Commentary

Ethical challenges & dilemmas for medical health professionals doing psychiatric research

Maintaining the highest ethical standards in the conduct of all biomedical research is what is expected of every researcher. In psychiatric research, it is no different. The ethical principles are the same though the challenges and dilemmas may be slightly different and may be more complex as compared with other areas of biomedical research. There are differences between the practice of medicine, which essentially addresses the medical needs of the patient and biomedical research, which is driven by the advancement of knowledge. This distinction is sometimes blurred as for instance, when case studies are reported in research journals. The Hippocratic principle that the patient’s interests come first may sometimes appear to be subordinated by the need to advance knowledge and this is what creates the need for ethical principles specific to research.

In all the international ethical guidelines for biomedical research, three key principles are emphasized: Respect for person; Beneficence, to do no harm and contribute to the welfare of the individual; and Justice to the individual and a fairness of distribution of benefit.

Respect for the person includes respect for person’s autonomy, his/her capacity for self-determination to make a non coerced, and informed decision about whether or not to participate in a research study. However, the capacity for self-determination may be impaired partially or completely due to illness, mental disability or circumstances. These individuals are considered vulnerable and need additional protection during this period of incapacitation.

In psychiatric conditions the capacity for self-determination may be in conflict with what is expected in ethical fulfillment of ‘beneficence’. The reality in India and in similar cultures is that the physician - patient relationships are highly skewed, with physicians often expected to make decisions on patient’s behalf. This creates a conflict of interest when the treating physician is also the research investigator and hence needs to be recognized and managed. One suggestion is to have an independent observer, who is not part of the study team to oversee recruitment and consenting of research participants. Various psychiatric disorders also present their own challenges in terms of their impact on patient’s ability to exhibit autonomy and his/her capacity for decision-making. For instance, poor insight in patients with schizophrenia may impede consenting processes and their general ability to make decisions. In mood disorders, a slowing of cognitive processes as seen in depression and marked distractibility in hypomania could affect the consenting process.

In cases of dementia and psychiatric disorders both overt and subtle disturbances in cognitive functioning could interfere with comprehension and understanding and raise questions of competence. However, consenting to participate in research should not be seen as a one-time event but an ongoing process, and it has been shown that it is possible even in such difficult circumstances to have patients understand that they are participating in research and to consent as best would any other person in that situation. Proxy consent or surrogate decision making by a legally authorized representative (family member/next of kin), usually the next best option assumes that the patient’s best interests will be upheld. This has its own ethical issues of coercion and conflicts of interest. Reduced competence - cognitive, emotional impairment may also result in therapeutic misconception - the tendency to confuse research participation with medical/mental health treatment.

This is more so in India where research and clinical care often occur together in the same setting, and overall low levels of health literacy make people less discerning.

The dilemmas for a researcher are whether to proscribe “incompetent adult patients” as being “vulnerable” and therefore, to avoid this kind of
research. Avoiding such research is not a justified ethical response as it is also the right of all persons to avail of the best treatment, to participate in research and to contribute to the establishment of best treatments. It is untrue and stigmatizing to assume that all psychiatric research "entails greater risk and has less potential benefit than research in other areas of medicine". Various epidemiological, clinical, and behavioural research have resulted not only in better outcomes for mental health conditions but also have had a great impact on mental health policy and the quality of lives of those with mental illness and their families. The work on cognitive impairment and decision making capacity, particularly to give consent for treatment or research has concluded that the way information is provided in the information sheet is key. Providing small and essential information in an easy to understand way and using an iterative process will help with comprehension and recall. This is in fact good informed consent practice in general. The Mac Arthur Competence Assessment Tool for Clinical Research is a good tool for formal assessment of competence to provide valid informed consent to participate in research.

The study by Mishra et al in this issue looks at the views of mental health professionals in Delhi to the ethics of psychiatric research. The focus is specifically on two components - informed consent and maintenance of confidentiality. The mental health professionals have come out with flying colours in their knowledge of and attitudes to the ethical principles and guidelines of these two components of research. The challenge however, is in practice, i.e. to use correct knowledge and the right attitude in real time research encounters with patients. It is also possible in this study that the questions posed and the mode of questioning have elicited socially desirable responses as per the expected norms. While an assessment of the knowledge of ethical principles and attitude towards the patient or research participant is important, it does not automatically translate to the right behaviour in practice.

Using qualitative approaches and case vignettes of challenging situations to elicit responses would probably have provided a more nuanced understanding of attitudes and practices of mental health professionals conducting psychiatric research as well as an appreciation of the philosophical basis behind the ethical principle and guideline. A more inclusive coverage of mental health professionals with more clinical psychologists and psychiatric social workers would have allowed for richer, more expansive and valuable data.

It is a challenge for ethics committees too, that during the conduct of the study ethical principles are not violated. The present focus is on scrutinizing what information the consent forms contain and what is stated about maintaining the highest standards of confidentiality. The role of ethics committees in safeguarding the interest of subjects is much more critical for vulnerable subjects and for research being conducted with them. It is important to understand practical difficulties experienced by the researchers, to get feedback from research participants on the process they experienced and understand the pressures that make a researcher deviate from what is known to be right. The options are to do this through qualitative methods, observational studies and feedback surveys. Ethics review boards need to develop ongoing procedures to gather these data. In addition, this will help in training mental health professionals wanting to do psychiatric research to not only focus on the right knowledge and the right attitude but to also be sensitive to the philosophical underpinnings, the social circumstances and develop skills to tackle the practical ethical dilemmas and challenges.

A possible way ahead for enabling researchers grappling with the multiple challenges and dilemmas associated with interventional studies is to set up Data and Safety Monitoring Boards with knowledgeable people in the area of research, statisticians, technical experts, ethicists and so on who are independent of the study, to periodically review the study and have interactive sessions with the study team. This practice is in effect in many multicentric clinical trials and has been found to be critical in the management of these studies and in providing advice in difficult situations.

The final challenge of all research is the adaptability of guidelines to the local socio-cultural context. Mishra et al bring out the differences in perceptions of individual autonomy in Western vs Eastern cultures and how the concept of family participation and deliberation in an individual’s decision making can challenge the consenting process as well as influence the disclosure of patient information to the family.

In summary, following existing guidelines on biomedical research with human subjects to the letter may not be sufficient. The medical researcher doing psychiatric research needs to be sensitive to the circumstances and follow the spirit rather than the letter...
of the guidelines. It is also important to have a deeper understanding of the dilemmas and the contradictions in following legal provisions, ethical guidelines, social norms, economic pressures and the imperatives of science.

Ultimately, the need is to do more research on research practice itself in the Indian context. Simple targeted studies have the potential to at least raise the level of awareness about the need to introspect on the protection of human volunteers in research - and that is welcome.

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