INFORMED CONSENT IN PSYCHIATRIC MEDICAL CARE: A PROSPECTIVE QUANTITATIVE STUDY

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INFORMED CONSENT IN PSYCHIATRIC MEDICAL CARE - A PROSPECTIVE QUANTITATIVE STUDY (Abstract): Respecting fundamental ethics principles entails the process of obtaining an informed consent, which is a necessary requirement for offering good psychiatric medical care and conducting research studies on human subjects, who are regarded as the vulnerable population. Presently, in Romania, the informed consent regarding medical interventions is covered by the law of the patient’s rights, Law 46/2003, chapter 3. The aim of this study is to evaluate the medical staff’s perception of the need of the informed consent in the practice of psychiatric medical care. Material and methods: This is a quantitative, inquiry based study, with prospective evaluation, based on the responses of 217 medical staff members involved in treating patients with psychiatric disorders. The study unfolded between July 2012 and July 2013, and the questionnaires were answered by medical staff members (psychiatrists, general practitioners, other clinical specialists, psychologists) from Iasi, Botosani, Vaslui, Suceava counties. Results: The age group distribution of the medical staff involved in the medical care shows statistically significant differences between the groups questioned ($\chi^2=227.14$; df = 5; $p=0.001$). Concerning the answers recorded at question no. 2, regarding informing the psychiatric patient, and comparing the studied groups of medical staff, a majority of affirmative answers was noted. Conclusions: The medical staff members involved in the patient’s treatment recognizes the necessity of a full informed consent when discussing about psychiatric medical care. In psychiatry, the variation of competence raises multiple ethics discussions Keywords: INFORMED CONSENT, PSYCHIATRIC PATIENT, MEDICAL STAFF.

The notion of “consent” is frequently encountered in medical records and in specialized literature as “informed consent”; this clarification has the role of emphasizing the informational component of this valid document (1). The informed consent (2) is a very important concept in the relationship between the medical staff and the patient (3). The informed consent is a concept that has developed significantly in the last few years (4). It represents the legal way of validating the respect of personal
autonomy in medical practice and research (5). From an ethics point of view, the informed consent is a necessary stipulation when conducting research and in medical care (6, 7, 8). The consent is a specific legal document, required in written form after the patient has been provided with the complete set of information. The patient must receive information on the necessity of hospitalization, treatment, diagnosis, benefits and on risks involved. The doctor has to use a language that is adequate to the patient’s educational level (9). The informed consent is the legal and ethics way by which a patient decides to join clinical research, after having received, understood and analyzed the given information. The decision to participate in the research must be uncorrupted and the informed consent must be signed before the study proceeds (10). Being an ethical and legal request, the informed consent is a documented request- ed both nationally and internationally, both in research and in medical care (7). The elements of an informed consent are: competence, communicating information, analyzing information, understanding information, voluntary decision (10).

This concept does not have old historical origins, and the written agreement, for both research and medical care, belongs to the modern ideologies of the 20th century (11, 12). Even though these regulations regarding the consent in clinical research have existed since the 19th century, the medical staff was either unaware of them, or ignored them (13, 14).

MATERIAL AND METHOD
This is a prospective questionnaire based study, applied to the medical staff involved in the healthcare of psychiatric patients. The study was conducted between July 2012 – June 2013 and had a research population of 271 members of the staff involved in the therapy of the psychiatric patient: psychiatrist, psychologists, general practitioners, doctors from other specialties (neurologists, neurosurgeons, emergency doctors) from medical centres in Iasi, Suceava, Botosani, and Vaslui. The questionnaires contain questions about the Mental Health Law, the informed consent, providing information, stigmatization, discrimination, confidentiality. The questionnaires followed all the steps from pre-testing, revision, validation and application in the final form. The results were statistically processed for each item, subsequently making the correlation of the answers according to different characteristics of the study groups. The Cronbach’s alpha value was 0.730, which offers an acceptable result when compared with the threshold of 0.70, and validates the use of the questionnaire to other categories of doctors and psychologists involved in monitoring people with psychiatric disorders.

Amongst the groups of doctors, the frequency distribution analysis according to the specialty highlights the prevalence of resident doctors in the group of doctors with other specialties, and of specialist doctors in the group of general practitioners, while in the group of psychiatrists, a homogeneous distribution can be noticed. The study uses the Kruskall-Wallis non-parametric method for highlighting statistical differences.

RESULTS:
In doctor groups, the distribution analysis according to specialty points out the predominance of resident doctors (54%) for the group of doctors from other specialties and specialist doctors (66%) for the group of general practitioners, whereas the psychiatrists group shows an even distribution. The
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application of the Kruskall-Wallis intergroup non-parametric test points out statistically significant differences between the specialty of the doctors who answered the questionnaire (Chi-Square = 15.22; df = 2; p = 0.001).

The groups distribution according to sex shows the predominance of females, sex ratio F/M = 2.3/1. The smallest percentage of females is found in the group of psychiatrists, and the peak frequency is found in the group of doctors with different specialty than general practitioners, but the distribution does not show statistically significant differences when compared to the other groups (χ²=0.38; df=3; p=0.944).

