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# Informed Consent and Medical Decision Making: Ethical Challenges

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## Abstract

*Informed consent is an ethical concept with an essential role in medical practice and research studies. The objective of this study was to analyse respondents' opinions regarding informed consent, confidentiality of medical data, and medical decision making. The study included 200 questioned persons and was conducted as an internet survey between March 2018 and March 2019. The group included respondents aged between 18 and 65 years. Our results show that respondents are very interested in their medical data, medical confidentiality, and their participation in the medical decision.*

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# INFORMED CONSENT AND MEDICAL DECISION MAKING: ETHICAL CHALLENGES

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## INTRODUCTION

In medical practice, the relationship between the doctor and their patient represents the basis of successful clinical medicine, thus improving the patients' health.<sup>3</sup> An essential factor that needs to be considered when talking about the relationship between a doctor and their patients is confidentiality, based on all the principles of medical ethics: autonomy, beneficence, non-maleficence and justice.

## THE IMPORTANCE OF INFORMED CONSENT AND ITS ETHICAL IMPLICATIONS

The patient's informed consent is compulsory in any medical act that implies risks for the patient. The patient authorizes the medical act before it is performed and supposes that the patient has received all the information referring to his/her medical status.<sup>4</sup>

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<sup>3</sup> S. H. Kaplan, "Characteristics of physicians with participatory decision-making styles," *Ann Intern Med* 124 (1996): 497–04.

<sup>4</sup> M.A. Stewart, "Effective physician patient communication and health outcomes: a review," *CMAJ* 152 (1995):1423–33.

In a medical environment, consent represents a person's willing agreement – a person who possesses sufficient mental capacity to be able to take a decision referring to a medical procedure or to a treatment suggested by a specialized medical member<sup>5</sup>

Informed consent is the process by which the healthcare provider informs a competent patient about the appropriate treatment, allowing the patient to decide voluntarily to accept or refuse a medical procedure for the treatment.<sup>6</sup> When there are two or more treatment options, autonomy and the competent patient has the absolute right to be informed and to decide the treatment to which he/she would be subjected to, being fully informed about all the risks and benefits.<sup>7</sup>

Consent can be:

- Expressed, verbally or in written form.
- Implicit, the presumption of the agreement.

## INFORMING THE PATIENT

Every patient is a citizen with full rights, thus beyond the disease state that determines the patient to ask for specialized help, these rights must be respected and should not diminish his/her illness, and on the contrary, they can be emphasized for the sake of the patient's protection.<sup>8</sup>

Certain aspects that raise a dilemma, both from an ethical and judicial point of view, can harden the doctor's decision referring to the patient:

- Informing the patient about a potentially serious/lethal disease vs. not informing the patient – therapeutic privilege.
- The doctor has the right not to inform the patient if they believe that the patient's health or life is in danger when they find out the diagnosis.

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<sup>5</sup> T.L. Beauchamp, "Informed consent: Its history, meaning, and present challenges," *Camb Q Health Ethics* 20 (2001): 515–523.

<sup>6</sup> C. Grady, "Enduring and emerging challenges of informed consent," *N Engl J Med* 372 (2015):855–862.

<sup>7</sup> Paul S. Appelbaum, "Assessment of Patients' Competence to Consent to Treatment," *N Engl J Med* 357 (2007): 1834–1840.

<sup>8</sup> D. Rothman, *Strangers at the bedside: a history of how law and ethics transformed medical decision making* (New York: Basic Books, 1991).

- The doctor has the right not to inform the patient who does not express the wish to find out the relevant information regarding their state of health or does not want to take decisions on their own.
- The doctor has the right not to inform the patient who lacks autonomy, understanding capacity, or has decisional competence.

We cannot talk about the therapeutic privilege in the following situations:

- The patient is independent and wants to know the truth about their state of illness.
- The patient suffers from a contagious disease that implies an obligatory declaration.
- The patient needs other medical or surgical interventions for which they must express their informed consent.<sup>9</sup>

## PATIENT AUTONOMY

Based on self-determination, each and every person having and being in their full state of mind can take decisions and administrate their own life and interests.

From a bioethical point of view, a person is independent when they are psychological competent,

- To understand their situation
- To be voluntary
- To have decisional capacity.

The autonomy of the person has three meanings:

- The bioethical principle based on the free decision in the medical practice.
- The philosophical principle of the existence of a rational being.
- The state of a person to present their psychic capacity and to be in the legal state of exercising their civil rights at the same time, that is to say, to be psychic competent.

