INFORMED CONSENT IN PSYCHIATRY

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الاجتماع التحضيري الإقليمي للهيئة الإسلامية لأخلاقات العلوم والتكنولوجيا خلال الفترة من 30-6-2013 إلى 2-7-2013
Objective

1) Difficulties pertaining to psychiatric illnesses in relation to the ethics of informed consent in adult psychiatry and how to overcome it.
Physicians are required by law and medical ethics to obtain the informed consent of their patients before initiating treatment.

Valid informed consent is premised on the disclosure of appropriate information to a competent patient who is permitted to make a voluntary choice.
Informed consent

Consent > Agreement

...It’s more than a signature on a piece of paper!
Informed Consent

- Is an autonomous act by a patient or research subject to expressly permit a professional person to perform a medical action on the patient or to include a person in a research project.
O’Neill’s – view in Consent:

- The purpose of informed consent procedure is simply to avoid deception and coercion.
الاجتماع التحضيري الإقليمي للهيئة الإسلامية لأخلاقات العلوم والتكنولوجيا خلال الفترة من 30 من 6 إلى 27 من 7 عام 2013.
Deception

- When deception is acceptable?
- Deception should be permitted in research only if
  - (1) Essential to obtain vital information,
  - (2) No substantial risk in involved,
  - (3) subjects are informed that deception or incomplete disclosure is part of the study, and
  - (4) subjects consent to participate under these conditions.
Informed Consent

- Survey included 1,600 study volunteers found:
  - 14% of the volunteers signed the informed consent document without even reading the form.
  - 30% of the study subjects claimed that they did not understand or were unsure if the study would carry additional risks and discomforts,
  - 11% did not understand or were unsure if they could quit the study at any time,

A 2002 CenterWatch survey
The elements of informed consent

1. **Voluntarism**, freedom from control and influences: Persuasion, Coercion, Manipulation

2. **Competence** capacity to understand and to act reasonably in their judgement.

3. **Disclosure**, certain information to make a rational decision of whether to accept or reject treatment.

4. **Understanding**, comprehend the information given and appreciate its relevance to their individual situation

5. **Decision**, patient’s authorization, thus allowing a physician to execute the proposed treatment, which would be most consistent with their authentic preferences, goals and values.

What are the difficulties in establishing informed consent with psychiatric patients?

- **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. 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).

- **Problems of decision and action** - psychiatric disorders can adversely affect one’s capacity to form sound decisions, judgments and the resulting actions.
The effect of psychiatric disorders on the patient’s capability.

Decision-making capacity

- Is the patient’s ability to make choices that reflect an understanding and appreciation of the nature and consequences of one’s actions and of alternative actions, and to evaluate them in relation to a person’s preferences and priorities.

American Hospital Association (1985, p.9).
**Competence**

- mean the ability to perform a certain task.
- Make choices based on an understanding of the *relevant consequences* of that choices on oneself and others.
- Competence is therefore best understood as specific rather than global.
- Competency may vary over time.
- Temporary constraints of competence caused by illness i.e depression,

Buchanan and Brock (1989)

People who have been declared legally incompetent to manage their financial affairs or who have been involuntarily committed to a mental institution might still be ethically competent to make decisions about accepting treatment.

Temporarily incompetent are:
- Unconscious people
- People under the influence of alcohol or drugs
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 about patients' competence to make treatment-related decisions.

Patients with Alzheimer's disease and other dementias have high rates of incompetence with regard to such decisions; more than half of patients with mild-to-moderate dementia may have impairment, and incompetence is universal among patients with more severe dementia.

Kim SYH, Karlawish JHT, Caine ED. Current state of research on decision-making competence of cognitively impaired elderly persons. Am J Geriatr Psychiatry 2002;10:151-165
Among psychiatric disorders, schizophrenia has a stronger association with impaired capacity than depression; roughly 50% of patients hospitalized with an acute episode of schizophrenia have impairment with regard to at least one element of competence, as compared with 20 to 25% of patients admitted with depression.

Adult patients with psychotic disorders are not automatically or always incompetent.

Grisso T, Appelbaum PS. The MacArthur Treatment Competence Study. III. Abilities of patients to consent to psychiatric and medical treatments. Law Hum Behav 1995;19:149-174. [Medline]

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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. (1)

Research has shown that most inpatients with mental illness have capacities to make treatment decisions similar to persons with medical illness. (2)

Any physician who is aware of the relevant criteria should be able to assess a patient's competence.


Criteria for Assessment of Decision-Making Capacity

Aids to Capacity Assessment

- General impression of capacity from clinical encounter
- Cognitive function testing, e.g., MMSE
- Specific capacity assessment tools, e.g., ACE
Consent obtained from an incompetent patient **is invalid**, physicians who do not obtain a substituted decision may be subject to claims of having treated the person without informed consent.

