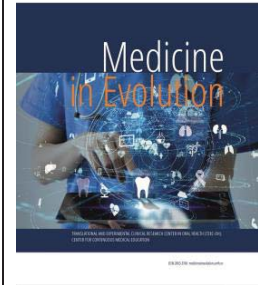


Informed consent in dental medicine



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Abstract

The medical act requires the patient's consent, and the foundation of this condition imposed under the legal provisions is the respect for the physical integrity, freedom and self-determination of each person. In order to carry out this study on the legal and practical implications of informed consent in dentistry, a questionnaire was drawn up consisting of 15 closed questions, which had the role of highlighting the legal consequences produced by the expression of informed consent by the patient regarding dental interventions performed. After completing the completion period, the questionnaires were centralized and analysed statistically. The main conclusion resulting from this study takes into account the need to carry out various campaigns in the future regarding the legal education in the medical field of the staff working in dental offices, and patients in order to offer them increased protection regarding in the relationship with patients.

Keywords: informed consent, the right to medical information, patient, dentist, College of Dentists

INTRODUCTION

Patient consent is a burdensome bureaucratic formality for dentists, who are already overburdened, however is an opportunity and key factor in the efficiency of the medical act [1-3].

Informed consent is regulated both in Law no. 95/2006 [4] regarding health reform, as well as in Law no. 46/2003 [5] regarding the patient's rights, that a medical intervention can only be carried out after the patient has expressed his consent freely and knowingly [6-9]. No medical treatment or procedure cannot be made without the patient's consent. The medical act involves an ethical component, which includes informing the patient and obtaining his consent and a scientific one, which includes the actual prevention, diagnosis and treatment procedures. Informed consent is no longer seen as a simple administrative formality for dentists, but as a relational process. It contributes to the patient's trust, patients' understanding of the medical procedures and the quality of the medical act [10-15].

Aim and objectives

Aim and objectives of this research are to statistically evaluate the knowledge and understanding of the informed consent by patients who request dental care in Timiș County.

MATERIAL AND METHODS

In this study were included 50 subjects, 17 males and 33 females with age between 21 and 60. 13 subjects belong to 20-30 years of age, 16 subjects belong to 30-40 years of age, 12 subjects belong to 40-50 years of age and 9 subjects belong to 50-60 years of age. 30 subjects are belonging to an urban area and 20 belong or live in a rural area. 30 subjects have a university degree and 20 high school degree.

A questionnaire consisting of 15 closed questions, centred on the role and importance of informed consent in dental medical practice was addressed to a group of 50 patients in different dental practices in Timișoara. Each question included three answer options. Questions about patient's gender, age, the environment of origin (urban/rural) and studies were included in the questionnaire.

The first question concerns if patients were informed in writing about the medical interventions performed, the risks that may occur as a result of each individual procedure, the existing alternatives to the proposed procedures, but also regarding the risks of not carrying out treatment and not complying with medical recommendations. What we wanted to observe if legal obligation, regulated with Law no. 95/2006 on health reform; Law no. 46/2003 on patient rights it is respected. On the other hand, the aim was also to see if patients know that there is currently a legislation in the medical field that recognizes their right to be informed by the dentist regarding all aspects related to their health condition. The second question has the role of analysing if patients are asked to carefully read the content of the document containing their agreement regarding the medical intervention they will undergo, before signing it. The valid expression of consent regarding the medical intervention presupposes the obligation of the dentist to ask the patient to read all the information mentioned in writing in the content of the form and to ensure that the patient has understood exactly what each medical procedure consists of.