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<sup>9</sup> A.E. Buchanan, D.W. Brock, *Deciding for Others: The Ethics of Surrogate Decision Making* (Cambridge: Cambridge University Press, 1990), 187-134.

## MEDICAL CONFIDENTIALITY

Confidentiality is not an absolute concept and there are situations in which the doctor has to infringe this right of the patient. The Tarasoff Case (1976) was one of these, which raised numerous questions referring to the idea of confidentiality and its limits.<sup>10</sup> Prosenjit Poddar, while treated by a psychiatrist, confessed to him of his intention to hurt Tatiana Tarasoff, and even though the doctor asked the authorities to arrest him after showing them the seriousness of the situation through the diagnosis of paranoid schizophrenia, Poddar was not imprisoned as he was not considered dangerous. Poddar eventually murdered Tatiana Tarasoff, and the victim's family sued the doctor invoking that they were not informed about Poddar's plans that put Tatiana's life in danger.

The confidentiality of the medical data is the patient's right and at the same time, the doctor's obligation.

When the patient addresses the doctor and presents them with the reasons their specialized help was sought for, these reasons are to be private for each and every patient, and they have the following implications:

- moral – they are confidential and are deontological and ethical protected by confidentiality.

The doctor will keep the professional secret and will act according to the legal right of each person to the respect of his private life referring to the information about his health.<sup>11</sup>

- legal – they are a professional secret protected by criminal and organic laws.

All the information referring to the patient's health, the results of the investigations, the diagnosis, the prognosis, the treatment, the personal data are confidential<sup>12</sup>

Professional secrets in the deontology of the medical practice is called confidentiality.

This confidentiality is the base of the relation of trust between the doctor and their patient, and it also contributes to the quality of the medical act due to the possibility to create a therapeutic alliance.

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<sup>10</sup> R. Weinstock, G. Vari, G.B. Leong et al., "Back to the past in California: A temporary retreat to a Tarasoff duty to warn," *J Am Acad Psychiatry Law* 34 (2006): 523–528.

<sup>11</sup> *The Deontological Code of the Romanian Doctors' College 2017*, Chapter III, art. 17.

<sup>12</sup> *The Law of the Patient's Rights 2012*, Chapter 4, art. 21.

The patient's confidence helps the doctor obtain information about the symptoms and the history of the disease so that the doctor can organize their knowledge and thinking in order to offer the best treatment.

It is a legal, moral, and deontological obligation for the doctor to respect the professional secrets in medicine. On the other hand, keeping the confidentiality strengthens and emphasizes the relation between the doctor and the patient, and this situation contributes to the stability of the therapeutic alliance and the patient's compliance, thus contributing to the quality of the medical act. It must be mentioned that regarding the patient's medical confidentiality, we cannot discuss subjectivism or the judicial system creating laws for that, including the Criminal Code; thus, the infringement of the confidentiality becomes not only a simple deontological violation, but also represents a criminal act. We must also add that there is no transparency in the confidentiality of the medical data except when the law especially requires it.

There are cases foreseen by the law that requires breaking the professional secret. When the judicial institutions ask the doctor to break the professional secret and the confidentiality of the patient's medical data – in the case the legal requirements for this action are met – the doctor will ask for a written demand and a closed door meeting.

In this article, we present the results of a 10-question survey which was presented to people during March 2018–March 2019. The study consisted of 200 participants, age 18–65 years old, having different jobs.

#### **Statistical analysis:**

For the statistical part, we used the  $\chi^2$  test. p-values of 0.05 and 0.001 were used to distinguish between different levels of statistical significance. In all cases, all questions of the survey had p-value < 0.001, with a statistical significance.

#### **Demographic characteristics of the participants:**

Participants were recruited online through Facebook. Participants included were 18 years and older. 146 participants (73%) were female and 54 participants (27%) were male, as presented in Fig. 1.

The participants were divided into 6 groups depending on their age, as follows: 18–25 years: 113 participants (56.5%); 26–35 years: 34 (17%); 36–45 years: 29 participants (14.5%); 46–55 years: 14 participants (7%); 56–65 years: 7 participants (3.5%); 3 persons (15%) were older than 65 years. This information is presented in Fig. 2.

