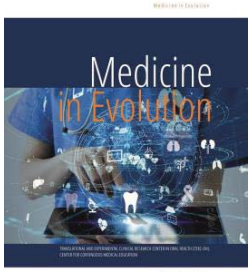
Assessment study of the views on the importance of informed consent in the medical act in dental health services in Timis County



Boscu L.[1], Popovici R.A.[1], Dinu S.[2*], Lintini T.R.[1], Salehi M.[1], Alsaeyd Ahmad M.K.[1], Popa M.[2]

[1]*Department 1, Faculty of Dental Medicine, Victor Babes University of Medicine and Pharmacy, Timisoara, Romania*
[2]*Department of Pedodontics, Faculty of Dental Medicine, Victor Babes University of Medicine and Pharmacy Timisoara, Romania*

Correspondence to:
Name: Ştefania Dinu
Address: Faculty of Dental Medicine, Victor Babes University of Medicine and Pharmacy, Eftimie Murgu Square, No. 2, 300041 Timisoara, Romania
Phone: +40 723224768
E-mail address: dinu.stefania@umft.ro

Abstract

Background: Informed consent is an ethical concept that is codified by law and must be put into daily practice in every health institution. Informed consent is based on the concept of respect for autonomy, which gives adults the right to govern their lives according to their own values and preferences. In Romania, for any type of clinical investigation, medical care or potentially risky treatment we need the written consent of the patient, certified by his/her signature. The objective of the study was to evaluate the signing and use of informed consent to dental health care in Timis County.

Material and method: A retrospective observational epidemiological study was conducted, in which we aimed to evaluate the signing and use of informed consent in current dental practice in Timis County. The research method used was the use of a questionnaire survey, which was put online on a group of dentists in Timis County, between March and May 2022.

Results: The habit of signing informed consent in dental services in Timis County is not present in 45% of respondents.

Conclusions: Our study revealed that the use of informed consent by patients in Timis County is not necessarily a practice habit, especially in rural areas.

Keywords: Informed consent, medical care, treatment

INTRODUCTION

Informed consent is an ethical concept that is codified by law and must be put into daily practice in every health institution. Three fundamental criteria are necessary for an informed clinical consent to be correctly completed: the patient must be competent, be adequately informed and not be coerced by medical staff or relatives. The doctor-patient interaction is rooted in the ethical concept of beneficence, but in the 19th and 20th centuries, jurisprudence and societal changes brought respect for autonomy and, with it, informed consent [1].

Informed consent is based on the concept of respect for autonomy, which gives adults the right to govern their lives according to their own values and preferences. Informed consent has been defined as "the autonomous authorization of a person for a medical intervention or participation in research" and consists of seven elements: patient capacity (also called competence), voluntariness, disclosure of material information (such as risks, benefits and relevant alternatives), recommendation of a plan, agreement, decision and authorization [2,3]. Informed consent can be given verbally or through signed documents, the latter often favoured by institutions when risks are higher (e.g. when anaesthesia/sedation or invasive procedures are required) to protect against liability.

Some accounts of informed consent suggest that clinicians' roles should be limited to providing information and presenting the patient with options. However, a preferred concept of informed consent is the "shared decision-making" model, in which clinicians and their patients or caregivers work together to decide the best care options for the patient, especially if there is more than one reasonable option [4,5].

In Romania for any type of clinical investigation, medical care or treatment with potential risk we need the written consent of the patient, certified by his/her signature. Exceptions to this rule are medical emergencies that put the patient's life at risk, but even in these cases an emergency report must be completed after the intervention justifying the lack of informed consent.

The purpose of the informed consent signing process is to provide patients with sufficient information to enable them to make an informed decision and preserve their autonomy. Patient consent must be obtained prior to each dental medical procedure. Indeed, professional regulatory bodies and other professional organisations issue regularly updated detailed guidance on this process [6]. The pillar of informed consent is an ongoing process whereby the patient is provided with sufficient information to enable them to make decisions voluntarily and without coercion. They must be given explanations (in appropriate language and terminology) to enable them to understand exactly their oral health condition, the type of treatment proposed and other treatment alternatives as well as their benefits and risks, and the consequences if action is not taken.

