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# Commentary



## Consent in psychiatry - concept, application & implications

In the past few decades, the practice of medicine has moved from a paternalistic view where a doctor decides what is best for a patient to a collaborative approach where disclosure of information is done to the patients and caregivers for decision-making. Conventionally, the doctor-patient relationship gave doctors an upper hand due to the advantage of the special knowledge. Informed consent is about giving a patient the special knowledge that makes him/her competent to take decisions in a more informed way. This would promote individual autonomy and freedom of choice. Informed consent has ethical, clinical and legal dimensions. It is the onus of the service provider to disclose adequate information to the service seeker and also help him/her to choose an appropriate intervention<sup>1</sup>.

Consent has four essential elements - capacity, voluntariness, decision-making and knowledge. Capacity is the ability to understand the nature of treatment and the consequences of them. Voluntariness is indicated by the willingness to undergo treatment. Knowledge means that sufficient information has been given to the patients to understand the nature and consequences of the treatment. It involves making the patient and family members aware of their condition, the proposed treatment and the risks and benefits of the proposed treatment, the available alternatives and their risks and benefits. Decision-making means the ability to take decisions. For a consent to be legally valid, all the above-mentioned elements should be present<sup>2</sup>.

#### **Informed consent in psychiatry**

In psychiatry, consent has a different essence. The decision-making ability component can be affected in a psychiatric illness as a result of deficits in mental abilities due to impairments in attention, mood, understanding and reasoning<sup>3</sup>. The capacity for rational decision-making comprises different cognitive abilities

such as understanding (the information disclosed), logical reasoning (between the choices), effective communication and also appreciating the significance of the decision. There is a concept of capacity to consent for psychiatric patients which is assessed by competence. The capacity to understand the offer and use the information in a rational manner to reach to a conclusion is called 'competency'. The MacArthur competence assessment tool<sup>5</sup> has been used widely for the assessment of competence in research and treatment settings<sup>5</sup>.

#### Scenario of consent in India

The Medical Council of India, Professional Conduct, Etiquette and Ethics Regulations, 20026 has a discussion about consent for various interventions in medical science. It says that to consent one should be competent enough to make a contract and thus should be of at least 18 yr of age, of sound mind and not disqualified by any law. For psychiatric patients, the current backbone of legal framework is the Mental Healthcare Act (MHCA) 2017<sup>7</sup>. Section 2 of the MHCA defines informed consent as consent given for a specific intervention, without any force, undue influence, fraud, threat, mistake or misrepresentation and obtained after disclosing to person adequate information including risks and benefits of and alternatives to the specific intervention in a language and manner understood by the person<sup>7</sup>. Section 22 discusses about the information to be provided to a person with mental illness (PMI) to obtain an informed consent. This includes the nature of the mental illness, proposed treatment plan, its known side effects, prognosis with and without the treatment, right to refuse treatment, admission criteria and the right to withdraw consent. MHCA presumes that all persons with mental illness have a capacity to make decision, and it is the responsibility of the mental health professional to prove otherwise. This is to ensure patient autonomy and participation of the patient in the decision-making process. Informed consent is compulsory for admission, electroconvulsive therapy, discharge planning and psychosurgery. For ablative procedures, permission should also be taken from the Mental Health Review Board. The nominated representative can provide consent when the PMI is unable to give so. For research purpose, the 'National Ethical Guidelines for Biomedical and Health Research Involving Human Participants', 2017, by the Indian Council of Medical Research<sup>8</sup> should be followed.

#### Legal and ethical angle

According to legal bindings, a medical practitioner has power over the patient, and thus, an intervention without a valid informed consent can be said to be negligence even when done in the best interest of the patient. This puts a lot of stake on the practitioner. This shows us the need to assess mental capacity and obtain a valid informed consent for an intervention. It is known that the healthcare system in India is complex. Majority of the public health system is overburdened. Most of the patients belong to a rural community and thus put a greater value on health over personal autonomy. Various factors play a role to determine the place of the patients in the spectrum of right to the knowledge. The models of non-disclosure or full disclosure are not sustainable and sometimes hamper the doctor-patient relationship. The individualized disclosure model needs to be followed looking into the demands of the situation and thus smoothen the decision-making process.

The study by Deshpande and colleagues in this issue<sup>9</sup> validating the cultural formulation interview showed that consent was a new concept for Indian patients, and the concept had to be introduced to them. The study was a major leap as there is a need to assess the capacity to consent for psychiatric patients in India. Section 4 of the MHCA, 2017, discusses the capacity to consent for mental healthcare and treatment decision<sup>7</sup>. It focuses on three variables viz., comprehension, appreciation of risk and communication of the decision. The assessment of mental capacity is essential before any researcher proceeds for the administration of consent. Further, at the same time MHCA, 2017, Section 99 also mandates that any professionals conducting research on persons with mental illness shall obtain free and informed consent from all persons with mental illness for the participation of research and

permission to conduct such research shall be obtained from concerned state authority<sup>7</sup>.