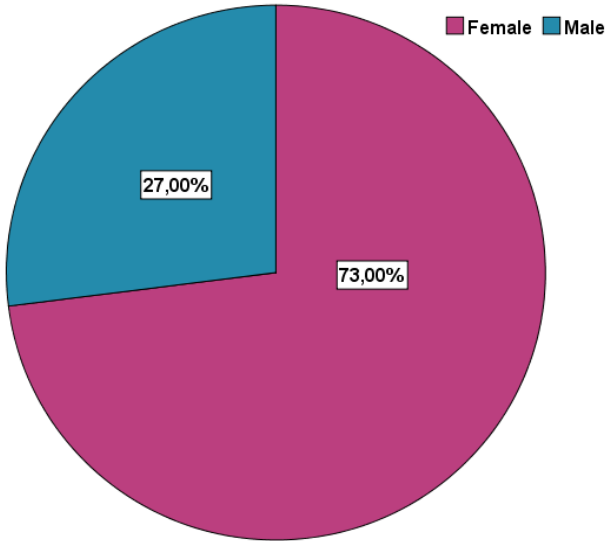


Fig. 1. Gender distribution of the participants

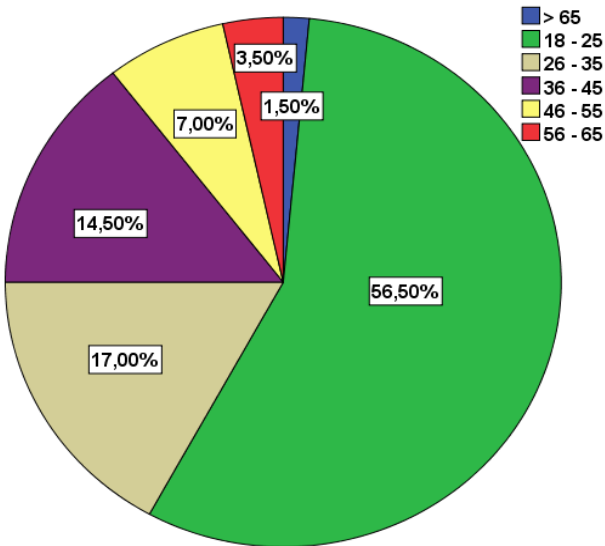


Fig. 2. Age group distribution of the participants

**Table 1. Survey questions**

<b>Question number</b>	<b>Question</b>	<b>Answer: Yes</b>	<b>Answer: No</b>	<b>Answer: Do not know</b>
Q1	Have you completed/signed an informed consent?	143 (71.5%)	44 (22%)	13 (6.5%)
Q2	Has the medical professional explained why you need informed consent?	129 (64.5%)	57 (28.5%)	14 (7%)
Q3	Do you believe that the explanations received from the medical staff were clear?	141 (70.5%)	41 (20.5%)	18 (9%)
Q4	Did the medical professional present the risks of medical/surgical treatment?	142 (71%)	43 (21.5%)	15 (7.5%)
Q5	Do you think you would need more explanation for the risks?	79 (39.5%)	98 (49%)	23 (11.5%)
Q6	Did the medical professional present you with alternative treatment options?	121 (60.5%)	66 (33%)	13 (6.5%)
Q7	Do you think your medical information is kept confidential?	108 (54%)	23 (11.5%)	69 (34.5%)
Q8	Are you concerned about the confidentiality of your medical data?	125 (62.5%)	69 (34.5%)	6 (3%)
Q9	According to your knowledge, does a person have the right to see their medical health record?	159 (79.5%)	14 (7%)	27 (13.5%)

Q10	Have you ever requested a consultation or a copy of your personal medical health record?	45 (22.5%)	150 (75%)	5 (2.5%)
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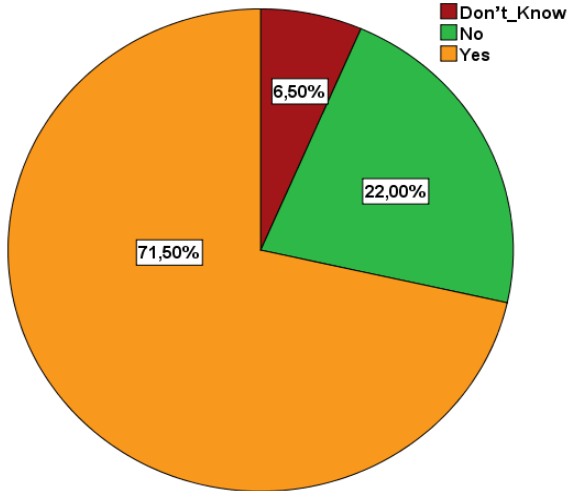


Fig.3. Q1 Have you completed/signed an informed consent?