The name(s) of the doctor(s) responsible for the medical act must be mentioned in the informed consent form. The doctor must thus inform the patient in accessible language about the purpose of the medical intervention/treatment used, the potential risks to which the patient is exposed, the prognosis of the conditions without treatment or the recommended medical/prophylactic care methods, some possible medical/social, psychological, economic consequences, etc., as well as the alternative treatment options that may or may not be provided in the dental service concerned, and the patient must be informed about the right to a second medical opinion.

The objective of the study was to assess the signing and use of informed consent to dental medical services in Timis County.

Aim and objectives

In this retrospective study we aimed to evaluate the signing and use of informed consent in current dental practice in Timis County.

MATERIAL AND METHODS

A retrospective observational epidemiological study was conducted, in which I aimed to evaluate the signing and use of informed consent in current dental practice in Timis County. The research method used was the use of a questionnaire survey, which was put online on a group of dentists in Timis County, between March and May 2022. At the end of the period, it was observed that 89 subjects practicing dental medicine in Timis County responded to the questionnaire, of which 58 were dentists, 21 were prophylaxis nurses and 10 receptionists from dental clinics in Timis County. The mean age of the respondents was 39.21± 8.6 years, with a minimum of 22 years and a maximum of 63 years. 65 of the respondent subjects were female, and 68 stated that they were working in urban areas.

RESULTS

Understanding of the need to complete and the duties of completing informed consent, of health care staff taken in this study. They are described in Table 1 and it can be observed that almost ninety-six percent of the subjects felt that the consent form gives permission to the dentist to perform the procedure and almost 84% felt that confirmed they are given enough data to help the patient decide for themselves. Nearly seventy percent felt that the form is for the protection of the dentist/clinic. 55.8% responded that once the informed consent form is signed, patients will not be able to claim compensation for any events associated with the medical work.

Table 1. Summary of awareness/understanding of the informed consent process by dental medical staff

	YES **No (%)**	**NO** **No (%)**
The consent form gives the dentist permission to perform the procedure	82 (95,34)	4 (4,66)
The consent confirms that sufficient information has been given to the patient so that they can decide	72 (83,72%)	14 (16,28%)
The signed consent is a legal necessity	61 (70,9%)	25 (29,1%)
The consent is filled in to identify the correct part of the procedure	66 (76,74%)	20 (23,26%)
After signing the consent, patients cannot claim compensation for any adverse events associated with the medical activity	38 (44,18%)	48 (55,8%)
The consent is to protect doctors, dentists and medical clinics	60 (69,76%)	26 (30,24%)
The consent form is not compulsory	23 (26,74%)	63 (74,25%)

The habit of signing the informed consent in dental services in Timis County is not present in 45% of the respondents (Figure 1). Of the 41 respondents who said that they do not usually provide informed consent to patients, 21 (80.77%) are in rural areas.

The place of signing the IC was usually the waiting room is in most cases the waiting room (72%) and it is signed before the patient comes in contact with the doctor, for the doctor to consult him or to establish a treatment plan (Figure 2).

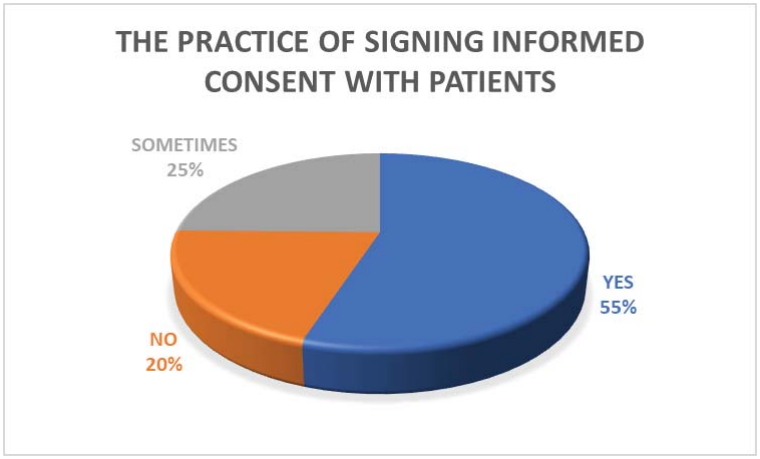


Figure 1. The practice of signing informed consent with patients

Figure 2. The place where the informed consent is signed

The explanations related to treatment, complications, costs in 69% are given by the doctor and in 31% by the nurse.

