Clinician perception regarding informed consent in neurological care

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ABSTRACT

Medical personnel involved in the neurological healthcare have a certain perception regarding the concept of informed consent, which leads to multiple ethical and legal discussions. Avoiding the stigmatization of the neurological patients with associated mental disorders is currently a challenge in Romania and is largely dictated by the importance of the two notions: informed consent and being viewed as a vulnerable population.

The purpose of the study is to evaluate aspects related to the level of perception and knowledge, towards the concept of informed consent and vulnerable population, as well as the rights of patients with neuro-psychiatric disorders by the personnel involved in their therapy.

Material and methods - The study is a prospective, quantitative, questionnaire type that surveyed 74 research staff members involved in the therapy of patients with neurological disorders (neurological doctors, neurosurgeons) from the Clinical Emergency Hospital "Prof. Dr. N. Oblu", Iasi, respectively members of the clinics and medical offices of family medicine in Iasi county. The questionnaire was carried out between May 2015 and May 2016.

Results - In cases of neurological emergency, a significant percentage of doctors consider that providing medical information ads no significant benefits and in a smaller proportion the absence of information is justified in the circumstances of associated psychiatric symptoms, on which the responsibility of the decision is transferred to the family. Although the medical team considers it is important to go through all the stages of informed consent, this is not reflected in their daily medical practice. The proportion of medical personnel that consider necessary providing information to a neurological patient, is different depending on their respective medical specialty, and a large majority think that the information should be tapered. **Conclusions** - The perception medical staff have regarding patients with neuro-psychic disabilities is in of itself stigmatizing.

KEYWORDS:

Informed consent, clinicians, neurological pathology.

INTRODUCTION

Informed consent has become the central pillar in the doctor-patient relationship, being the obligatory process by law located at the base of the whole medical practice, representing also the fundamental deontological norm in the main medical codes (1). Currently, obtaining informed consent is a process, still viewed as a bureaucratic component / stage and not as a form of legal validation of the medical act.

From an ethical point of view, the controversies in obtaining a valid consent are due to the competence of the cases (2). The decision must be biased and implicitly provided by a competent person, after having received, understood and correctly interpreted the information presented (CIOMS guide, 2002)(3). As history also demonstrates, we observe that at present the consent document is a mandatory requirement in healthcare and research, both internationally and nationally (4).

Currently, medical ethics is strongly marked by the evolution and promotion of human rights. In a multicultural world, with multiple and varied moral customs, the most valuable international human rights agreements are the foundation of medical ethics. Agreements are unanimously accepted across cultural boundaries (5). At the base of medical ethics are four universally valid fundamental moral principles, long analyzed and disputed, with a common approach in all fields of application (6).

Within this broad framework of the "tetralogy of bioethics" (7), moral facts are identified, on which principles, rules, rights and moral ideals are applied. This fundamental framework encompasses principles such as: the principle of respect for autonomy, the principle of beneficence (beneficence), the principle of non-harm (non-maleficence), the principle of justice and equity (4). Respect for a person's autonomy implies respecting the

right of self-determination and offering the possibility of self-government (8), after a complete information of the individual.

In bioethics, autonomy is a "key" principle, derived from paternalism and admits that there is a decisive equality on the medical activity in the competent individuals, even if at the same time these choices conflict with the medical decisions. Caplan and his colleagues admit that some decisions are influenced by religious, philosophical or even their own beliefs (9).

What does giving an informed consent, whilst in possession of all relevant facts, actually mean? It is a process through which the patient authorises the medical action involving his own person, taking note of his or her own set of values, purposes and beliefs, while the doctor acts as a „medical consultant” who has the means and knowledge to fulfil the medical scenario in the patient's best interest. An individual's autonomy is defined by the coexistence of understanding capacity, voluntary act performing and decision taking ability.

The diachronic perspective of maintaining this personal autonomy and protecting a vulnerable group of patients, is thoroughly debated through research (10). In the cases of mental ailments, underage individuals, or some dementia patients, who are unable to offer a valid consent, it becomes mandatory that their decisive rights are overtaken by another person, or an institution capable of taking the decision for them (family members, a specialized medical committee, state agents). In other words, in that situation, the legal or personal representative (family) of the patient gets the authority to give consent upon medical assistance or research related issues (11). In order for this to be justifiable, socially speaking, a sufficient clause is that the representative is able to choose for himself (12).

