

RESEARCH ETHICS

Assessment of mental capacity in patients recruited in clinical trials in psychiatry and its relationship to informed consent

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Abstract

Insufficient attention is paid to the need for assessing the mental capacity of participants in clinical trials, particularly those in psychiatry. Assessment of mental capacity is paramount especially in patients suffering from certain brain disorders and psychiatric illnesses, as lack of capacity can invalidate the consent given. Suggested below is a framework for assessing mental capacity in a systematic way with the hope that those writing on the subject of clinical research give it due importance.

Publications on clinical drug trials in India rarely mention any assessment of the mental capacity of patients taking part in the trials. Informed consent is generally mentioned, with a majority of patients being seen to give such consent, while in some patients mentally incapable of giving consent, consent is obtained from relatives (1) This is of particular relevance to clinical drug trials for psychiatric disorders. Systematic assessment of mental capacity is essential in psychiatric disorders such as acute mania, acute psychosis, schizophrenic illnesses with florid psychotic symptoms, where capacity may be impaired thus invalidating informed consent obtained from these patients.

There has been significant discussion and controversy about an article published in the *British Journal of Psychiatry* in 2005 of a randomised placebo controlled trial in acute mania (2). This article has already been discussed at length in a previous issue of this journal (3, 4, 5). There was no mention of any assessment of the mental capacity of the patients but signed informed consent was obtained from all those patients who were acutely ill and suffering from a manic episode requiring hospitalisation. This led to questions being asked about the validity of the informed consent obtained.

The standard framework of informed consent (Table 1) makes it clear that gaining informed consent from research participants is an ongoing ethical issue (6) and at each point involves the participant's mental capacity for valid consent.

Informed consent framework

Potential participants need to understand the following issues:

- Purpose of the research
- Practicalities and procedures involved in participation
- Benefits and risks of participation, if appropriate, the

alternative therapies

- Details of data management and use
- The role of the participant if he/she agrees in the research
- Consent form
- How information will be provided to them throughout the study
- That their participation is voluntary
- That they can withdraw from the study at any time, without giving any reason and without compromising their future treatment
- The insurance indemnity where appropriate
- That the research is approved by research ethics committee
- Contact details should they have further questions or wish to withdraw
- Details of the research sponsor or research funding body.

Informed consent is an ongoing requirement so it must be ensured that participants continue to understand the information above and any changes in that information and continue to consent to participate throughout the study.

Even patients receiving electroconvulsive therapy (ECT) are rarely assessed for their mental capacity in a systematic fashion, though consent for the treatment is obtained from them or their relatives. This issue has been addressed in a recent article by Rajkumar *et al* from Christian Medical College, Vellore, and published in this journal in 2007 along with a specially designed ECT fact sheet—a welcome step that needs to be uniformly adopted across the country(7).

In the United Kingdom, the Mental Capacity Act (2005), which became operational in 2007, mandates punishments, including imprisonment, for people who mistreat persons who lack capacity (8).

Some steps must be taken to assess the mental capacity of patients before they are recruited into clinical trials, as well as during the research. This is especially necessary in psychiatry. We detail these steps below.

Assessment of mental capacity

What is mental capacity? Mental capacity is the ability to make a decision. Capacity can only be assessed in relation to a particular decision and a particular time - a person may have

the capacity to make some decisions but not others, or the capacity may vary over time.

1. A person lacks capacity in relation to a matter if at the material time he is unable to make a decision for himself because of an impairment of, or disturbance in, the functioning of the mind or brain.
 - a. The incapacity could be caused by mental illness, learning disability, brain damage, dementia or any other cause.
 - b. Although capacity is presumed, any issue as to whether a person lacks capacity must be decided on the balance of probabilities.
 - c. The impairment or disturbance may be permanent or temporary.
 - d. Assessment of mental capacity is a decision specific test. It will not be possible to label any person as lacking capacity solely as a result of a particular medical diagnosis.
2. A person will be judged unable to make a decision for herself if he/she is unable
 - a. To understand the necessary information
 - b. To retain that information
 - c. To use it as a part of a decision making process
 - d. To communicate her decision by any appropriate means.
3. The following should be noted (test for capacity):
 - a. The requirement for the person to "understand" must include understanding an explanation of the information when provided in a way that is appropriate to that person's circumstances, as for example using simple language or visual aids.
 - b. Short term retention of the information should not be assumed to prevent a person from being regarded as unable to make a decision.
 - c. Information includes knowing the reasonably foreseeable consequences of the decision or when to take it.
 - d. The more serious the decision to be made the greater the test and the greater the responsibility of those involved.
 - e. The person's age, appearance, condition or behaviour does not by itself establish that the person lacks capacity.
 - f. The person who assesses the capacity is the person who is responsible for making the decision or taking the action after consultation and if necessary having obtained appropriate advice.

There should be a formal assessment of mental capacity of all patients entering clinical trials before consent is obtained. Also, all published clinical trials should show the exact percentage of patients giving consent as well as the percentage of relatives giving consent. It is a common practice in clinical trials done in India to obtain consent from relatives if patients are incapable of giving consent. This is ethically questionable and needs to be debated in a larger context. In the western world, no clinical trials can proceed and receive ethical approval with the consent of relatives alone (9).

The concept of 'delayed consent' in emergency situations (for

example an accident, cardiac arrest, emergency admission) or 'consent by proxy' (in cases of children, dementia or other cognitive impairment, learning disabilities or mental illness) are notable provisions in the ethical/legal framework available in western countries but no such statutory framework is available in India.

It should also be borne in mind that capacity can change during the course of treatment and patients should have the right to refuse interventions in a clinical trial if they regain full capacity and do not want to take further part in the trial due to an improvement in their illness. A person with capacity has every right to make his or her own decisions however wise or eccentric the decision may be, or appear to be, to others. To prepare for this, clinical trial participants can set up an advance directive to make clear what they would like to happen if they have a relapse during a trial. If this is set up at the beginning, researchers have to stick to this agreement. However, researchers may be obligated to give additional treatment if this is thought to be necessary to protect the participant from harm or reduce his or her pain or discomfort.

Recommendations

If an assessment of mental capacity of people undergoing clinical trials in India was done systematically as prescribed above, it would go some way in diffusing the ethical controversy surrounding such trials. It would also be helpful if editors of journals publishing these trials insist on this before accepting the article for publication just as many are now insisting on the informed consent provision (10,11). Full assessment of mental capacity is paramount, both ethically and legally, before valid informed consent can be obtained. This good research practice should get proper attention in India if our research is to gain wider international acceptance.

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