CASE STUDY RESPONSE

Protecting psychiatric patients in research

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Renu Addlakha (RA) discusses a number of pertinent ethical issues in the summary of her research (1). These issues could be generally divided into three categories: confidentiality, freedom of participation and consent, and the therapeutic misconception.

Confidentiality

RA stated that she had been given permission by the institution to review patient charts. She correctly noted that while this permission may have given her legal access to the charts it did not absolve her from the ethical need to obtain explicit consent from patients and/or their families to use the files.

RA assured study subjects that information provided to her would be kept strictly confidential. Is it possible that in some instances, for example, if a subject were to indicate that she had abused a child, there would be specific legal requirements to report such information to the appropriate authorities? In Canada we can rarely promise absolute confidentiality and a similar constraint may apply to researchers in India.

Freedom of participation and consent

The research study was made possible through the co-operation of the department of psychiatry. In addition to conducting the research, RA was invited to participate in various departmental activities like medical consultations, rounds and case conferences. Patients then correctly identified RA as being part of the hospital establishment and were placed in the position of feeling obligated to participate in her study in order to ensure the continuation of their treatment. RA sensibly handled this potentially coercive situation by ensuring that patients were reminded that the study and their treatment were independent and by providing them the time to think about participation and to ask questions. In North America, as in Asia, patients may feel obligated to participate in research because of authority, education and class factors. Perceived coercion may be subtle but very real.

In Canada many psychiatric patients would be considered competent to provide their own consent to participate in research rather than having their families consent. No doubt there are cultural differences in this. For example, patients may be hospitalised at different levels of disease in different countries. If there is doubt about a patient's competency, it is best to have a formal competency assessment conducted by a psychiatrist who is not involved in the research study. This assessment would supplement any advice provided by the attending staff.

Therapeutic misconception

RA notes that patients' families often believe that "participation in research might lead to additional privileges at the treatment level". I suspect the problem is actually a deeper one in that patients and their families may confuse research with treatment and may feel that those in authority in the hospital would not ask them to participate in an activity that would not have a direct treatment benefit for them.

Conclusion

It would appear that RA conducted a thoughtful and ethical study. One might suggest that in future studies of this kind, resources permitting, provision be made to reimburse research participants for their time and expenses (if any). This would fall within the principle of non-exploitation (2).

References

1. Addlakha Renu. Ethical quandaries in anthropological fieldwork in psychiatric settings. *IJME* 2005; 2: 55-56.
2. Indian Council of Medical Research. *Ethical guidelines for biomedical research on human subjects*. New Delhi: ICMR; 2000.