The researchers took measures through processes such as audiotaping or non-disclosure of identity helped in reducing bias<sup>7</sup>. They went through various workshops, and thus, training was adequate and quality control was assured. There was also a process to ensure that the patients could comprehend what was being said and to only take those patients for the study who understood the consent procedure which was explained to them. This avoided the chance of not understanding consent be treated as not giving consent. A total of 67 patients were included, but the sample size was restricted due to practical issues. The study introduced the concept mostly as a part of the research but as the title suggests, more background information regarding consent in outpatients should have been touched on. The study used a translated version of the Cultural Formulation Interview but still, there was a difficulty among the patients regarding some Hindi words. Keeping MHCA in mind, there is an urgent need to formulate a consent taking procedure and translate it into various regional languages for wider applicability. Among the enrolled patients, seven patients were psychotic, but choosing outpatient would have eliminated the severely ill patients. The viewpoint expressed in the study that consent can be taken from outpatients can also be explained through the finding that majority of the diagnosed patients were non-psychotic9. It was also seen that the patients were more concerned about the care giving. The view expressed that even after having psychiatric illness consent can be given by them needs further exploration. There were also various reasons to refuse the consent procedure. Cultural variations also played a role. An individual approach in consent taking process is thus much inevitable. There is a definite need to do more studies in this area focussing on consent in outpatients only. The process of taking consent in outpatients can be difficult keeping in mind the shortage of workforce resources. However, solution to mitigate them should be thought on and such practices should be made a part of the routine day to day procedure keeping in mind the ethical and legal implications of MHCA9.

#### Specific challenges in psychiatry

As discussed, the decision-making capacity of the PMI can be coloured due to various factors such as psychopathology, insight about illness and the cognitive dysfunction. If we take a case of acute psychosis most of

the time, the patient would understand the information given to him. However, the presence of a delusion (such as persecutory delusion or nihilistic delusion) might influence his decision-making. Here, it is the responsibility of the mental health professional to prove that the delusion is affecting his decision making and thus currently have no capacity to provide consent. However, the exact procedure to do so remains unanswered. Insight also plays a major role as the need for treatment would be recognized then only. Impaired insight can also play a hindrance. Emergency treatments also pose a major problem<sup>10</sup>. Although treatment can be provided without consent at this phase, a consent needs to be taken from the nominated representative. For homeless mentally ill, there is no specific hierarchy of stakeholders to provide consent if the homeless mentally ill has absent capacity. For mental retardation, the Section 14 of the Rights of Persons with Disabilities Act<sup>11</sup> says that there is the provision of guardianship for decision-making provided the person with disability is unable to take a decision. For neurocognitive disorders such as dementia or caregiver can take decision on behalf of the patient.

### Need for a modified informed consent procedure

It has been seen that all patients taking psychiatric treatment are not fully incompetent to give consent. In the mentioned study9, several patients with even major mental disorders could understand and provide consent. Gross excitement or intoxication were common barriers. The main indices which can result in impaired capacity to give consent are lack of reasoning and understanding. Hence, if the consent process is tailor-made to overcome these cognitive deficits, it becomes more meaningful and practicable in clinical settings. Young psychiatrists should be trained to take care of the ethical issues both in research and clinical setting. When patients do not have the mental capacity, it is sometimes needed to use ethical values to act in the best interest of the patients. The concept of therapeutic privilege gives the liberty to physicians to decide the degree of disclosure, but the basic treatment should always be explained. If therapeutic privilege is used and some information is not disclosed due to the best interest of patients, then it should be documented, and the information should be provided as soon as the patient's condition improves. Detailed documentation, continued education and provision of collaborative decision making can be effective and also provide adequate legal protection. A detailed

discussion, simplifying the language, breaking the information in components easily understandable by the patients, repeating the information disclosed and giving opportunity to ask back may help in this process. With digitalization, there is a provision of computerized learning aids, video presentation which can help to make the process easier<sup>12</sup>. However, this is disadvantageous sometimes for the Indian population because of the complexity of computerized measures and also the non-availability. It is thus imperative that informed consent can be used for psychiatric patients. It indeed has some limitations but adequate modifications as needed for them can be done to ensure that they have been also taken as a part of the decision-making.

Conflicts of Interest: None.

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#### References

- 1. Ali F, Gajera G, Gowda GS, Srinivasa P, Gowda M. Consent in current psychiatric practice and research: An Indian perspective. *Indian J Psychiatry* 2019; *61*: S667-5.
- Braddock CH 3<sup>rd</sup>, Edwards KA, Hasenberg NM, Laidley TL, Levinson W. Informed decision making in outpatient practice: Time to get back to basics. *JAMA* 1999; 282: 2313-20.
- 3. Gupta UC, Kharawala S. Informed consent in psychiatry clinical research: A conceptual review of issues, challenges, and recommendations. *Perspect Clin Res* 2012; *3* : 8-15.
- Kitamura T. Assessment of psychiatric patients' competency to give informed consent: Legal safeguard of civil right to autonomous decision-making. *Psychiatry Clin Neurosci* 2000; 54: 515-22.
- Appelbaum PS, Grisso T. MacArthur competence assessment tool for clinical research (MacCAT-CR). Professional Resource Press/Professional Resource Exchange; 2001.
- Medical Council of India. Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002. Available from: https://www.mciindia.org/documents/ rulesAndRegulations/Ethics%20Regulations-2002.pdf, accessed on September 16, 2019.
- Duffy RM, Kelly BD. India's Mental Healthcare Act, 2017: Content, context, controversy. *Int J Law Psychiatry* 2019; 62: 169-78.

- 8. Indian Council of Medical Research. National Ethical Guidelines for Biomedical and Health Research Involving Human Participants. New Delhi: ICMR; 2017.
- 9. Deshpande SN, Mishra NN, Bhatia T, Jakhar K, Goyal S, Sharma S, *et al.* Informed consent in psychiatry outpatients. *Indian J Med Res* 2020; *151*: 35-41.
- 10. Amer AB. Informed consent in adult psychiatry. *Oman Med J* 2013; 28:228-31.
- 11. Narayan CL, John T. The Rights of Persons with Disabilities Act, 2016: Does it address the needs of the persons with mental illness and their families. *Indian J Psychiatry* 2017; *59*: 17-20.
- 12. Morán-Sánchez I, Luna A, Pérez-Cárceles MD. Enhancing the informed consent process in psychiatric outpatients with a brief computer-based method. *Psychiatry Res* 2016; 245: 354-60.