ETHICS IN ETHICS COMMITTEES

About student research and blanket consent from patients

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My first organised experience of learning about the working of ethics committees in India, and my interaction with some individuals who had served or were serving on them, was around 1998. I had just started research to formulate ethical guidelines for social science research in health for a national committee appointed for the purpose at the Centre for Enquiry into Health and Allied Themes, Mumbai. In the course of this work we were confronted with the issue of ethical norms for student research and the need for ethics review of their research protocols. Most of those I met told me that their ethics committees never looked at student research proposals. A few years after the guidelines were published I started serving on ethics committees, and noticed that student research was not brought for ethics review. The justifications for this practice turned out to be the same that I had heard from members earlier.

The point often made was that student research is done under the supervision of the institution's senior faculty who are responsible for the ethical conduct of research by their students; so no ethics review of student research is necessary. However, the fact that the committee was reviewing these senior faculty's research, and some if not many of these proposals were falling short of ethical standards, gradually made most members disregard such arguments and request the institutions to bring student research for review.

Another point made with equal vehemence was that if ethical standards for sponsored research were applied to student research, then the cost of such research would be prohibitively high. Thus, student research would be in jeopardy. Obviously, this argument needed testing, and that was not possible without getting student research for review. Besides, while the working of the ethics committee does demand resources of the institution, there was no evidence to suggest that the cost of research done by faculty members had significantly increased due to ethics review. A related point was about what kind of research students should take up. Obviously if students are asked to do complex intervention research, the cost will be high, but not primarily because of ethics review. Indeed, ethics committees will demand moral justification for any effort to pass additional costs due to research on to patients. It is important to note that student research is also institutional research; the research topics chosen by or allocated to students are not mere decisions of students but also topics of their supervisors. Further, institutions might have used their own internal research priority setting mechanism to identify issues for student and intra-mural research. Thus, if an institution or supervisor takes up student research that has high risk, the cost of minimising such risk will be proportionately high, unless of course the student is allowed to cut corners, in science as well ethics.

We were also told not to bother with student research as it was "useless" research; the quality of most proposals was very poor. Our medical education is dominated by technical clinical training, usually in a hospital setting. Students are not trained rigorously in research methodologies. Since research is given no importance in their training and assessment, in most institutions the quality of student dissertations is abysmal. In the ethics committees, the resistance to bring student research for ethics review came usually from the clinical faculties. Of course departments promoting good research were less insecure and overcame their reluctance to ethics review early. In any case, doing "useless" research raised a basic ethical question: if it is useless, why should it be allowed? Indeed, some institutions saw merit in ethics review simply because it would improve the standard of student research and they would be able to come out of the trap of "useless" research.

It was not possible to convince all institutions that they must bring their student research to the committees. In institutions open to learning, the discussion in the ethics committee soon shifted from "whether" to "how". Not only the institution, but the ethics committee also needed some learning and adjustment. Ethics committee members serve as volunteers, and in teaching institutions the ethics review workload can be very high, for which they are not allowed free time from their own work in their institutions. They usually do not appreciate student research proposals increasing their workload three or four times and sometimes more, depending on the number of post graduate and doctoral students.

However, I found that if the institution showed readiness to establish a better and more efficient system for student research, the committee was able to find its own efficient methods – for instance instituting ethics review by its sub-committees. Interestingly in some institutions all student research is brought to the committee for ethics review; in some only a few departments do it and in others no student research is ethics reviewed.

Unfortunately, while ethics committees review research, they do not research their own work. So no evidence is collected to understand the consequences of ethics review on the quality and cost of student research, and the topics chosen by students. Overworked volunteer members of the ethics committee may not have time for such an exercise, but they can invite others to do this research for them. But that would mean "opening up" ethics committees to research – a topic that needs separate discussion.

Blanket consent on the excuse of encouragement to student research

Recently an issue related to ethical standards for student and intra-mural research in an institution was referred to some of us for ethics consultation. I suspect that this issue is not confined to one institution. Apparently the institution has, on its own, decided that when patients seek admission to its hospital, they should be asked to give written general consent saying that they have no objection to the use of their medical records - not only case papers but also all specimens of their body tissues and perhaps also X-rays, ultrasound scans, etc – for use in any research. The only promise that the institution made in return for this blanket written consent was that it would ensure that the identity of patients (names and photographs) would not be disclosed during the research or its reporting.

Three justifications were given in this instance for using blanket consent. First, teaching institutions have many students, who need to do retrospective research using patient records. Any demand that students go back to patients to get their informed consent, particularly when they are using records of patients who were treated several years earlier, would make student and intra-mural research extremely difficult or prohibitively costly, if not impossible. The second justification is general – that such research produces a public good, improving patient care at institutions and in general. Institutions have an ethical obligation to continuously improve patient care, for which they need to do research. So they need blanket consent from all patients getting admitted at the institutions now and in the future. It is not clear whether this justification is applicable only for public teaching institutions or also for private not-for-profit and for-profit teaching institutions, which also need to continuously improve patient care. The third important justification is related to the feeling that researchers today face many problems from society. Blanket consent from all patients would help prevent such problems. It is not clear what exactly to make of such arguments, but we can safely assume that institutions are wary of litigation – either directly from patients or from troublesome NGOs claiming to represent patients. Perhaps they also fear criticism from the media and journals.