The third question was referred to the respect and dentist professionalism, considering that the dentist exhibits an ethical behaviour and respects patient's rights. The fourth question is regarded to estimated costs of the treatment, costs that the patient must know from the beginning. The dentist is under no obligation to communicate the final costs of the treatment

to the patient from the outset, as they may change in relation to subsequent medical interventions that may be necessary. The patient is able to decide whether to accept the medical intervention proposed by the dentist, in relation to the related costs, or the expression of consent in this regard can only take place if this information has been previously transmitted. The fifth question in the questionnaire concerns if the patients know the legislation applicable in Romania in the medical field, which regulates the patients rights in relation to the medical staff. Question six refers to emergency medical intervention which were performed without consent. The legislation gives the dentist the right to intervene without first requesting the informed consent of the patient. Question seven, asks if patients are familiar with the terminology used by the dentist, if they understand it and if they are provided with all the information they need. The patient's informed consent form must be drawn up with utmost diligence, in as much details as possible and in a way that the patients can understand. Question eight, refers to the legislation in the medical field which imposes that the refusal of the treatment expressed by the patient have to be made in written. Ninth question is regarding the expression of consent to the medical act in the case of minor patients or those with special needs. The legislation gives the responsibility to family or tutors. Question number ten analyse the frequency with which patients have so far turned to the College of Dentists to complain about the possible violations of their rights by dentists. However, turning to the College of Dentists to complain about possible abuses cannot take place if patients do not first of all know what the role and duties of this professional body are and how it can protect their interests. Question eleven is related to complaints and trials, question twelve is asking if the patients have knowledge about the College of Dentists and it's obligations and activity and question thirteen is related to the patients consent to be photographed. Question fourteen is referring to the consent requested by the dentist before he transmits data related to patients state of health to any medical interventions or family members and the last question is asking if the patients are feeling protected by the legislation of the medical field.

Data were statically processed with the statistic software R. To preview the data it was used barplot function from package ggplot2. The answer's number for each question was analysed using the barplot conditioned by the environment. The collected data and information were coded as follow: rural=0, urban=1. Each answer had three options of answers and were coded as follow: first option of answer for all the questions=0, second option of answer for all the questions=1, third option of answer for all the questions=2.

RESULTS

The collected data were analysed according to the environment.

Question 1: Have you been informed in writing by the dentist about the medical intervention proposed to be performed, the potential risks of each procedure, the existing alternatives to the proposed procedures, but also about the risks that may arise with not carrying out the treatment and not following the medical recommendations? 0-Always, having even been handed a copy of the document containing this information was marked by ; 1-Only in the case of certain dental interventions I was given this information in writing, but in the vast majority of cases I was not informed about all these aspects; 2- I was never given this information in writing, only verbally. The results showed that from 27 subjects, 8 from rural and 19 from urban always have been handed a copy of the document, 14 subjects received the content for certain dental intervention and 9 subjects answered that were not informed in written only verbally (Figure 1a).

For question 2 asks if before the dentist handed and asked to be signed the document containing the informed consent regarding the procedures to be performed, did he ask you to

read it beforehand? 0-yes, in all cases read before signing the informed consent form answered 24 of the subjects; 1- only in the case of dental interventions that entailed a certain complexity from the perspective of the operations to be performed answered 18 subject, 2- I was never asked to read the informed consent form before signing it answered 8 subjects (Figure 1b. For question 3, when asked if a copy of the informed consent has been handed by the dentist after each individual medical intervention? 16 from rural and 27 subjects from urban environment answered that in all cases the dentist kept a copy of the informed consent signed by me at the office, without handing me a copy, none of the subjects requested during each dental intervention to be given a copy of the informed consent and 7 subjects encountered situations where they received a refused of the copy of the informed consent- (Figure 1c).

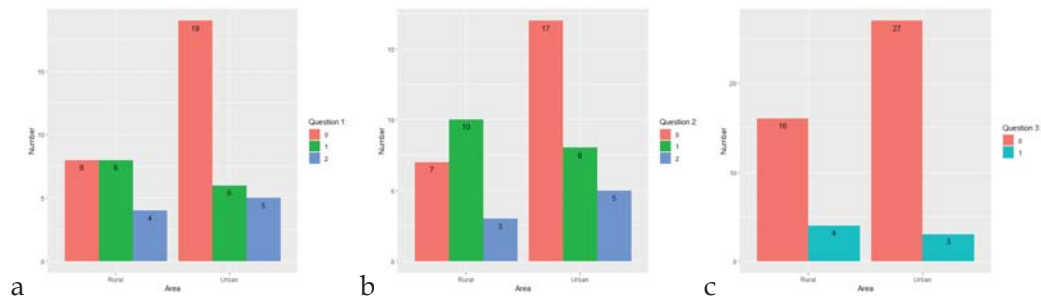


Figure 1. The collected data were analysed according to the environment: a. Question 1-written information about the medical intervention and potential risks
 b. Question 2-consent regarding the procedures
 c. Question 3-patients receiving a copy of the informed consent