Concerning age groups, there can be distinguished a higher percentage of subjects questioned with ages between 30 and 39 years of age (49.8%). The distribution by age of the medical staff involved in medical care shows statistically significant differences between the groups questioned (χ²=227.14; df = 5; p=0.001):

- In the psychiatrists group, most of the subjects have ages between 30 and 39 years old (56.1%), and 12.3% have ages over 60 years of age;
- In the group of doctors with different specialties, subjects in the age group 30 – 39 years old prevail (46%), followed by the under 30 years group (32%);
- 46% of the general practitioners had ages between 30 and 39 years, and 36% had ages in the 40 – 49 years interval;
- 50% of the psychologists had ages between 30 and 39 years and 38.3% between 40 and 49 years.

Concerning answers recorded at question no. 2, affirmative answers in all studied groups were noted when comparing the groups that were studied.

“Do you consider that patients with psychiatric disorders must be informed about the benefits and side effects of the treatment before initiating it?:

a. Yes, the psychiatric patient has the right to an adequate informed consent that has to be followed;

b. In the case of patients with psychiatric disorders, I would provide a minimum of information;

c. The patient with psychiatric disorders must not be informed;

d. I do not know” (tab. I).

### TABLE I

<table>
<thead>
<tr>
<th>Question no. 2</th>
<th>Psychiatrist</th>
<th>Different specialties</th>
<th>General practitioner</th>
<th>Psychologist</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Yes</td>
<td>55</td>
<td>96.5%</td>
<td>41</td>
<td>82.0%</td>
</tr>
<tr>
<td>Minimum info.</td>
<td>2</td>
<td>3.5%</td>
<td>7</td>
<td>14.0%</td>
</tr>
<tr>
<td>No</td>
<td>2</td>
<td>4.0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I don’t know</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean rank</td>
<td>98.22</td>
<td>114.20</td>
<td>114.10</td>
<td>110.66</td>
</tr>
</tbody>
</table>

The mean rank of the answers to question no. 2 did not show any statistically significant differences between the questioned groups (Chi-Square = 6.88; df=3; p=0.076):

- Only 3.5% of the psychiatrists consider that they would provide the minimum of information regarding the therapeutic approach;
- Providing minimum information is
found in 13-14% of each of the other groups questioned;

- In the general practitioners group, 4% do not consider that patients with psychiatric disorders must be informed about the benefits and side effects of the treatment, while in the psychologists’ group 1.7% does not know what to answer to this question.

**DISCUSSION**

The purpose of the study was to assess the perception of healthcare professionals with regard to the need and importance of informed consent in medical care. The process of obtaining a valid informed consent is extremely important in both medical research and psychiatric healthcare. Transposing the informed consent in the medical practice is frequently hampered by difficulties in informing the patient in such a manner for him to understand the information, by spoiling its voluntary character etc. (7). The study shows statistically significant differences between the specialty of the doctors who answered the questionnaire (Chi-Square = 15.22; df = 2; p = 0.001). In psychiatry, the variation of competence creates multiple ethical discussions. An informed consent is valid only when the study’s subject or the patient receives all the relevant information and comes to a decision freely (15). The significant impairment of the cognitive functions, especially in patients with certain psychiatric disorders, compromises the minimal conditions necessary for a valid informed consent in most of the cases. Also, there are cases when the informed consent cannot be obtained or the informed consent is invalid for minors, some patients with dementia, patients with mental retardation, patients considered a vulnerable category (16). The ethical controversies in psychiatry regarding the admission, respectively the treatment, are channelled especially on the situations in which the person with the psychiatric disorder cannot give his/her consent (17, 18).

In psychiatric healthcare, the medical staff assigned to a patient with psychiatric disorders should try and obtain the free consent of the patient; however, most of the times, they feel compelled to limit the patient’s freedom and use constraint (19, 20). This study shows that for the group of general practitioners, 4% do not consider that patients with psychiatric disorders must be informed. The mental capacity of patients with psychiatric disorders is an issue that raises multiple ethical and legal concerns, especially in cases where coercive measures are required (21, 22, 23). In cases of dementia, depending on the type: Alzheimer disease, vascular dementia or any other form of dementia, severe cognitive impairment is always correlated with incompetence (24). Studies show that for patients with psychiatric disorders, like schizophrenia and depression, at least one of the components of the informed consent is impaired (25). All elements of an informed consent are impaired in patients with schizophrenia (26). In schizophrenia, obtaining a valid consent is a continuous challenge, especially in medical research (27).

Diminished mental capacity is more frequent in patients with psychotic disorders rather than in patients with non-psychotic disorders (28). According to studies, the most important predictor for reduced mental capacity in psychiatric disorders is the absence of awareness of the disease and of the necessity of the psychiatric treatment (29). In the last 20 years a great focus has been directed towards developing tools for assessing mental capacity (31).
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According to some studies, factors strongly associated with diminished or absent mental capacity are non-voluntary admission, compulsory treatment, severity of symptoms and certain types of psychoses (22). Patients with psychiatric disorders, who were hospitalized non-voluntarily in psychiatry hospitals, are more frequently associated with reduced or absent mental capacity, when compared to patients who were hospitalized voluntarily (23). Multiple studies demonstrated that the severity degree of the psychiatric pathology is associated with reduced or absent mental capacity (30, 33).

CONCLUSIONS
In this study, the majority of staff members involved in therapy recognize the psychiatric patient’s right to be informed. However, a small percentage of the participants, more precisely of the general practitioners, invalidate this right.

In psychiatry, the variation of competence raises multiple ethical discussions. The impairment of cognitive functions, especially in some psychiatric disorders, undermines the necessary conditions for a valid informed consent. The issue of informed consent in psychiatric care is extremely complex.

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