- priest/ philosopher
- lawyer
- statistician

Subcommittees?

If the ethics committee is charged with three principal goals: patient care, research and education of faculty and other personnel; it is logical to entrust each of these to a subcommittee. Monthly meetings of a large, single committee once a month over an hour and a half or two hours are unlikely to do justice to these goals.

Frequency of meetings

This will depend on the goals set for the committee. If the committee is only to restrict itself to processing applications for research, the number of such proposals will govern the dates on which meetings are to be held. Most ethics committees meet at least once a month in order to ensure that no research proposal is held up at the level of the committee.

Each member must attend at least 75% of all meetings.

Structure of each meeting

Silverman² suggests that no more than half an hour at the start of each meeting be devoted to 'business issues': reading the minutes of the previous meeting, reports from subcommittees, new issues. The remaining time must be used to discuss and explore the different moral values within the institution. This is where free discussion on **ethics** is encouraged and decisions sought on this basis. He suggests that discussions on specific cases, their reports having been prepared and circulated in advance, are most likely to yield results. Such cases could be selected with a view to provoking discussions on informed consent, the means by which diagnosis is disclosed to the patient and relations, expenditure incurred by patients, the rationale and justification for expensive tests or therapies, relevance of research being undertaken within the institute...

He also recommends that time be spent at each meeting on reviewing relevant papers on medical ethics published in recent issues of journals, the focus being on how these can be used to improve standards in the institution.

Research

All research proposals must conform to standard scientific and ethical guidelines. These must be scrutinised by a designated member of the committee to ensure that there is no glaring deficiency. (In case of such a deficiency, the proposal should promptly be returned to the researcher with a note on what is needed.)

All proposals received before a stipulated date must be discussed at the next meeting.

The committee must pay special attention to:

- Will the study add substantially to existing knowledge?
- Is the study scientifically, statistically and ethically valid?
- Is it relevant?
- Are the results of this study likely to prove harmful? Pilgaokar¹ points out that we have a moral responsibility to desist from any inquiry as soon as it becomes clear that it is likely to endanger mankind.
- If experiments on animals form an essential component, are humane practices built into the project?
- If human subjects are involved, special attention must be paid to how truly informed consent is obtained, what measures have been provided in case of complications that may harm the subjects and how those defaulting from the study will be followed up if a drug or implant with medium or long term action is being used. Pilgaokar¹ has summed up the requirements of truly informed consent, listing the various kinds of information that must be conveyed to subjects.

Care of patients

Is the institution providing the best possible medical care? This could be considered under the following heads:

- The art of bedside medicine
- Relief of suffering
- Cure of disease
- Iatrogenic disease: incidence, trend over time
- Cost to patient: tests, drugs, other costs. Can these be lowered?
- Prompt attention to needs of the patient.
- Care of the seriously ill
- Dying patients
- The dead patient

Education of the staff within the institution'

This could cover all aspects of patient care and research.

Other activities of an ethics committee

Silverman² also recommends that the committee:

- produces guidelines on a broad range of topics. Disclosure of diagnosis, diagnosis of brain death, requesting permission to harvest organs for transplantation, truly informed consent are some examples.
- sets up and ensures proper functioning of a forum for redressal of complaints from patients and families. This forum must receive complaints in writing, helping illiterate patients to prepare such documents.

Complaints, proceedings of hearings on them, decisions and action taken must be kept on record.

- produces a document for the benefit of patients and their families informing them of services provided by the institution, rights of patients and relatives, their responsibilities, means by which they may seek redressal for any harm that may be done to them...
- surveys practices within the institution on a continuing basis: standards of patient care, unnecessary expenditure enforced on patients, obtaining truly informed consent. Patients and relatives could be polled on deficiencies/malpractice witnessed by them and their suggestions for improvement.
- obtains feedback from faculty, other staff on the functioning of the ethics committee; perceived deficiencies and Suggestions on how it might function more effectively. It may be necessary to permit anonymity of those making observations in order to safeguard them from victimisation and encourage free and frank observations.
- conducts seminars/workshops/mini-conferences on biomedical ethics, better research.. .

Why do some ethics committees fail?

Committee set up for the wrong reasons: Such reasons include a) an attempt at avoiding prosecution under the Consumers Protection Act; b) ensuring that research proposals made by members of the faculty sail smoothly through national and international agencies that offer grants and require clearance by a local ethics committee before they will take up the proposal for scrutiny; c) to form yet another 'power group within the institution that can hold the rest of the faculty to ransom.

Goals that are too ambitious: Silverman² refers to the phase when ethics committees, like infants, 'fail to thrive. When formed, there is much enthusiasm and activity by members of the committee. A little later, a feeling of frustration emerges as unrealistic goals set for the committee are not achieved. He refers to plans to educate the entire faculty and resident staff on medical ethics (including those in research) in a short while as an example of such a goal.

Lack of support by the institution: If all research protocols and matters of ethical concern are not placed before the committee and if the recommendations of the committee are flouted by the administration, demoralisation is inevitable.