The perception of the medical staff who work in Timis county about the importance of the patient's completion of the I.C., 40% say that it is not important to fill in the I.C., and 31% do not believe that it is mandatory (Figure 3).

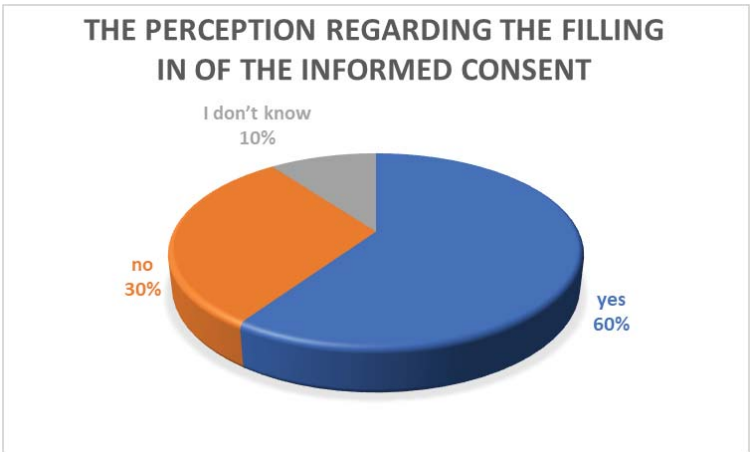


Figure 3. The perception regarding the filling in of the informed consent

DISCUSSIONS

Our study revealed that obtaining informed consent from patients in Timis County is not common practice, especially in rural areas. In many cases although they are filled in, most of the time they are given by the nurse or receptionist, in the waiting room, before any first contact of the patient with the doctor.

For patients with medical risks, assessment and precautions to be taken during treatments are essential. Risk factors include: the increasing number of elderly patients, the increasing use and administration of a wide range of drugs in dentistry and medicine in general, the stress level of patients determined by socio-economic conditions, and last but not least, the lack of health education among the population [6].

As the need for informed consent becomes more evident in the dental profession, a dental professional should know which procedures actually require written informed consent. The answer to this question is relatively simple: any procedure that is "invasive or irreversible" requires informed consent. The fact that a patient visits a dental office for an examination implies that he or she wants the doctor to conduct a clinical examination to determine what treatment might be needed, but most dentists take for granted that over 90% of their procedures are surgical in nature [7]. All procedures, from a simple oral restoration to the removal of a complicated third molar, dental abscess, may require irreversible alteration of body tissues with the risk of complication or unwanted side effect. Even minor occlusal treatments or incisions can affect the surrounding dentition, canine elevation, masticatory function. The mouth is extremely dynamic, subject to the forces of the tongue, lips, cheeks, and teeth. Any change in that environment, even with the physician's best intentions, can lead to undesirable outcomes, and those possibilities must be presented to the patient and documented in writing [8,9].

Although "invasive and irreversible" procedures require information and consent, most diagnostic procedures, such as general clinical examinations, periodontal probing, and radiographs do not require such formal consent [10]. It is assumed, for the most part, that patients want the physician to obtain all the information necessary to make a complete and accurate assessment of their general and oral condition at the initial examination or can determine the reason for any pain in question. Sometimes, however, patients will specifically state that they want to forego diagnostic procedures such as radiographs or periodontal probing. The practitioner's focus should be to obtain immediate "informed refusal" in these cases [9,11].

In one study the difficulties of researching consent for simple dental implants in primary care were presented.4 Previous studies in the UK have shown that many patients are unaware that the informed consent process protects their interests and have had the misconception that it is designed to protect hospitals, clinics and doctors [12,13]. Another study in general practice found that patients had a limited understanding of the legal status of written consent: 46% thought the primary function of consent forms was to protect hospitals and 68% thought consent forms allowed doctors to take control; only 41% of patients thought consent forms made their wishes known [14]. Similar results were reported in a paediatric surgical setting: 51% of patients felt that consent was to protect hospitals and 23% felt that by signing the form they had waived their right to claim compensation if complications occurred [15]. Such findings are also reflected in our study in primary dental care: 60% of health professionals felt that the consent process was to burden them with more paperwork and carried out to protect the hospital/state practice. In addition, 40% mistakenly thought that signing a consent form was a legal requirement [16]. To our knowledge, this is the first study to systematically audit both satisfaction and understanding of the consent process in primary dental care in Romania.