Declaration of Helsinki

For a research subject who is legally incompetent, physically or mentally incapable of giving consent or is a legally incompetent minor, the investigator must obtain informed consent from the legally authorized representative in accordance with applicable law.

http://www.wma.net/e/policy/b3.htm
2. Universal Declaration on Bioethics and Human Rights

Article 7 – 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.

3. International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS)

Guideline 15

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.
إذن المريض:

أ - يشترط إذن المريض للعلاج إذا كان تام الأهلية، فإذا كان عديم الأهلية أو ناقصها اعتبار إذن وليه حسب ترتيب الولاية الشرعية ووفقاً لأحكامها التي تحصر تصرف الولي فيما فيه منفعة المولي عليه ومصلحته ورفع الأذى عنه، وعلى أن لا يُعتد بتصرف الولي في عدم الإذن إذا كان واضح الضرر بالمولى عليه، وينتقل الحق إلى غيره من الأولياء ثم إلى ولي الأمر.

ب - لولي الأمر الإلزام بالتداوي في بعض الأحوال، كالأمراض المعدية والتحسينات والوقائية.

ج - في حالات الإسعاف التي تتعرض فيها حياة المصاب للخطر لا يتوقف العلاج على الإذن.

د - لابد في إجراء الأبحاث الطبية من موافقة الشخص التام الأهلية بصورة خالية من شائبة الإكراه - كالمساجين - أو الإغراء المادي - كالمسماعين - ويجب أن لا يتسبب على إجراء تلك الأبحاث ضرر. ولا يجوز إجراء الأبحاث الطبية على عديمي الأهلية أو ناقصيها ولو بموافقة الأولياء " . انتهى من مجلة مجمع الفقه الإسلامي العدد السابع ج/ 3 ص/ 209/1412 هـ.
Consequences of a Finding of Incompetence

- Does the patient have decision making ability?
  - YES
  - NO
  - VARIABLE

- DECIDES FOR HIMSELF
- ONCE COMPETENT
- NEVER COMPETENT
- LAST COMPETENT DECISION

- ADVANCE DIRECTIVE
  - YES
  - NO

- Living Will Or
  - Durable Power of Attorney
- Prior discussion documented
  - YES
  - NO

- Valid Surrogate
- Prior Wishes
Conclusions and Recommendations:

1. Consent obtained from an incompetent patient is invalid, physicians need to obtain a substituted decision maker in order to protect them from potential harm.

2. To increase the awareness and the education in the area of ethics in dealing with the mental illness and psychiatric patient particularly.
Thank you
Table 1. Legally Relevant Criteria for Decision-Making Capacity and Approaches to Assessment of the Patient.

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Patient’s Task</th>
<th>Physician’s Assessment Approach</th>
<th>Questions for Clinical Assessment*</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communicate a choice</td>
<td>Clearly indicate preferred treatment option</td>
<td>Ask patient to indicate a treatment choice</td>
<td>Have you decided whether to follow your doctor’s [or my] recommendation for treatment?</td>
<td>Frequent reversals of choice because of psychiatric or neurologic conditions may indicate lack of capacity</td>
</tr>
<tr>
<td>Understand the relevant information</td>
<td>Grasp the fundamental meaning of information communicated by physician</td>
<td>Encourage patient to paraphrase disclosed information regarding medical condition and treatment</td>
<td>Please tell me in your own words what your doctor [or I] told you about:</td>
<td>Information to be understood includes nature of patient’s condition, nature and purpose of proposed treatment, possible benefits and risks of that treatment, and alternative approaches (including no treatment) and their benefits and risks</td>
</tr>
<tr>
<td>Appreciate the situation and its consequences</td>
<td>Acknowledge medical condition and likely consequences of treatment options</td>
<td>Ask patient to describe views of medical condition, proposed treatment, and likely outcomes</td>
<td>What do you believe is wrong with your health now?</td>
<td>Courts have recognized that patients who do not acknowledge their illnesses (often referred to as “lack of insight”) cannot make valid decisions about treatment</td>
</tr>
<tr>
<td>Reason about treatment options</td>
<td>Engage in a rational process of manipulating the relevant information</td>
<td>Ask patient to compare treatment options and consequences and to offer reasons for selection of option</td>
<td>How did you decide to accept or reject the recommended treatment?</td>
<td>Delusions or pathologic levels of distortion or denial are the most common causes of impairment</td>
</tr>
</tbody>
</table>

* Questions are adapted from Grisso and Appelbaum.\(^3\) Patients’ responses to these questions need not be verbal.