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Ethical aspect of psychiatric research: patient's capacity to provide informed consent

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Background

The past few decades have been marked by an ever-increasing awareness of bioethical issues among the scientific community and general public. Informed consent is a question of central importance in contemporary medical ethics, and clinical practice is inconceivable without considering the issues it raises. The determination of psychiatric patient's capacity to understand the risks and benefits of participation in clinical research trials remains an important and controversial issue among psychiatric research community. The purpose of this study is to summarize and critically present the challenges and moral parameters arising from the assessments of the ability of individuals with impaired cognitive function to give informed consent for clinical research enrollment.

Materials and methods

A literature search from 1991 to 2007 was carried out using the ScienceDirect, and Medline electronic databases. The identified research studies were further examined and synthesized.

Results

Recent research indicates that although certain psychiatric disorders might place patients at increased risk of being unable to provide informed consent, psychiatric diagnosis alone does not adversely affect the capacity to consent to research. Decision-making capacity for research is not general but should be viewed as situation specific. Many studies argue that there should be a clear distinction between severity of cognitive deficits and severity of disorder's symptoms. A number of factors such as cultural and religious values, external pressures and developmental factors often escape attention of the researchers, and have not yet formed a systematic element of research interest. Intervention (e.g. presentation method, educational procedures etc) seem to improve understanding and decision -making ability. The currently used scales providing help in assessing competence in clinical practice and their evaluation are also discussed in our study.

Conclusions

The issue of informed consent has been the object of discussion and disagreement from many perspectives, which are not limited only to the field of medicine. Investigators with mental impaired participants have a greater responsibility for building appropriate safeguards. The inappropriate exclusion of competent individuals may suggest a paternalistic intervention against patient's autonomy and free will. The need for balance between the protection of the psychiatric patient and the necessity to develop efficient and safe drugs proposes a framework that does not just pursue legal immunity but describes a more general moral attitude and scientific mentality.