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Review Article

Informed Consent in Adult Psychiatry

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Abstract

This article addresses some of the groundwork of informed consent in people with mental illness whose decision-making capacity has obviously been compromised. This article examines four crucial aspects in particular, namely: i) the main elements of informed consent; ii) difficulties pertaining to psychiatric illnesses; iii) the effect of psychiatric disorders on the patient's capability; iv) how to assess situations in which consents may not be required.

Keywords: Informed consent; Adult psychiatry; Voluntarism; Competency; Psychiatric disorders; Assessment; Ethical dilemma.

Introduction

Informed consent is perhaps the most widely recognized ethical safeguard in clinical care and research. However, the discussion on how to safeguard the ethical principle in people with mental disorder poses some dilemma. By definition, people with mental disorders do not always tend to have diminished cognitive function and poor judgment, and are therefore not necessarily impaired for consent.[1] In most countries, the existing medical ethics policies require health practitioners to obtain informed consent from the patient prior to commencement of intervention, whether invasive or otherwise. Informed consent, as the most fundamental factor for the best medical practice, owes its origin to the father of medicine, Hippocrates. Currently, ethical standards and its consent counterpart have been shown to have great implications for treatment and healthcare research.[1] During the last half of the 20th century, there was a relatively new but remarkable emphasis placed on informed consent, and it was generally more prominent in medical practice and in research.[2]

International codes of research ethics, such as the Declaration of Helsinki, outline key considerations of informed consent in a person who is legally incompetent, physically or mentally incapable of giving consent, or is a legally incompetent minor. Under these conditions, the investigator must obtain informed consent from the legally authorized representative in accordance with applicable law. Most recently, the International Ethical Guidelines adopted by the Council for International Organizations of Medical Sciences (CIOMS) reassert the primacy of informed consent in Guideline number 15.[3] Research involving individuals who, by reason of mental or behavioral disorders, are incapable of giving adequately informed consent requires the investigator to ensure that in cases where prospective subjects lack capacity to consent, permission is obtained from a responsible family member or a legally authorized representative in accordance with applicable law.[4] Similarly, the Universal Declaration on Bioethics and Human Rights from UNESCO outlines in Article 7 that: *Persons without the capacity to consent: In accordance with domestic law, special protection is to be given to persons who do not have the capacity to consent.*[5]

As a concept, informed consent is an integral constituent of the principle of respecting one's autonomy and the notion of an individual's right to control and weigh out the pros and cons for their participation in medical care or research.[6] Generally, in psychiatric practice as well as in conditions where an individual's mental capacity is most likely to be compromised and their mental ability to consent is therefore impaired, the challenge arises as to how to elicit informed consent given such obstacles in such circumstances. This is a dilemma which most psychiatrists and other healthcare professionals are likely to encounter. The scope of this article is not intended to cover the medicolegal issues related to confidentiality, diagnosis reliability, treatment (e.g. admission, restraint, type of treatment, ECT), and also the psychiatric emergencies relevant to adult psychiatry or the concept of lucid interval, civil criminal responsibility and drug intoxication. Thus, this article aims to present and highlight the important element of informed consent in relation to patients with diminished mental capacity, as well as determining situations where consent may not be required.

Elements of Informed Consent

Before explaining the contesting issue pertaining to informed consent, it is essential to first dwell upon the definition. Technically, informed consent is defined as the process whereby explicit information is provided to a patient or an experimental subject which would be relevant for them to decide on whether or not to have a particular treatment or to participate in a particular experiment.[7] According to Faden and Beauchamp, it is an autonomous act by a patient or research subject to expressly permit a healthcare professional or research conductor to perform a medical action on the patient or to include a person in a research project.[8] Informed

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consent is also defined as the voluntary acceptance of a plan for medical care by a competent patient after the physician adequately discloses the plan, its risks, benefits and alternative approaches.[9] The validity of informed consent is premised upon the full disclosure of appropriate information to a competent patient who is permitted to make a voluntary choice.[10] It incorporates five important components as follows:

i. ***Voluntarism*** is the first element of informed consent which indicates that the client acts voluntarily without being subjected to the control and influence of another. This requires the patient to be free from external influences like coercion, persuasion and manipulation in order to begin treatment or to participate in research studies. Faden and Beauchamp have suggested that **coercion,** by definition, carries the element of pressure from external sources and is thus incompatible with informed consent. However, **persuasion** is not viewed as full-blown coercion and should therefore be accepted as a required path to obtain informed consent. Healthcare professionals by virtue of their training and expertise in the field are capable of persuasion through the 'pros and cons' of certain medical procedures to be undertaken.[8] In contrast, persuasion should not be equated with **manipulation,** whereby a patient is swayed into an intervention or a research study, suggesting that coercion or persuasion is likely to be viewed as outright lying. Similarly, withholding information and misleading a client through exaggerations like framing information positively for instance, *"We succeed most of the time with this therapy"* rather than negatively for example, *"We fail with this therapy in 35% of cases,"*[11] is undoubtedly orthogonal to the spirit of informed consent.