According to recent studies, the main cause of disability is represented by stroke, which is also classified as the second cause of death worldwide (12). Evaluating the decision taking ability of patients suffering from cerebrovascular disease, with affected executive communication capacity, is a challenge, both from an ethical and a legal point of view. A stroke may be followed by persistent or temporary symptoms, such as: motor deficit, cognitive functions decline, even post stroke dementia. Normal aging and neurological deficits are considered “independent predictors” (13) for obtaining an adequate informed consent.

Are the rules of informed consent truly followed when considering a medical emergency? There are enough emotional and rational “barriers” regarding understanding information. It is already known that even patients without cognitive impairment might have questionable decisive abilities, but adding to that a neurological deficit, even after its acute phase, the physical strain and the psychological stress of giving an answer in such a short time span, makes this even harder to discuss. The frequent and common consequences of cerebral infarction, such as speech impairment, cognitive dysfunctions, or depression (14), need a multimodal approach, especially in the case of a medical emergency, when their grade of decisional influence is major and long-lasting.

MATERIALS AND METHODS

This study is a prospective one, questionnaire based, and it was applied to medical staff involved in neurological medical assistance between the months of May 2015 and May 2016. The quiz had as targeted individuals 74 employees: neurologists and neurosurgeons working at the “Prof. Dr. N. Oblu” hospital, in Iasi, but also general practitioners from the clinics and offices in Iasi. The main element

studied was the extent to which patients understand and apply the informed consent.

The questionnaires went through pretesting, revising, and validation processes beforehand, and some related questions have been permitted in order to analyze honesty while answering. The Cronbach alpha value was 0,777, which gives us an acceptable result considering the set milestone of 0.777, thus validating the use of the quiz on clinicians.

The questionnaires were applied through a direct method, whilst maintaining full anonymity, therefore respecting confidentiality, a very important note in managing neurological afflictions.

RESULTS AND DISCUSSIONS

Statistical Analysis:

- 2 independent groups: X² is a test without set parameters, that compares 2 or more frequency allocations observed in the same pool of patients; It should be used when announced events are excluded;
- For more than 2 independent samples: the Kruskal-Wallis test;

Demographic characteristics:

In the analyzed lots, the frequency distribution, taking into account the specialties interested, highlights the majority of resident doctors, in the neurosurgery group (66,7%), as well as in the neurology one (77,1%), while amongst the general practitioner lot primary physicians are represented in a greater number (81%). Applying the Kruskal-Wallis test between groups underlines the statistically significant differences between the specialties of the physicians taking the questionnaire (Chi-square = 19,38; df = 4; p = 0,001) (fig.1)

Fig.1. Distribution of inquired doctors based on their specialties

The distribution based on gender showed that a larger proportion of neurologists (71,4%) and general practitioners (66,7%) are females whilst in the neurosurgeons group the

males had a larger proportion (83,3%), these differences being statistically significant. (Chi-Square =8,94; df=2; p=0,003) (Fig.2).

Fig.2. Group distribution based on gender

The population distribution based on age group showed that a larger proportion of the inquired doctors were in the 20-29 age group

(37,8%), and to be noted that 8,2% were over the age of 60. (Fig.3).

Fig.3. Distribution of inquired doctors based on age groups

MEDICAL PERSONNEL EVALUATION QUESTIONNAIRE

Q1. Law/Government Ordinance referencing to reform in health services that also includes patient's written consent:

- Government Ordinance (OG) 11/2015
- Law 95/2006
- Both and OG 11/2015
- I do not know

Comparing study groups and their answers to question 1, referencing to reform in health services that also includes patient's written consent, we find that only 34,3% of neurologists know the legislative framework involved in health services reform. (Fig.4.).

Fig.4. Percentage of responses regarding reform in health services , on study groups

Q2. In your opinion, what are the components of a valid informed consent?

- mental capacity and voluntary character
- communication, understanding of therapy recommendations and comprehension of information
- decision and authorization
- mental capacity, voluntary character, decision and authorization
- mental capacity, voluntary character, communication, understanding of therapy recommendations, decision and authorization

Regarding the answers recorded for question 2 (Fig.5), a comparison between study groups clearly shows that a considerable proportion (82-90%) of medics consider: mental capacity, voluntary character, communication, understanding of therapy recommendations, decision and authorization, to be important components of a valid informed consent. (Chi-Square = 1,27; df=8; p=0,230)

Fig.5. Percentage of responses regarding the components of a valid informed consent, on study groups

Q3. Presuming that the personal data of neurology patients would not be confidential but public record, do you consider that the patient would suffer prejudice?

a) YES, the social and professional reinsertion of the patient would be compromised

b) YES, but the patient would not suffer major repercussions

c) NO, there would not be repercussions

d) I do not know

All of the general practitioners, 72% neurologists and 66% of neurosurgeons consider that the social and professional reinsertion of the neurological patient would be compromised if the personal data of neurology patients would not be confidential, but public record and only 28-29% neurologists and neurosurgeons (Fig.6) consider that unveiling personal data from the written consent sheet would not have repercussions toward the patient (Chi-Square = 2,81; df=6; p=0,094).