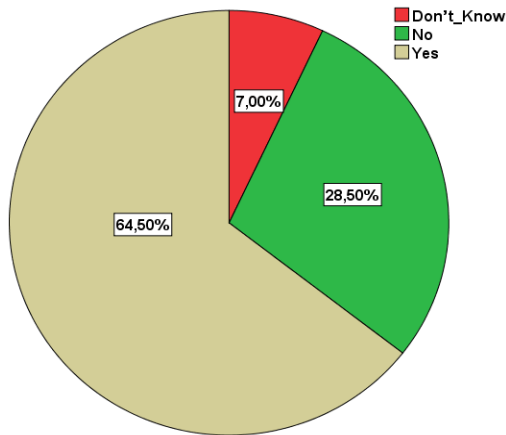


Fig.4. Q2 Has the medical professional explained why you need informed consent?

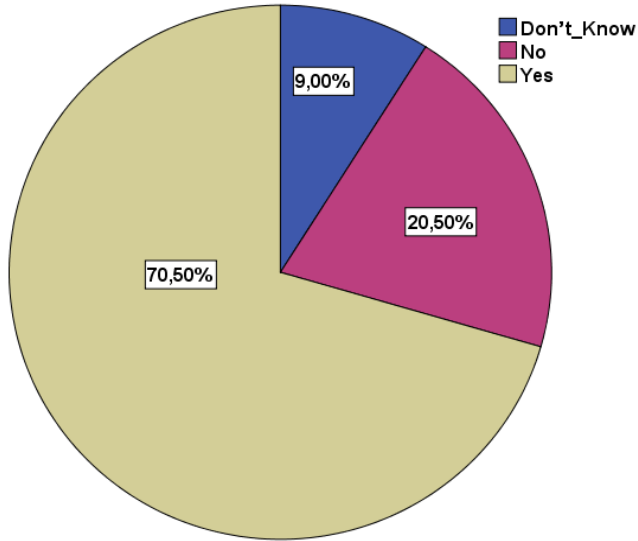


Fig. 5. *Q3* Do you believe that the explanations received from the medical staff were clear?

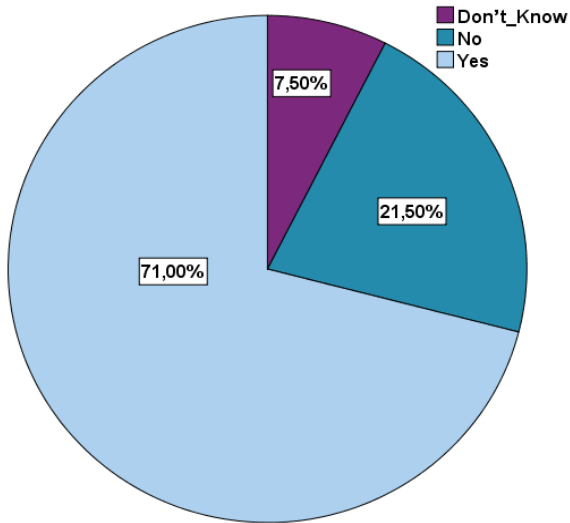


Fig. 6. *Q4* Did the medical professional present the risks of medical/surgical treatment?

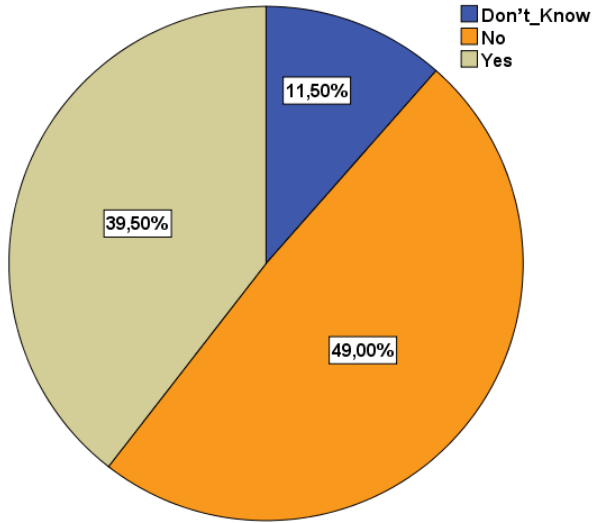


Fig. 7. Q5 Do you think you would need more explanation for the risks?