ii. The second component which forms an integral part of valid informed consent is **Competency.** This concept implies ones capacity to understand and to act reasonably in their judgement.[1] It is more of a legal rather than a medical concept.[10,12] In practice, it is fair to assume that adults are capable of decision-making unless there is strong evidence stating otherwise.[6,11] However, this implies that individuals with compromised decision-making abilities are likely to be incompetent decision-makers.

iii. The third component of valid informed consent is **Disclosure** suggesting that an individual requires certain information to make a rational decision of whether to accept or reject treatment.[13] According to Beauchamp and Childress,[12] three different standards are compounded to form this important component of informed consent, described as: a) A professional practice standard - which requires disclosure of only the information that professionals typically provide; b) A reasonable person standard - which requires disclosure of the information that a thoughtful lay person would consider to be relevant to such a decision; and c) A subjective standard - which requires disclosure of information considered to be the substance to the decision which must be made by a specific person. It is important to note, however, that none of these standards articulate a notion of full or complete information, or otherwise unattainable information, perhaps even for undesirable goals.

iv. The fourth component is **Understanding,** which requires the patient to comprehend the information given and appreciate its relevance to their individual situation. This phenomenon has been thought to be "substantial" in understanding by Beauchamp and Childress.[6,12] Though, there is little consensus in either law or ethics with regard to what constitutes sufficient understanding.[7]

v. The fifth component is **Decision** which refers to the patient's authorization, thus allowing a physician to execute the proposed treatment, which would be most consistent with their authentic preferences, goals and values.[6,12] Consent forms facilitate and document this authorization but should be seen as secondary to the process through which the patient and the physician discuss and negotiate the proposed treatment.[6]

The aforementioned discussion has focused on elements of informed consent which is generally geared towards patients with intact cognitive, emotional and behavioral functioning. Whereas the following section of this article aims to highlight the difficulties in establishing informed consent with psychiatric patients which can be viewed with three distinct features:

External undue pressures - as psychiatric patients are often vulnerable, there is a particular danger of external undue (though mostly unintentional) pressures arising from the unequal power relationship between the doctor and the patient.[14,15] This can be reduced by the presence of a third party like a close relative or an advocate.

Problems of understanding - disorders involving disturbances of cognitive or intellectual functioning (for instance, in mentally challenged patients, or in patients with dementia or patients in confused states) which are often compromised in mentally ill patients, thus rendering them incapable of assimilating or comprehending the disclosed information at the time due to a wide variety of difficulties in communication which may be associated with arrays of psychopathology. Anxiety, for example, is a barrier to communication as it may interfere with comprehension and therefore affect the retention of information. Similarly, depression may produce a decline in intellectual processes that resembles dementia.[14,16]

Problems of decision and action - psychiatric disorders can adversely affect ones capacity to form sound decisions, judgments and the resulting actions. For example, obsessive-compulsive disorders often involve a generalized inability to make decisions. Likewise, anxiety and severe depression, when accompanied by hopelessness and delusions can disturb the decision-making processes.[14,16] While in psychotic disorders, there may be profound impairment of insight.[6,16] Patients with these psychiatric conditions will benefit from treatment and from intensive efforts in education with regards to their understanding of relevant information.[16] A psychiatric consultation is important to treat the underlying condition that may interfere with rational choices.[11]

Capacity Assessment and Psychiatric Disorders

When incapacity is suspected, physicians may not know which standard to apply and as a result, their evaluations may omit mention of the relevant criteria or may not apply them specifically to decisions about the treatment.[10] Several criteria can be used

clinically to assess a person's capacity. For full capacity, Grisso and Appelbaum (1998) stated that a patient must be able to: (a) make choices, (b) understand (retain and repeat) the given information, (c) appreciate (believe) its content, and (d) rationally process the information. These criteria are also used in most existing guidelines, for example those issued by the Royal College of Psychiatrists (2000).[6,11,17,18] Physicians should also be aware of the relevant criteria and should be encouraged to use a structured approach for assessment, when an explicit competence evaluation is required.[10]

When an individual is deemed incompetent, his or her right to make autonomous decisions can be overridden.[13] The following two categories have been suggested to classify the incompetent: 1). People who have been declared legally incompetent to manage their financial affairs,[11] and 2). Temporarily incompetent people who are classified as either unconscious people or people under the influence of alcohol or drugs.[11] Patients whose competence is impaired are commonly found in medical and surgical inpatient units, and less frequently in outpatient clinics. Between 3% and 25% of requests for psychiatric consultation in hospital settings involve questions relating to the patients' competence to make treatment-related decisions.[19] Adult patients with psychotic disorders are not automatically or always incompetent.[13] However, patients with Alzheimer's disease and other dementias exhibit higher rates of incompetence with regard to such decisions. In addition, more than half of the patients with mild-to-moderate dementia may have impairment, while incompetence is universal among patients with more severe dementia.[20] Among the psychiatric disorders, schizophrenia has shown a more potent association with impaired capacity than depression. Roughly 50% of patients hospitalized with an acute episode of schizophrenia have impairment with regards to at least one element of competence compared with 20% to 25% of patients admitted with depression.[21]