Question 4, when asked if the patient been informed each time by the dentist about the estimated costs of the treatment before its completion? 0- the costs were communicated after the completion of the medical intervention- 9 answers, 5 from rural and 4 urban; 1- the dentist mentioned in writing in the content of the form by which I was requested the informed consent what are the estimated costs for each individual operation- 26 answers, 9 rural and 17 urban; 2- in very few cases I was informed in writing about the estimated costs of each individual intervention-15 answers, 6 rural and 9 urban (Figure 2a).

Question 5, asks if the patients are aware of the fact that there is currently legislation in Romania that regulates the patient's rights, including the right to be informed about the state of health, but also about the medical interventions proposed to be carried out? 0- I don't know concretely what is the law that currently regulates patients' rights- 26 answers, 16 rural and 10 urban; 1- I only researched the patient rights law when I filed a medical malpractice lawsuit against a dentist; -6 answers, 1 rural and 5 urban; 2-I learned about the existence of the law of patients' rights through the knowledge that professes in the legal field. - 18 answers, 3 rural and 15 urban (Figure 2b).

Question 6 refers to the fact in case of emergency dental interventions, the patient's informed consent is not necessary, as the doctor can perform the intervention in his absence? 0- I was informed about this aspect by the dentist during the first visit to the office-10 answers, 5 rural and 5 urban; 1- I documented myself and saw that there are a number of normative acts applicable in the medical field that regulate this exceptional situation in terms of emergency cases- 9 answers, 1 rural and 8 urban; 31 subjects, 14 from rural and 17 from urban were was aware (Figure 2c).

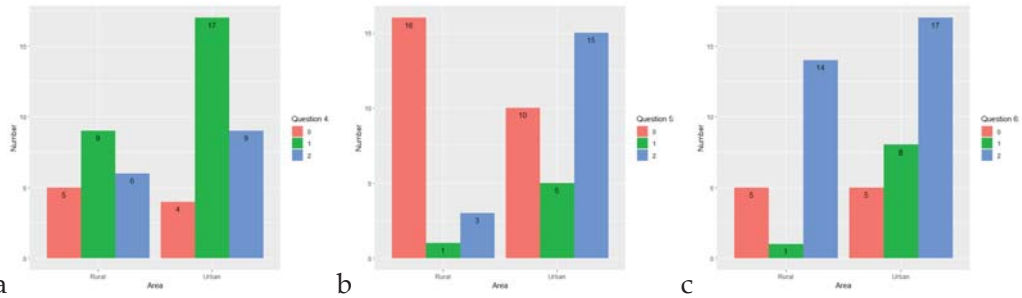


Figure 2. The collected data were analysed according to the environment: a. Question 4 -costs of the treatment before its completion; b. Question 5- current legislation regarding patient's rights; c. Question 6 - informed consent is not necessary is not needed for emergencies

Question 7 asks if the information contained in the patient's informed consent form regarding the medical act is sufficiently detailed, explained in your understanding, and the specialized terminology is adapted to your level of knowledge? The results show that 15 of the patient's informed consent is written in a summary manner, and the specialist terminology is not explained in detail by the dentist. For 23 of them the informed consent was drawn up in detail by the doctor regarding each operation carried out separately, and the specialized terminology was adapted to the level of knowledge; - and for 12 subjects the patient's informed consent must be drawn up by the dentist in collaboration with legal specialists, in order to offer the greatest possible protection to the medical service provider in the event of a medical malpractice lawsuit (Figure 3a).

Question 8, in case the patient did not want to express its consent regarding a medical intervention that was proposed, the dentist requested patients refusal in writing, not before explaining to you the consequences that may arise with this refusal? 14 subjects were not aware of the fact that there is a legal obligation to refuse in writing a possible medical intervention. For 6 patients, in all situations the refusal of medical intervention was expressed verbally, the dentist not asking me to express this refusal in writing. Thirty subjects have not been put in a position to refuse to express my consent regarding a medical intervention, but knew that the refusal must take place in order to be validly expressed (Figure 3b).