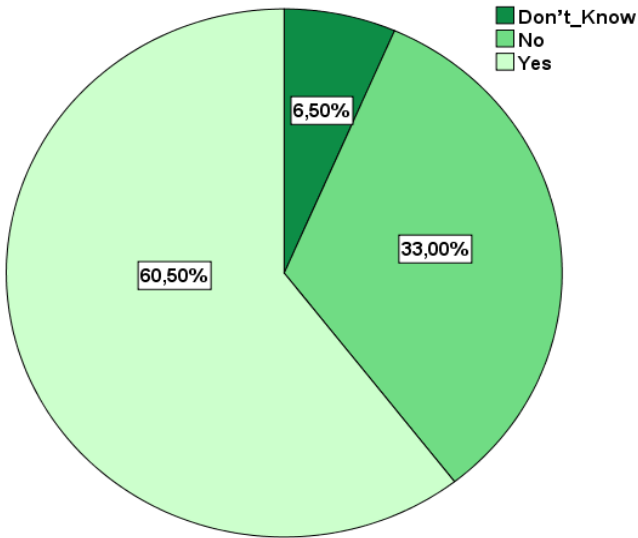


Fig. 8. Q6 Did the medical professional present you with alternative treatment options?

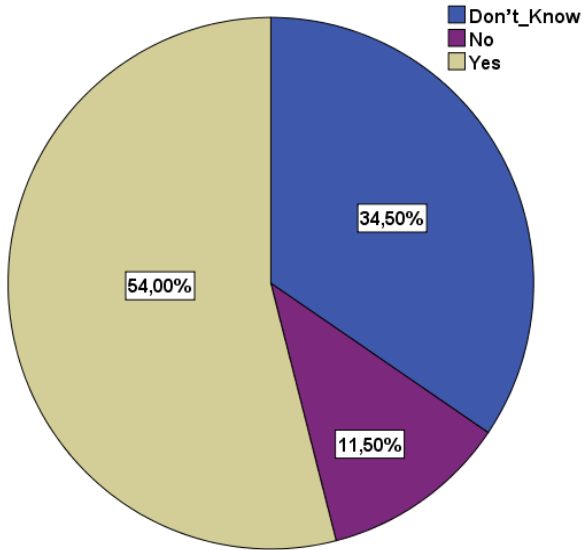


Fig. 9. Q7 Do you think your medical information is kept confidential?

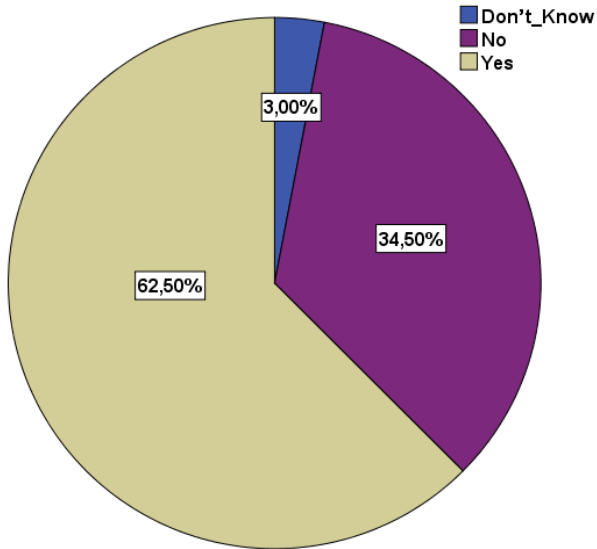


Fig. 10. Q8 Are you concerned about the confidentiality of your medical data?

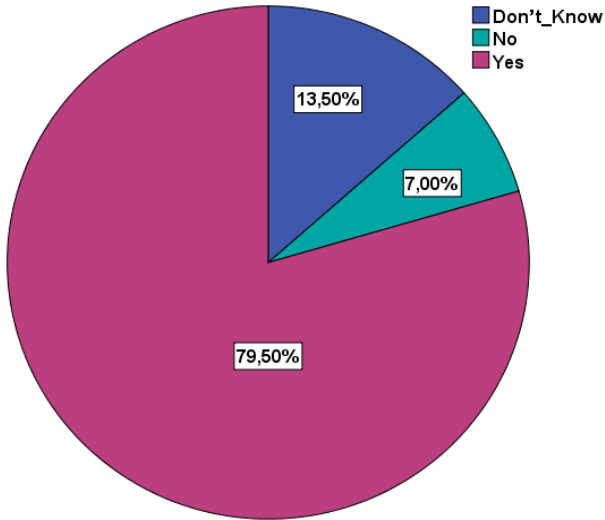


Fig. 11. Q9 According to your knowledge, does a person have the right to see their medical health record?