Fig.6. Percentage of responses regarding personal data confidentiality as a form of defence against prejudice, on study groups

Q4. In which of the following situations, you consider appropriate to omit informing the neurological patient:

a) in cases of neurological medical emergency

b) any associated psychiatric symptomatology

c) when verbal communication is not possible (aphasic patient)

d) in cases when the neurological patient transfers decision responsibilities to family members

Regarding the answers recorded on question no. 6, comparing study groups, it was noted

that 22-33% of physicians (Fig.7), regardless of specialty, consider that the patient can be

uninformed if he transferred decision responsibility to a family member.

Fig. 7. Percentage of responses regarding information omission on the neurological patient on study groups

Q5. How do you proceed if the neurological patient does not have the capacity to give consent:

- a) the decisions regarding the medical care of the neurological patient belong to the personal representative (1st degree relative) or conventional (a third party decided by the patient)

- b) the decisions regarding the medical care of the neurological patient belong to the legal representative (guardian / curator)
- c) a medical team (medical committee)
- d) another opinion:

Fig. 8. Percentage of responses regarding physician's action depending on patient ability to consent, on study groups

To this question, medical team decision was the answer indicated by 33.3% of the neurosurgeons, 20% of the neurologists and 38.1% of general practitioners (Fig.8).

Q6. In your opinion, the information provided to the patient depends on:

- a) filtered information that the physician deems necessary
- b) the information that the patient requests

- c) the information that the physician considers necessary to be provided, as well as the one that is requested by the patient
- d) all available / necessary information on the case

We note that 61.1% of the neurosurgeons, 42.9% of the neurologists and 42.9% of the family doctors consider that the patient can be informed on his or her request (Fig. 9).

Fig. 9. Percentage of responses regarding information provided to the neurological patient, on study groups

Q7. In your practice, do you focus on a valid informed consent (IC) and allot it enough time for each neurological patient?

a) yes, informed consent of my patients is valid

b) I do not allot enough time for a valid informed consent

c) I provide the minimum information for obtaining informed consent

d) my patient only signs the informed consent form

Fig. 10. Percentage of responses regarding obtaining a valid informed consent

The answers to this question did not reveal statistically significant percentage differences between the study groups: 74.3% of the

neurologists, 83% of the neurosurgeons, as well as 90.5% of the general practitioners support their action to obtain a valid consent (Fig. 10).

Fig. 11. Correlation of answers regarding knowledge of components of a valid IC and the time allotted to obtain it

The correlation of answers regarding knowledge of the components of a valid informed consent (IC) and the time allotted to obtain it highlights the following aspects (Fig. 11):

- the mental capacity and the voluntary character as well as the decision, were 100% associated with obtaining a valid IC;
- If the patient communicates and understands the information about therapeutic recommendations, the physician does not allot enough time to obtain a valid IC.

CONCLUSIONS

The medical personnel involved in the care plan prove limited knowledge of the health reform legislation regarding patient informed consent.

All physicians find trust to be very important in the patient-doctor relationship in order to obtain therapeutic success. The perception of the medical staff regarding the neurological patient of stigmatization and discrimination, which contributes to the process of self-stigmatization among this patient group. Very interesting is the fact that general practitioners and neurologists in a very high percentage consider that trust is extremely important in the doctor-patient relationship, for therapeutic success.

It was noted that regardless of specialty, physicians consider that mental capacity, voluntary character, communication, understanding of therapy recommendations, decision and authorization are the components of a valid consent. Physicians believe that the act of consent is a form of defense, not an ethical act.

Beginning with these considerations and continuing with the comparative analysis of legislations from different countries of the world, we will propose the following aspects as requiring modifications, additions or revisions in the Romanian legislation: implementation of advance directives in the legislative system through which the neurological patient can express his future wishes regarding his neurological care, both in emergency and in terminal stages.

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