Question 9 is referring to the fact that in the case of minor patients or those with special needs, the dentist must request the expression of consent regarding the medical intervention by the legal representative? The majority of the subject, 34 answered that know that there is this requirement in the case of minor patients, given their young age or the special situation they are in, being lacking in discernment or having discernment in the process of being formed (Figure 3c);

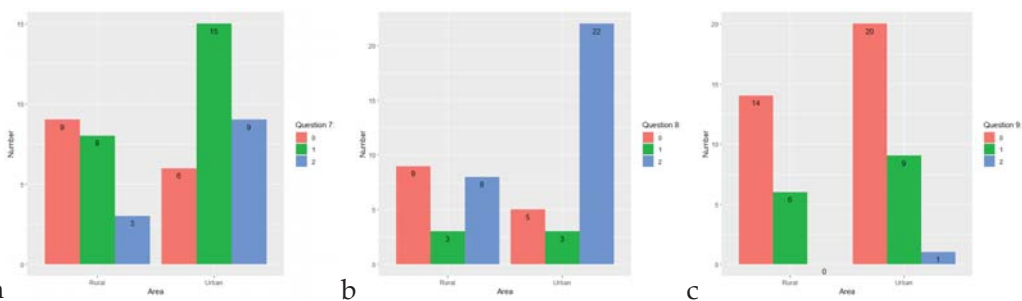


Figure 3. The collected data were analysed according to the environment: a. Question 7 - understanding of the informed consent; b. Question 8 - request of the written refusal; c. Question 9 - consent for minor patients and patients with special needs

Question 10 asks if the existence of a record of the patient's informed consent in medical practice contributes to increasing trust in the doctor and improving the communication relationship? For 26 subjects the patient's informed consent contains all the information he needs to be able to express his consent to the medical act in full knowledge of the case and for 23 subjects is not valid in all situations. Only for 1 subject the consent does not increase the trust and improve the communication with the dentist (Figure 4a).

Question 11, asks if patients have turned to the College of Dentists or to lawyers specialized in the field of medical malpractice to claim the violation by the dentist of patients rights, or malpractice. All subjects answered that was not the case until the moment they participated to this research (Figure 4b).

Question 12 asks if subjects are aware of the existence of the College of Dentists in Romania and the role it plays in terms of the relationship between you and the attending dentist? Eleven subject from urban and 10 from rural do not have information related to the role and duties of the College of Dentists; 9 subject from rural and 19 from urban heard about the existence of the College of Dentists, but don't know what its role is and how it can protect their rights. Only 1 subject from urban area knew in detail about the College of Dentists (Figure 4c).

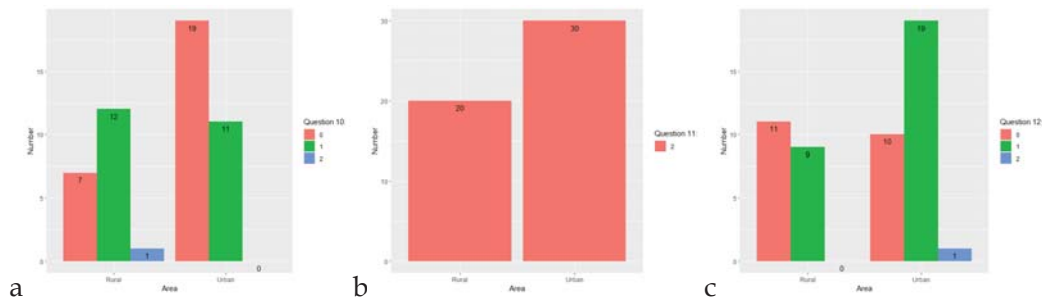


Figure 4. The collected data were analysed according to the environment: a. Question 10 - informed consent in medical practice contributes to increasing trust; b. Question 11- patients that have turned to the College of Dentists for claims; c. Question 12 - awareness about the College of Dentists

When asked for consent by the dentist in order to be photographed in the dental office for the pictures to be used in various scientific studies for 27 subject 7 from rural and 20 from urban in all cases the dentist requested my written consent before taking the photographs (Figure 5a).