The committee must also be provided adequate infrastructure for its deliberations, inquiries, follow up studies and maintenance, analysis of records. It will be necessary for the committee to enter into correspondence with other experts and groups, record proceedings of its meetings, circulate the minutes, interact with experts on other ethics committees, funding agencies and

similar groups.

Funds and secretarial help are mandatory for the proper functioning of such a committee.

The entire institution must want and welcome the formation of such a committee, seeing it as a means for improving standards, providing better care to patients and carrying out research of the highest standards.

Poor selection of members on the committee: If these individuals are already short of time, it is unlikely that they will pay much attention to the tasks to be attended to on behalf of the committee. cursory inspection of documents, little or no follow up action and frequent absences from meetings of the committee are expected consequences.

The members must possess a strong motivation for im-

proving the conditions under which patients are treated and research practiced. They should have already devoted some time and energy in identifying current slip-ups and malpractice and the means to be employed in correcting them.

They must also be conversant with current trends in national and international biomedical ethics. Without continued self-education, they are likely to lapse into rigidity of approach and dogmatic decisions.

References

1. Pilgaokar, Anil: Ethics in biomedical research. Unpublished paper presented at annual meeting of the Medico Friend Circle, 1995.
2. Silverman Henry J: Revitalizing a hospital ethics committee. *HEC Forum* 1994;6: 189-222.

FROM OTHER JOURNALS

*All's not well with clinical trials*¹

Research by US epidemiologist Kenneth Schulz and colleagues shows that a considerable number of doctors involved in clinical trials cheat by interfering with the randomness of clinical trials by ransacking private offices, cracking secret codes and probing contents of secret envelopes. Some may do so in order to ensure that their patients get the best treatment but, in attempting to fulfil their obligations to the patient, they vitiate their roles as medical researchers, skew results and invalidate the trial.

Doubt has been expressed by Samuel Hellman on whether a clinician can simultaneously fulfil the dual roles of doctor and researcher. The fundamental divergence between the clinician wishing to do his best for the individual patient and the researcher whose primary interest lies in collecting groups of patients suggests that Hellman's essay (pages 5- 10 of the special supplement in this issue) deserves study.

The interested reader will also find much of interest on pages 1-16 of the special supplement on Ethics Committees.

*Voluntary euthanasia*²

Independent legislator, Michael Moore, introduced his Medical Treatment (Amendment) Bill 1995 into the Legislative Assembly of the Australian Capital Territory, seeking to allow doctors to provide direct help in dying to terminally ill patients who requested it. The bill was defeated on 22 November with two rebel members of parliament cross-

ing the floor to vote with the Liberal Party.

In the state of Victoria, doctors petitioned the government for a review of laws prohibiting voluntary euthanasia. This appeal was rejected.

In the Northern Territory it is expected that any day now the Rights of the terminally ill bill will be gazetted and become operational. Patients with severe pain from advanced cancer are already travelling from other states to see direct, immediate help in dying under this law. 70 year old Marta Alfonso-Bowes, who had reached Darwin and sought a lethal injection was dejected when she found that the law was not yet in operation. After a failed attempt at suicide, she succeeded in taking her own life on 24 September after taking an overdose of tablets.

The following news item in this journal describes how seven doctors have joined Dr. Jack Kevorkian in unveiling guidelines for medically assisted suicide in the USA. The group feels that patients and doctors and not politicians or courts should determine when incurable patients should be helped to die. The guidelines call for a written request from the patient, signed by a doctor and two adults with no financial interest in the case. A specialist in the patient's illness, one on the management of pain and a psychiatrist will have to verify in writing that the patient was mentally competent, suffered from an incurable disease and had uncontrollable suffering.

The journal also refers to a paper in the Journal of the American Medical Association (1995;274:1634- 1626) where a long term study costing twenty-eight million US dollars showed that many patients die under cold and painful circumstances. The study also shows that dying patients often fail to make their wishes known and when they do, encounter indifference by doctors to their request to be spared life-sustaining treatment.

*Care of dying patients in hospital*³

This paper describes a prospective study of 50 dying patients in 13 wards in four large teaching hospitals in the west of Scotland. The opening sentence grabs attention. 'Though most terminally ill patients indicate a preference to die at home, . . . more than 60% of all death (over the past two decades) occurred in an institution.' The conclusion is equally riveting. 'Care of many of the dying patients observed in these hospitals was poor. We need to identify and implement practical steps to facilitate high quality care of the dying. Much can be learned from the hospice movement...'

References

1. Kuhse Helga: Clinical trials. *Monash Bioethics Review* 1996; 5:1-2
2. Anonymous: Voluntary euthanasia - Australia. News in brief. *Monash Bioethics Review* 1996;15:3-4
3. Mills Mina, Davies Huw TO, Macrae William A: Care of dying patients in hospital. *Monash Bioethics Review* 1996;15:11-19