This administrative order reminded me of my student days in the 1970s. Public teaching hospitals had notices stating that they were teaching institutions and using the hospital facility would automatically imply patients' consent to examination and participation in treatment by students for their learning. I was told this was the institution's official policy, perhaps backed by law. If patients did not accept it, they could seek care elsewhere. In other words care would be denied. Patients were not supposed to object if asked to sit through clinical sessions where their bodies were used for teaching or examination purposes. These notices of course made medical students very bold, and it was common to find a dozen stethoscopes on the chest of any "interesting" patient, and many "mass examinations" of vulnerable patients. While students learned with interest in non-stop clinical sessions, the patient had to bear those three hours, not always in comfort. While we were not very sensitive about them, most patients of that time did not openly protest against such treatment, implying that the policy was politically and morally acceptable. Indeed, many patients readily helped us during final examinations as by that time they knew a few things useful for us to discover in their bodies that we might not have discovered on our own.

But does the goodness of patients for whom doctors are "demi-gods" justify using their implied or blanket consent, and denying care if a patient refused to give it? The minimum morally binding balancing act could have been a counter-weighing ethical code of conduct for students and teachers, with the rights of patients flowing from this code displayed as prominently in the notices. Besides, if non-acceptance could condemn a patient to the harsh sentence of denial of care, the violation of the code and of patients' rights should also carry stringent punishment for students and their teachers. But the latter aspects are often absent in the making of laws and codes.

I feel something similar about obtaining blanket consent from patients for retrospective research. No doubt this is a bureaucratic order and not any informed consent. The official issuing the order did not contemplate that some patients might refuse to sign the consent form. If they do refuse, will the institute refuse to provide care? If no such drastic measure of refusal is contemplated, then the institute will need to establish a system of having two kinds of records – one for consenting and another for non-consenting patients – and perhaps also a third set of records of patients who neither provided consent nor explicitly refused as they were never asked. This third type of record may need review before being assigned to the first or second category. In any case, if the institution does not want to deny care, it will need to create a system for separating the records of non-consenting patients. Evidently, in the present case the institution did not want to establish any such complex system. On the contrary it wanted it to be so simple that students and doctors could do research without hindrance. Perhaps it did not cross the mind of the head of institution, or other doctors, who are not used to patients saying no to their demands, that some patients can refuse to consent.

Interestingly, it did not occur to the head of the institution to consult the institute's ethics committee for a decision that has profound implications for research ethics. For, the institution on its own is setting a standard for ethics review and denying the ethics committee the right to even deliberate on it. This could be due to the misconception that the issue is administrative, not ethical. Or the institution has contempt for the ethics

committee and views it as a hindrance created to satisfy the fancy ideas of disgruntled elements. Or the institution knew that it would be difficult to provide a strong moral justification to the committee and the committee would not approve this practice. If the ethics committee disagreed with this practice and was truly independent in its functioning, what would the institution do if the ethics committee rejects proposals for retrospective research using blanket consent ? Disband it and establish a new committee that agrees with its order?

How good are the justifications provided by the institution (mentioned above)? Let us start from the perceived problem from society, or litigation. In clinical practice, blanket consent would be taken for invasive procedures or treatments - something like "I agree to undergo any procedure or treatment using any anaesthesia by any doctor." But the law came down heavily against it, and now it is not acceptable. There is no guarantee that an administrative order will provide real immunity to the institution against litigation; on the contrary, the very existence of a written order may invite litigation. How can one give informed consent without specific information? How can patients give voluntary consent when the gun of denial of treatment is held at their heads?

Second, is it possible to argue that in all retrospective studies using patients' records and tissues – old and new – there is no ethical obligation to inform patients of new findings during research? What if the patient wants to know, is easily contactable and an easy remedy is available for the problem detected? Does the institution have any obligation to offer treatment as a part of research in such cases? What is wrong in allowing ethics committees to make their own judgment on the potential risks, their mitigations and the kind of benefits participants are entitled to?

Another important issue is whether student research is a justification or an excuse. For, while the argument in this case is for student research, the consent is for all retrospective research using patient records. Will this blanket consent also apply to retrospective research done for commercial purposes, by Indian or foreign sponsors? Will it apply when done by the institution's faculty, with or without sponsorship from, say, public institutions in India and abroad? When private or public sponsorship for commercial ends is available for research, to what extent does the justification about lack of resources hold?

If the institution denies care to those who refuse to sign blanket consent, this is likely to create a storm. Blanket consent may also undermine the authority of ethics committees, which are supposed to regulate research. More debate is needed to find a solution that does not violate patients' rights and also facilitates good research. Indeed, the excuse of student research will draw scepticism unless teaching institutions and authorities conducting assessment of students show a genuine commitment to promoting good student research as a part of medical training.

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Blanket consent for retrospective studies : patients' obligation

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May I inject a dissenting note? (1)

Public hospitals, especially those that are attached to medical colleges, perform invaluable services for their patients free of cost. They have three obligations: patient care, teaching and research.

Since all patients are treated free of cost, patients have an obligation towards the institution.

It has been the practice to use organs and tissues removed at surgery or at autopsy for teaching, research and mounting in museums. I see nothing wrong in using material obtained from patients for retrospective studies, especially since the confidentiality of patients is being respected.

Were we to deny this to teaching hospitals, they will suffer a major handicap in two of their three functions.

Remember that public hospitals attached to medical colleges have perennial problems obtaining funds, getting competent teachers and retaining them and generally carrying out their intended tasks.

Let us not add to their problems on grounds that really make no practical difference to the vast majority of patients seeking care in these hospitals.

Reference

1. Jesani A. About student research and blanket consent from patients. *Indian J Med Ethics*. 2009 Oct-Dec. 6(4): 216-8.