Question 14 refers to the fact that dentist has to ask patients consent before he transmits data related to patient's state of health and medical interventions to other family members? 17 from rural and 28 from urban were informed by the dentist from the first visit to the office that any information related to my state of health will not be transmitted to other people, including relatives, except with my express consent; only 1 subject from urban environment even encountered a situation in which the professional secrecy was violated by the dentist, data of health status being transmitted to various relatives, without prior consent being requested; 3 from rural and 1 from urban environment were not aware until now that the dentist is obliged by law to ask for my consent before disclosing information about my health to my relatives (Figure 5b).

Question 15 refers asks if patients felt protected by medical legislation in their relationship with the dentist? 3 subjects from rural and 14 from urban believe that the legislation in Romania currently does not offer real protection to patients in the relationship with the dentist, being lacunar and ambiguous in various aspects; 14 from rural and 13 from urban do not know the Romanian legislation in the medical field well enough regarding the

rights I have in the relationship with the dentist; and only 6 subject from both rural and urban feel protected by the law at this moment (Figure 5c).

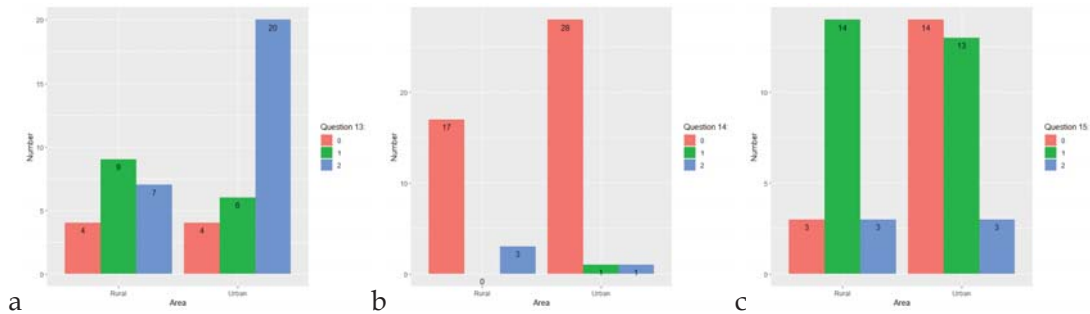


Figure 5. The collected data were analysed according to the environment: a Question 13- consent for photographs; b. Question 14 - patients consent before data transmission, c. Question 15-patients trust and protection by the medical legislation

DISCUSSIONS

All these findings led us to consider it extremely necessary to provide better information to patients regarding their rights in the relationship with the medical staff, but also regarding the entire legislation applicable in the field. These objectives can be achieved by conducting legal education programs in the medical field, supported by legal specialists, to which both dentists and patients have access.

The participation of patients and dentists legal education programs would contribute to the acquisition of solid knowledge and to an increased protection of the rights of patients who use health services. Moreover, once patients know what their rights are during the provision of medical care, they will know how to protect these rights, which will also lead to the reduction of complaints addressed either to the College of Dentists or to the court regarding possible accusations of medical malpractice.

CONCLUSIONS

Upon completion of this study, following a statistical analysis, we found that most of the patients do not know the legislation currently applicable in Romania that regulates their rights through which they benefit in the relationship with the medical staff. Although there is a law of patients' rights, namely Law no. 46/2003, patients are not familiar of it, as there is a lack of information regarding the legislative content of this regulation applicable in the medical field.

Following the centralization of the questionnaires, we found that most patients do not have information about the situations in which the dentist has the right to perform an emergency medical intervention without their consent. Another aspect found with the centralization of the questionnaires and the realization of the statistical analysis, was the fact that, for the most part, patients do not know the role of the College of Dentists in terms of protecting their rights during the provision of medical assistance.

Subjects who live or belong in urban areas and intellectuals are better informed about their rights the informed consent and dentists obligations. Also not all the dentists or dental offices always respect all the stipulation of the law.

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