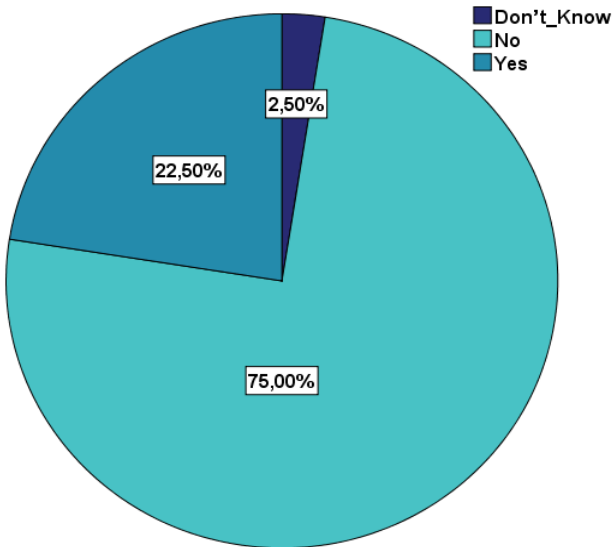


Fig. 12. Q10 Have you ever requested a consultation or a copy of your personal medical health record?

The majority of the participants confirmed that they had signed an informed consent (71.5% – 143 persons), but they also mentioned the fact that the physician offered them the complete information regarding the informed consent (64.5% – 129 persons) (Fig. 3). Regarding the feedback related to the explications that resulted from the discussions between the physician, more than half of the questioned persons considered the explanations to be very clear (70.5% – 141 persons), detailed (54% – 108 persons) or enough (63.3% – 126 persons) (Fig. 4). 33.5% of the questioned persons felt that that explanations could be more detailed, 26.6% were not sufficient to aid them, and 20.5% responded that the explanations were not sufficient or easy to understand (Fig. 5).

Regarding the risks that can occur during a medical or surgical procedure or treatment, they have to be informed about these by the physician. Only 71% (142 persons) from the questioned persons confirmed that they had been informed about these risks. A percentage of 21.5% (43 persons) denied this, while 13 persons (7.5%) did not know what to answer (Fig. 6). Almost half of the persons who completed the questionnaire – 98 persons (49%) – said that regarding the risks, they did not need to be informed, but a percentage of 39.5% (79 persons) said that the physician did not offer clear information (Fig. 7).

Regarding the treatment, other therapeutic options, or the responsibility of the decision maker, the majority of the questioned persons (121 persons – 60.5%) said that they received information about other treatments, while 124 persons (62.0%) felt involved in the decision making related to the proposed treatment (Fig. 8). The confidentiality of the medical information became an important subject for those who need medical care, and in this case, more than half of the questioned persons – 125 participants (62.5%) – are worried about this; meanwhile about 108 persons (54%) believe their medical information is kept safely (Fig. 9, Fig. 10).

When the participants were asked about the right of the patient to see their medical records, 159 persons (79.5%) agreed with this, while 14 persons (7%) did not agree with this. Also, 27 persons (13.5%) did not know what to answer.

When participants were asked if they asked for their medical records, 75% – 150 participants – did not ask for their medical records, while 45

persons (22.5%) asked for their medical records, and only 5 persons (2.5%) did not know what to answer.

## CONCLUSION

The first priority in a committed doctor-patient relationship is considering the well-being of the patient, involving the patient in all the medical decisions that concern their health, and respecting the patient's decisions, thus respecting their autonomy.

From the responses of the survey, we can conclude that the participants were concerned about the informed consent and the explanations received from the medical staff about their health and well-being. Also, participants are very involved in medical decision-making when it comes to the recommendations about the medical treatment. Last but not at least, people are concerned about the confidentiality of their medical data.

To our knowledge, this is the first study in Romania related to the attitudes of the general population toward informed consent, the confidentiality of medical data, and medical decision making.

## DECLARATION OF INTEREST

The authors declare there is no conflict of interest related to this article.

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