Among psychiatric patients, lack of insight (the lack of awareness of illness and the need for treatment) has been reported to be the strongest predictor of incapacity.[22] Research has shown that most patients with mental illness in inpatient units have the capacity to make treatment decisions similar to persons with medical illnesses.[13] Nevertheless, judgment of competence is specific to the particular decision that is made about treatment; a patient with a severe mental disorder may be incompetent in some aspects but competent to decide upon a particular treatment in other aspects. For example, a patient with schizophrenia and paranoid delusions may be capable of deciding on medical treatment for a heart attack.[23] Thus, psychiatric consultation may be helpful in particularly complex cases or when mental illness is present.

Over the past two decades, numerous tools have been developed to assess decisional capacity. There is no gold standard, although some instruments have been more widely adopted than others.[24] Patients should generally be informed of the purpose of the evaluation.[10] The psychiatrist would often conduct a mental state examination such as Folestein Mini-Mental Status, the short portable mental status questionnaire or the cognitive capacity screening examination.[16] The MacArthur Competence Assessment Tool for Treatment is a structured interview that, unlike many other instruments of assessment, it incorporates information specific to a given patient's decision-making situation.[10] Yet even with these instruments, no threshold of capacity clearly defines competence.[13] When possible, a decision that a patient is not competent should be deferred until at least two evaluations have been performed at different times. Collateral informants such as family members and nursing staff may also play a helpful role in assessing competence.[10] According to Gelder et al. there are three vital steps in the assessment of competency in adult patients:

Step 1: Identify the information relevant to the decision by examining the decision that needs to be contemplated, as well as the nature of alternative reasonable decisions and the pros and cons of each reasonable decision.

Step 2: Assess cognitive ability by assessing whether the person has the cognitive ability to carry out all three elements of the decision-making process, as well as understand the information, believe the information, and finally weigh up the information and come to a decision. In addition, consider the following causes of impaired cognitive ability, particularly delirium, dementia and other neurological disorders which may impair cognition or may constitute learning disability.

Step 3: Assess other factors which may interfere with one's capacity like delusions, hallucinations and affective disorder which may manifest in depression, manic illnesses, and lack of maturity, as well as assessment of emotional and cognitive maturity.

Some authors have argued for a sliding scale strategy which would allow for the standards of competence in decision-making to slide with risk. In this approach, the sliding scale would appear to be more stringent as the degree of risk related to the treatment decision increases.[12,13] For example, if a serious risk such as death is present, then more stringent standards of competence are required, but in cases where a low or insignificant risk is present, then more relaxed or lower standards of competence may be applied. Thus the same person, for example a child may be competent to decide whether to take a tranquilizer but incompetent to decide on whether or not to authorize an appendectomy.

Finally, if it is clear that a patient lacks the capacity to make treatment decisions, a substitute decision maker must be sought. In emergencies, physicians can provide appropriate care under the presumption that a reasonable person would have consented to such treatment. While for patients with advance directives, either the treatment choice that the patient made in advance or the choice of a surrogate decision maker may be indicated. However, in the absence of an advance directive and when time is available, the recourse is usually to contact family members.[10,16] Consent obtained from an incompetent patient is invalid and physicians who do not obtain a substituted decision may be subjected to claims of treating the patient without informed consent.[10]

Exceptions to Requirement of Consent in Adult Psychiatry

There are **three** special circumstances in which explicit consent is not needed in adult psychiatry. These are: a) **Necessity**, that is a

circumstance in which grave harm or death is likely to occur without intervention and there is doubt about the patients competence,[25] and b) **Emergency,** which constitute the following two situations, i) if the patient is incapable to give a consent and no surrogate is available to give the consent, and ii) if there is a danger to the patient's life or danger of serious health impairment and immediate intervention is necessary to avert this danger.[26]

Consent Waiver in Adult Psychiatric Research

Under certain circumstances, an investigator may feel that his/her study justifies a request to waive consent. Some examples are retrospective study based entirely on medical records and registry or large-scale non-interventional population study. Consent waiver may be granted based on the following criteria: i) the research involves no more than minimal risk to the subject, the waiver or alteration will not adversely affect the rights and welfare of the subjects, and ii) the research could not practicably be conducted without the waiver or alteration, and whenever appropriate, the subjects (including their physicians, as applicable) are provided with additional pertinent information after study participation.[25]

Conclusion

Informed consent is the requisite for the protection of patients' rights and interests. The biggest challenge in obtaining informed consent from a psychiatric patient is how to assess the patient's competency. Patients can benefit from treatment of psychiatric disorders which may adversely affect their capacity to understand and reach a rational decision about treatment. However, it is important to remember that a person who is mentally ill may not necessarily be incompetent to consent to treatment. Furthermore, there is evidence indicating that most inpatients with mental illnesses have a similar capacity to make decisions about treatment as patients with other medical illnesses.

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