CONCLUSIONS

Our study revealed that the use of informed consent by patients in Timis County is not necessarily prevalent in dental practice, especially in rural areas.

In many cases although it is filled in, most of the time it is given by the nurse or medical registrar in the waiting room before the patient's contact with the doctor.

It is mandatory for dentists to be aware of this legal responsibility to adequately inform patients and obtain informed consent before performing any type of medical care.

Informed patient consent to the benefits and risks of any medical diagnostic and treatment procedure: is mandatory; its absence signifies abuse of the patient by the doctor; if the patient suffers harm, lack of informed consent means liability of the doctor and inoperability of insurance.

REFERENCES

1. Cocanour CS. Informed consent-It's more than a signature on a piece of paper. Am J Surg. 2017 Dec;214(6):993-997. doi: 10.1016/j.amjsurg.2017.09.015. Epub 2017 Sep 20. PMID: 28974311
2. Toy A, Shah N, Rosenbaum N, Dennick R. Consent for simple dental implant treatment: matching practice with theory. Prim Dent J 2015; 4:19–25.
3. Kakar H, Gambhir RS, Singh S, Kaur A, Nanda T. Informed consent: corner stone in ethical medical and dental practice. J Family Med Prim Care 2014; 3:68–71. See the FDA Information Sheet "Recruiting Study Subjects," for further information.
4. The regulations allow use of a "short form" consent form when the elements of informed consent are presented orally to the subject. For a discussion of the short form written consent, see section III.E.4.b, Short Form.
5. GDC. Standards for dental professionals: Patient consent 2014. Available online at http://www.gdc-uk.org/Dentalprofessionals/Standards/Documents/PatientConsent%5B1%5D.pdf (accessed November 2022).
6. Hajivassiliou E, Hajivassiliou C. Informed consent in primary dental care: patients' understanding and satisfaction with the consent process. Br Dent J, 2015;219:221–224. https://doi.org/10.1038/sj.bdj.2015.687
7. FDA's guidance, "Questions and Answers on Informed Consent Elements, 21 CFR § 50.25(c)."
8. Grady C. Enduring and emerging challenges of informed consent. N Engl J Med. 2015 Feb 26;372(9):855-62. doi: 10.1056/NEJMra1411250. PMID: 25714163.
9. Katz AL, Webb SA; COMMITTEE ON BIOETHICS. Informed Consent in Decision-Making in Pediatric Practice. Pediatrics. 2016 Aug;138(2): e20161485. doi: 10.1542/peds.2016-1485. PMID: 27456510.
10. Emanuel EJ, Emanuel LL. Four models of the physician-patient relationship. JAMA 1992; 267:2221–2226.
11. Steven M, Broadis E, Carachi R, Brindley N. Sign on the dotted line: parental consent. Paediatr Surg Int 2008; 24: 847–849.
12. Litch CS, Liggett ML. Consent for dental therapy in severely ill patients. J Dent Educ 1992; 56:298–311.
13. Fields LM, Calvert JD. Informed consent procedures with cognitively impaired patients: A review of ethics and best practices. Psychiatry Clin Neurosci. 2015 Aug;69(8):462-71. doi: 10.1111/pcn.12289. Epub 2015 Apr 13. PMID: 25756740.
14. Akkad A, Jackson C, Kenyon S, Dixon-Woods M, Taub N, Habiba M. Patients' perceptions of written consent: questionnaire study. BMJ 2006; 333: 528.
15. King J. Consent: the patients' view--a summary of findings from a study of patients' perceptions of their consent to dental care. Br Dent J 2001; 191:36–40.
16. Holden AC. Gaining and recording consent: a practical guide for the dental team. Prim Dent J 2015; 4:54–59.