SHORT COMMUNICATION

Neuroscience and informed consent

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Introduction

"*Non omne quod licet honestum est*" – this ancient sentence is still alive, particularly in medical research. That´s why the members of medical profession and especially psychiatry must consequently keep in mind protection of rights of individual human beings, their integrity and dignity, regardless of political, religious, ethnic or social backgrounds.

After World War II during Nuremburg trials the world learned about the experimentation committed by the Nazis on unwilling human subjects. The Nuremburg code, issued in 1947, was perhaps the first official document that called for the consent of individual participant in scientific research. Declaration of Helsinki, adopted by the 18th World Medical Assembly in 1964, added provisions of research protocols, protection of confidentiality and professional integrity in the conduct of research and publication of results. Several populations were identified as needing special protection: children, pregnant women and fetuses, prisoners and mentally ill.

Informed consent still remains the cornerstone of the ethics of neuroscience research. Other relevant issues are drug discontinuation, medication-free intervals and placebo control groups, financial payments to participants in research studies, exclusion of potentially suicidal patients from biological and therapeutical research, approach to prodromal and early phase of neuropsychiatric disorders and problem of stigmatization and discrimination against the individuals with the genetic risk for neuropsychiatric disorders.

How to measure the decisional capacity of neuropsychiatric patients?

Neuropsychiatric disorders are often associated with the cognitive impairment. The most frequently observed deficits are those in attention/working memory, executive functions and the learning of new information. Many neuropsychiatric disorders disturb thinking – if the thinking is disturbed, capacity to consent is also likely to be compromised (Carpenter *et al* 2000).

In the 70th and 80th of past century ethicists and clinicians considered the decisional capacity of patients with psychotic disorders as a function of their illness severity. More recent studies in search of more precise understanding deficits responsible for reduced capacity have investigated several cognitive domains and metacognitive processes with promising results (Palmer & Jeste 2006).

Appelbaum & Grisso (1995) defined four dimensions of decisional abilities:

- Understanding of disclosed information,
- Appreciation of the significance of the information for one´s own condition and situation,
- Reasoning with the information,
- Expression of choice and decision.

The same authors constructed the first standardized tools to assess patients´ capacities to make valid decisions: MacCAT – CR (Mac Arthur Competence Assessment Tool for Clinical Research, 1996) and

MacCAT – T (Mac Arthur Competence Assessment Tool for Treatment, 1997). Numerous studies utilizing these tools have been conducted since that.

Results

According to summary of existing data we can say that:

- The strongest predictor of decisional incompetency of patients with neuropsychiatric disorders are cognitive impairments.
- The presence of neuropsychiatric diagnosis is not enough to indicate that patient is unable to give valid consent to research participation.
- Decisional capacity can be improved.
- Where there is no serious harm, it is generally considered ethical to ask neuropsychiatric patient to participate in a placebo-control trial.
- Exclusion of potentially suicidal patients from research protocols inevitably limits the generalizability of basic and intervention research.
- Financial compensation for participants in clinical research should not be listed in consent documents as a "benefit for patients".
- Although it is not yet possible to speak about genetic influence on neuropsychiatric disorders with certainty, there will come a time, when we will have a much fuller understanding at the relationship between genes and disorders. And that will be also the time when other – so called "third parties" (family members, health insurance providers, employers) will request access to the information.
- Present research has shown that patients with neuropsychiatric disorders who have demonstrated the capacity to give valid informed consent can identify also another aspects of research designs (Nábělek *et al* 2007).

Conclusion

Although we must confirm that many questions of etiology, treatment and prevention of neuropsychiatric disorders are not satisfactory resolved just because we are not able to realize ethically acceptable studies, we must hope that future development will improve the risk/benefit ratio of research approaches and bring clearly define values, guidelines and standards. Until that still remains the bonmote of Saks *et al* (2006): "Must all participants in studies of consent capacity have capacity to consent?"

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